Chlamydia Rapid Test Kit
Instructions For Use

PRODUCT NAME

FRENOVO Chlamydia Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Chlamydia Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Chlamydia trachomatis in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. It is composed of elementary bodies (the infectious form) and reticulate or inclusion bodies (the replicating form). Chlamydia trachomatis has both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of Chlamydia infection in women include cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility.1 Vertical transmission of the disease during parturition from to neonate can result in inclusion conjunctivitis or pneumonia. In men, complication of Chlamydia includesurethritis and epididymitis. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia infection. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic. Traditionally, Chlamydia infection has been diagnosed by detection of Chlamydia inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labor intensive, expensive, long (18-72 hours) and not routinely available in most situations.

FRENOVO Chlamydia Rapid Test Kit is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical, male urethral and male urine. In the test, antibody specific to the Chlamydia antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Chlamydia that is coated onto particles. The mixture migrates up to react with the antibody to Chlamydia on the membrane and generates a color line in the test region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that 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 filled in one zip bag
3. Extraction Buffer: Bottle A & B with 8.0 ml filled in each bottle.
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 Chlamydia Rapid Test Kit can be performed using female cervical swab, male urethral swab and male urine specimens. The quality of specimens obtained is of extreme importance. Detection of Chlamydia 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 Chlamydia 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.

- To collect Male Urine Specimens:

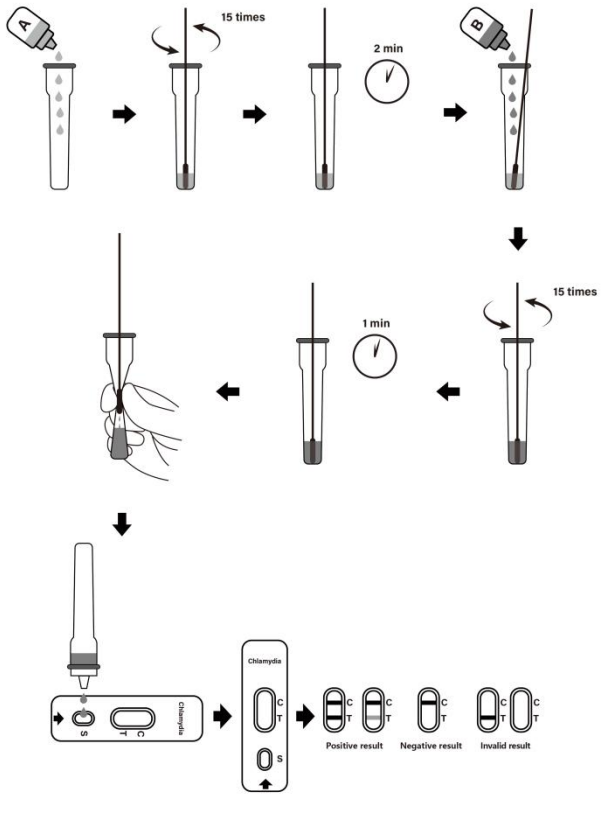
Collect 15-30ml of clean first morning urine in a sterile urine cup. First morning urine specimens are preferred to achieve the highest concentrations of Chlamydia antigen. Mix the urine specimen by inverting container. Transfer 10ml of the urine specimen into a centrifuge tube, add 10ml distilled water and centrifuge at 3,000 rpm for 15 minutes. Carefully discard the supernatant, keep the tube inverted and remove any supernatant from the rim of the tube by blotting onto absorbent pad. Use a swab scrape the urine sediment,ready for use.

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. Hold the extraction buffer bottle A vertically and add 5 drops (approx. 300ul) of extraction buffer solution A into the extraction tube. Extraction buffer A is colorless. 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 vertically add 5 drops(approx. 300ul) of extraction buffer solution 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 Chlamydia antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Chlamydia antigen 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.

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of Chlamydia in female cervical swab, male urethral swab and male urine specimens. Neither the quantitative value nor the rate of increase in Chlamydia concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of Chlamydia in the specimen or not.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Chlamydia present in specimens is not adequate or is below the detectable level of the test.
5. Excess blood on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. A positive result for Chlamydia does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

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		Total Results
Chlamydia Rapid Test Kit	Results	Positive	Negative	
	Positive	137	1	138
	Negative	2	285	287
Total Results		139	286	425

Clinical sensitivity=97.60% (95%CI * 93.15% to 99.50%)

Clinical specificity=96.91% (95%CI * 92.94% to 98.99%)

Accuracy=97.21% (95%CI * 94.58% to 98.79%)

Cross Reaction

The antibody used in the Chlamydia Rapid Test Cassette (Swab/Urine) has been shown to detect all known Chlamydia serovars. Chlamydia psittasi and Chlamydia pneumoniae strains have been tested with the Chlamydia Rapid Test Cassette (Swab/Urine), and were shown to cross react when tested in suspensions of 10^9 Colony Forming Units (CFU)/ml. Cross reactivity with other organisms has been studied using suspensions of 10^9 CFU/ml. The following organisms were found negative when tested with the Chlamydia Rapid Test Cassette (Swab/Urine):

Acinetobacter calcoaceticus	Enterococcus faecium
Pseudomona aeruginosa	Candida albicans
Proteus mirabilis	Hemophilus influenzae
Acinetobacter spp	Staphylococcus aureus
Neisseria meningitides	Proteus vulgaris
Neisseria gonnorhea	Branhamella catarrhalis
Enterococcus faecalis	Klebsiella pneumoniae
Salmonella choleraesius	Gardnerella vaginalis
Group B/C Streptococcus	

Date of Issue:

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°C	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
CE	CE mark		Biological risks
EC REP	European Authorized Representative		

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INSTRUCTION APPROVAL AND REVISION DATE

Revision Date: