CE IVD

FRENOVO

Gonorrhea Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Gonorrhea Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Gonorrhea Rapid Test Kit is an immunochromatographic assay for the qualitative presumptive detection of Neisseria gonorrhoeae in female endocervical swab and male urethral swab specimens. This kit is intended for use as an aid in the diagnosis of Gonorrhea.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

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. But there are 5% ～ 20% of men and 60% of women patient that do not show any symptoms. Spread of the organism to the fallopian tubes and abdomen may cause severe lower-abdominal 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.

FRENOVO Gonorrhea Rapid Test Kit detects Neisseria gonorrhoeae through visual interpretation of color development on the internal strip. Gonococcal Antigen-specific polyclonal antibody is immobilized on the test region of the membrane. During testing, the specimen reacts with monoclonal anti-Gonococcus antibodies conjugated to colored particles and precoated onto the label pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient Gonococcal antigens in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched (with desiccant).
2. Extraction Tubes (with Caps): 20 pieces (with 300ul Buffer A) filled in one zip bag.
3. Extraction Buffer: Bottle B with 8.0 ml .
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Biohazard disposal waste container
- Disposable gloves and/or protective clothing
- Sampling swab

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate swab, tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix extraction buffer/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of extracted solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit and extraction buffer should be stored between 2-30°C and the shelf life is 24 months.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction buffer has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SPECIMEN COLLECTION

FRENOVO Gonorrhea Rapid Test Kit can be performed using female cervical swab, male urethral swab specimens.The quality of specimens obtained is of extreme importance. Detection of Gonorrhea requires a vigorous and thorough collection technique that provides cellular material rather than just body fluids.

To collect Female Cervical Swab Specimen:

Any plastic-shaft swab may be used for sampling. 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 Gonorrhea organism. Firmly rotate the swab 360°in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens. If the test is to be conducted immediately, put the swab into the extraction tube.

To collect Male Urethral Swab Specimens:

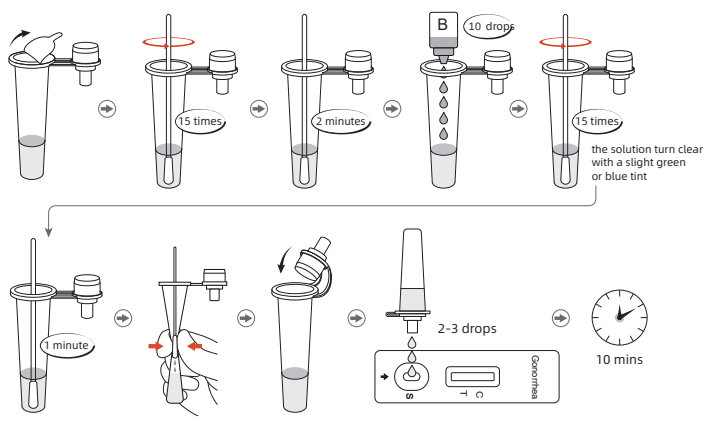
Standard plastic-or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least 1 hour period to specimen collection. Insert the swab into the urethral about 2-4 cm, rotate the swab 360°in one direction (clockwise or counterclockwise), let stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before collection swab.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 immediately testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swab may be stored for 4-6 hours at room temperature (15-30℃) or 24-72 hours refrigerated (2-8℃) for 24 hours. Do not freeze. All specimens should be allow to reach the room temperature (15-30℃) before testing.

TEST PROCEDURE

Allow the test device, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction tube on the work station and tear open the aluminum foil.Immediately insert the swab, compress the bottom of tube and rotate swab 15 times. Let stand for 2 minutes. Hold the extraction buffer bottle B and vertically add 10 drops(approx. 300ul) of extraction buffer B to the extraction tube. The solution would turn turbid. Compress the tube and rotate the swab 15 times until the solution turn clear with a slight green or blue tint. Let stand 1 minute. Press the swab against the side of tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible.
3. Install the tube cap on the extraction tube, then put 2 to 3 drops into the sample well of the Test cassette, start the timer.
4. Read the results at 10 minutes, and the results after 15 minutes are no longer valid.

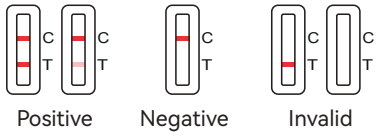


INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that Gonorrhea has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Gonorrhea has been detected and the result is positive for antigen.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.



Positive Negative Invalid

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of Gonorrhea in female cervical swab, male urethral swab specimens. Neither the quantitative value nor the rate of increase in Gonorrhea concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of Gonorrhea in the specimen or not.
3. Detection of Gonorrhea is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of STD, presence of symptoms, etc. The minimum detection level of this test may vary according to serovars.
4. Women with vaginal discharge should be evaluated for risk factors of cervicitis and pelvic imflammatory diseases caused by other organisms including Candida albicans, Trichomonas vaginalis or Bacterial Vaginosis.
5. Excess blood on the swab specimen may interfere with test performance and may yield a false positive result.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
7. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Clinical samples		PCR		
Gonorrhea Rapid Test Kit	Results	Positive	Negative	Total Results
	Positive	134	2	136
	Negative	3	389	392
Total Results		137	391	528

Clinical sensitivity=97.81% (95%CI * 93.73% to 99.55%)
Clinical specificity=99.45% (95%CI * 98.16% to 99.94%)
Accuracy=99.05% (95%CI * 97.80% to 99.69%)

Cross Reaction

Cross reactivity with organisms has been studied using suspensions of 10 organisms has been studied using suspensions of 107CFU/ml. The following organisms produced negative results produced negative results.

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

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2℃ 30℃	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks	CE	CE mark

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