TOYO DIAGNOSTICS

INSTRUCTIONS FOR USE

Gonorrhea Antigen Detection in Swab

Only for professional *in vitro* diagnostic use.

Product Code : TGNH01

A rapid test for the qualitative detection of Gonorrhea antigen in female cervical swab and male urethral swab specimens.

BACKGROUND INFORMATION

Gonorrhea is a sexually transmitted disease caused by the bacterium *Neisseria gonorrhoeae*. Gonorrhea is one of the most common infectious bacterial diseases and is most frequently transmitted during sexual intercourse, including vaginal, oral and anal sex. The causative organism can infect the throat, producing a severe sore throat. It can infect the anus and rectum, producing a condition called proctitis. With females, it can infect the vagina, causing irritation with drainage (vaginitis). Infection of the urethra may cause urethritis with burning, painful urination, and a discharge. When women have symptoms, they often note vaginal discharge, increased urinary frequency, and urinary discomfort. Spread of the organism to the fallopian tubes and abdomen may cause severe lowerabdominal pain and fever. The average incubation for Gonorrhea is approximately 2 to 5 days following sexual contact with an infected partner. However, symptoms may appear as late as 2 weeks. A preliminary diagnosis of Gonorrhea can be made at the time of examination. In women, Gonorrhea is a common cause of pelvic inflammatory disease (PID). PID can lead to internal abscesses and long-lasting, chronic pelvic pain. PID can damage the fallopian tubes enough to cause infertility or increase the risk of ectopic pregnancy. A smear or swab of urethral or cervical discharge may be taken and tested using a Gonorrhea Rapid Test Device.

INTENDED USE

The Gonorrhea Rapid Test Device (Swab) is a rapid chromatographic immunoassay for the qualitative detection of *Neisseria gonorrhoeae* in female cervical swab and male urethral swab specimens to aid in the diagnosis of Gonorrhea infection.

REAGENTS

Gonorrhea antibody coated particles and antibody specific to Gonorrhea antigen.

METHOD

Gonorrhea Test uses solid-phase immunochromatographic technology for the qualitative detection of Gonorrhea antigen in female cervical swab and male urethral swab specimens. The test is a two-site immunometric assay and selectively detects Gonorrhea antigens in samples with a high degree of sensitivity. Antibodies specific to Gonorrhea antigen were immobilized on the test area "T" of the nitrocellulose membrane. Gonorrhea antibody coated particles, were dried on a conjugate pad. Sample is introduced from sampling pad. If there is Gonorrhea antigen in the sample, Gonorrhea antigen binds to the mobile Gonorrhea antibody coated particles. Together they move to the test area "T". Gonorrhea antigens bind to the immobilized antibodies specific to Gonorrhea antigen and as a result of this, Gonorrhea antigen that have already bound to mobile Gonorrhea antibody coated particles become immobilized in the test area "T" thus creating a visible colored signal due to the accumulation of Gonorrhea antibody coated particles in the test area "T" (a colored test line), indicating positive test result. If there is no Gonorrhea antigen in the sample then sample moves to the test area "T" together with unbound (free) Gonorrhea antibody coated particles. Immobilized antibodies specific to Gonorrhea antigen cannot bind to mobilized Gonorrhea antibody coated particles, therefore no visible colored signal in test area "T" (no colored test line) can be obtained, indicating negative test result. Regardless of Gonorrhea antigen content of the liquid sample, accumulation of Gonorrhea antibody coated particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line should be visible in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS

1. For professional and in vitro diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. Use only sterile polyester swabs to obtain endocervical specimens.
7. Excessive blood (>20 µL in case of female swabs and >10 µL in case of male swabs) may cause false positive results.
8. Endocervical samples from female patients should not be collected during menstrual period.
9. Detection of Gonococcus is dependent on the number of organisms present in the specimen. This can be affected by specimen collection methods and patient factors such as age, history of Sexually Transmitted Diseases (STDs), presence of symptoms, etc. The minimum detection level of this test may vary according to serovar.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. This test will indicate only the presence or absence of Gonorrhea antigen in the sample, and should not be used as the only basis for the diagnosis of Gonorrhea.

As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.
Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

SAMPLE COLLECTION AND PREPARATION

- The Gonorrhea Test Device can be performed using female cervical swab and male urethral swab specimens.
- The quality of specimens obtained are extremely important. Detection of Gonorrhea antigen requires a vigorous and thorough collection technique that provides adequate amount of antigen.
- To collect **Female Cervical Swab Specimens :**
  - Use the swab provided in the kit. Alternatively, any plastic-shaft polyester swab may be used.
  - Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the gonococcus organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise) for 15 seconds, and then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do **not** use 0.9% sodium chloride to treat swabs before collecting samples.
  - If the test is to be conducted immediately, put the swab into the extraction tube.
- To collect **Male Urethral Swab Specimens :**
  - Standard plastic or wire-shaft sterile polyester swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least one hour prior to specimen collection.
  - Insert the swab into the urethra about 2-4 cm, rotate the swab 360° in one direction (clockwise or counterclockwise), for 10 seconds, and then withdraw. Do not use 0.9% sodium chloride to treat swabs before collecting samples.
  - If the test is to be conducted immediately, put the swab into the extraction tube.
- It is recommended that specimens be processed as soon as possible after collection. If immediate testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4-6 hours at room temperature (15-30°C) or 24 hours refrigerated (2-8°C). Do not freeze. All specimens should be allowed to reach room temperature (15-30°C) before testing.

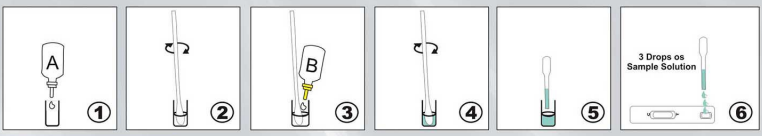
Kit components : Test devices, test tubes, droppers, Work station, Reagent A (0,15M NaOH) Reagent B (0,2N HCl), sterile female cervical polyester swabs, instructions for use.

Additional materials required but not provided : Sterile male urethral swabs, timer.

Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

TEST PROCEDURE

1. Take the test device out of its pouch. Bring the tests and samples to room temperature.
2. Extract the Gonorrhea antigen according to the specimen type.
   - Hold the Reagent A bottle vertically and **add 5 full drops of Reagent A** (300 µL) to the extraction tube. Reagent A is colorless. Immediately insert the swab, compress the bottom of the tube and **rotate the swab 15 times**. Let stand for 2 minutes.
   - Hold the Reagent B bottle vertically and **add 4 full drops of Reagent B** (200 µL) to the extraction tube. The solution will turn turbid. Compress the bottom of tube and **rotate the swab 15 times** until the solution turns clear with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand for 1 minute.
   - Press the swab against the side of the tube and withdraw the swab. Keep as much liquid in the tube as possible.
3. Place the test on a clean and level surface. **Add 3 drops of the extracted solution** (100 µL) to the specimen well (S) of the test, then start the timer. Avoid trapping air bubbles in the specimen well (S).
4. Wait for the colored line(s) to appear. **Read the result at 10 minutes**. Do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS

Negative : Only one colored line is visible in "C" area, indicating that Gonorrhea antigen does not exist.
Positive : Two colored lines are visible in "C" and "T" areas, indicating that Gonorrhea antigen exists.
Low concentration of Gonorrhea antigen may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

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QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Clinical Study

The Gonorrhea Rapid Test Device has been evaluated with specimens obtained from patients of STD clinics. Culture is used as the reference method for the Gonorrhea Rapid Test Device. Specimens were considered positive if Culture indicated a positive result. Specimens were considered negative if Culture indicated a negative result.

For Female Cervical Swab Specimens:

Method		Culture		Total Results
	Results	Positive	Negative	
Gonorrhea Test Device	Positive	72	2	74
	Negative	5	83	88
Total Results		77	85	162

Sensitivity: 94 % **Specificity: 98 %**
+ Pedictive V: 97,3 % **- Pedictive V: 94,4 %**

For Male Urethral Swab Specimens:

Method		Culture		Total Results
	Results	Positive	Negative	
Gonorrhea Test Device	Positive	75	2	77
	Negative	7	91	98
Total Results		82	93	175

Sensitivity: 92 % **Specificity: 98 %**
+ Pedictive V: 97,4 % **- Pedictive V: 93 %**

Intra and Inter Assay

Within-run and Between-run precision have been determined by using Gonorrhea negative; low, middle and high positive specimens. Ten replicates of each level were tested each day for 5 consecutive days. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Cross reactivity with other organisms has been studied using suspensions of 10^7 Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the Gonorrhea Test Device:

Acinetobacter calcoaceticus	*Pseudomona aeruginosa*	*Proteus mirabilis*
Acinetobacter spp	*Gardnerella vaginalis*	*Chlamydia trachomatis*
Enterococcus faecalis	*Salmonella choleraesius*	*Group B/C Streptococcus*
Enterococcus faecium	*Candida albicans*	*Hemophilus influenzae*
Staphylococcus aureus	*Proteus vulgaris*	*Klebsiella pneumoniae*

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SYMBOLS USED

CE

Manufacturer

EC REP Authorized European Representative

Attention, see instruction for use

Consult instruction for use

IVD *In vitro* diagnostic medical device

Σ n Number of test

For single use only

Storage temperature

LOT Lot number

REF Catalog number

Expiry date