FRENOVO

Candida albicans / Trichomonas vaginalis / Gardnerella vaginalis antigen Combo Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Candida albicans/ Trichomonas vaginalis/ Gardnerella vaginalis antigen Combo Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Candida albicans/ Trichomonas vaginalis/ Gardnerella vaginalis antigen Combo Rapid Test Kit is an immunochromatographic assay for the rapid qualitative detection of Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis in female vaginal swab samples in vitro.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Candida albicans is a major fungal pathogen of humans. It exists as a commensal in the oral cavity, gut or genital tract of most individuals, constrained by the local microbiota, epithelial barriers and immune defences. Their perturbation can lead to fungal outgrowth and the development of mucosal infections such as oropharyngeal or vulvovaginal candidiasis, and patients with compromised immunity are susceptible to life-threatening systemic infections. Trichomoniasis is a sexually transmitted disease (STI) with important public health ramifications; it has been associated with vaginitis, cervicitis, urethritis, and pelvic inflammatory disease (PID). Trichomoniasis also impacts upon birth outcomes and is a co-factor in human immunodeficiency virus (HIV) transmission and acquisition.Trichomonas vaginalis is a motile organism with a size comparable to a white blood cell. It has at least 4 flagella that provide undulating motility. The organism resides in the lumen of the urogenital tract. The organism releases cytotoxic proteins that destroy the epithelial lining. During an infection, the vaginal pH usually increases. Gardnerella vaginalis is an anaerobic bacterium that resides in the normal vaginal flora. Normally, vaginal flora is predomi- nated by the Lactobacilli species, but when organisms such as Gardnerella begin to overgrow and become the dominant species, this leads to bacterial vaginosis (BV). Bacterial vaginosis is characterized by the presence of clue cells, which are epithelial cells of the cervix that are covered with rod-shaped bacteria.

FRENOVO Candida albicans / Trichomonas vaginalis / Gardnerella vaginalis antigen Combo Rapid Test Kit uses a double antibody sandwich method to detect Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis by immunochromatography.

When the appropriate amount of test samples treated with dilution buffer is added to the sample well of the test cassette, the sample will move forward along the test strip by capillary action. If the sample contains Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis antigen, and the concentration is higher than the limit of detection, the antigen will form immune complexes with corresponding Candida albicans, Trichomonas vaginalis, or Gardnerella vaginalis antibody labeled with gold particles respectively, which are captured by CA line, TV line and GV line. If test sample contains Candida albicans, forming a red CA line, indicating a positive result for Candida albicans. If test sample contains Trichomonas vaginalis , forming a red TV line, indicating a positive result for Trichomonas vaginalis. If test sample contains Gardnerella vaginalis , forming a red GV line, indicating a positive result for Gardnerella vaginalis.

Additionally, the test strip also contains a control line (C line). The C line should be formed to indicate that the sample has been transported properly through the membrane regardless of whether sample contains antigens or not. If the C line does not appear, it indicates that the test result is invalid and the sample need to retest.

KIT COMPONENTS

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched (with desiccant).
2. Extraction Tubes (with Caps): 25 pieces filled with 600ul extraction buffer individually.
3. Package insert: 1 piece attached.
4. Sampling swab: 25 pieces individually pouched.

MATERIALS REQUIRED BUT NOT PROVIDED

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

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.

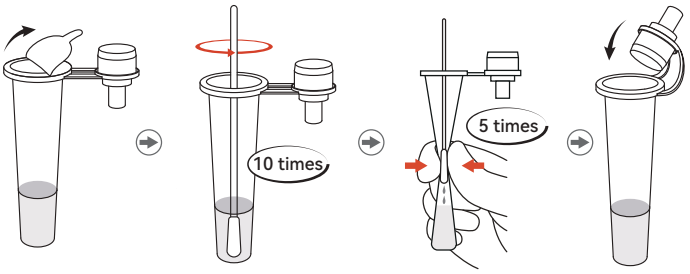
SPECIMEN COLLECTION

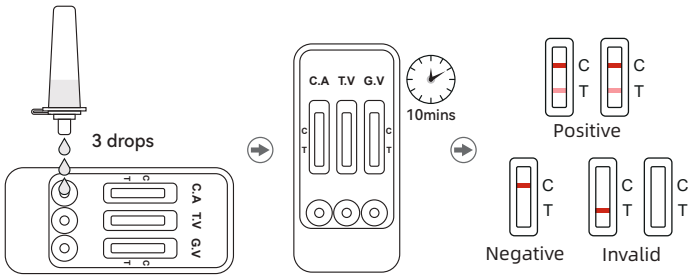
1. Secretions were obtained from the posterior vaginal fornix with sampling swabs.
2. Sample should be transferred into the dilution buffer provided in this kit as soon as possible after collection.
3. Samples should be tested immediately after collection. If the sample cannot be detected immediately, it can be placed at 2-8°C for 72h. For long-term storage, it can be stored at -20°C for 3 months.

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. Tear the seal of the dilution buffer, and insert the swab (after collection) into the dilution buffer. Rotate the swab against the inner tube wall 10 times. Squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer, then remove and discard the swab.
3. Install the tube cap on the extraction tube, then put 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 only the quality control C line appears and the detection line (T line) is not visible, the sample contains no Candida albicans, Trichomonas vaginalis and Gardnerella vaginalis antigens or the concentration is lower than the limit of detection and the result is negative.

Positive result: If the quality control C line appears, and one or more red lines appear in the CA / GV / TV detection line area (T line), indicating that the sample contains one or more pathogenic microorganisms.

Invalid result: If the C line does not appear, the result is invalid and a new test must be performed.

Note: The color intensity of the detection line is related to the concentration of pathogenic microorganisms in the sample, the result should be determined by whether the detection line is colored or not regardless of the color intensity.

LIMITATIONS

1. The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples or repeated frozen-thawed samples can affect the test results. Test results can also be affected by temperature and humidity.
2. Low concentration of Candida albicans, Trichomonas vaginalis and Gardnerella vaginalis antigens in the sample may cause negative results, so the possibility of infection cannot be completely ruled out.
3. This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
4. The test results of this kit are for clinical reference only and are not the sole basis for clinical diagnosis. The clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.
5. The patient should avoid sexual intercourse, vaginal douching or vaginal medication, for 24 hours prior to sampling as this may affect the test results.
6. This test kit should be used by qualified person with professional experience.

PERFORMANCE CHARACTERISTICS

Limit of Detection-LoD

Limit of Detection (LoD) studies determined the lowest detectable concentration of the Candida albicans, Trichomonas vaginalis and Gardnerella vaginalis, which ≥95% of all (true positive) replicates test positive.

The LoD of Candida albicans is 104 CFU/mL; the LoD of Trichomonas vaginalis is 104 cells/mL; the LoD of Gardnerella vaginalis is 105 CFU/mL.

Cross Reactivity

Cross reactivity and potential interference of Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit were evaluated by testing microorganisms in the absence or presence of Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis. The listed items in the following table may be present in the clinical samples. Each of the microorganism was tested in triplicate with no false positive results.

Protential Cross-Reactant	Concentration Tested
Neisseria gonorrhoeae	1.0×10^6CFU/mL
Mycoplasma hominis	1.0×10^6CFU/mL
Chlamydia trachomatis	1.0×10^6CFU/mL
Acinetobacter	1.0×10^6CFU/mL
Ureaplasma urealyticum	1.0×10^6CFU/mL
α-Hemolytic streptococcus	1.0×10^6CFU/mL
γ-Streptococcus	1.0×10^6CFU/mL
Proteus vulgaris	1.0×10^6CFU/mL
Enterococcus faecalis	1.0×10^6CFU/mL
Pseudomonas aeruginosa	1.0×10^6CFU/mL
Staphylococcus epidermidis	1.0×10^6CFU/mL
Escherichia coli	1.0×10^6CFU/mL
Shigella dysenteriae	1.0×10^6CFU/mL
β-Hemolytic streptococcus	1.0×10^6CFU/mL
human papillomavirus	1.0×10^5PFU/mL
Staphylococcus aureus	1.0×10^6CFU/mL

Interfering Substances

A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be articially introduced into clinical samples do not inference with the detection of Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis in the Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit at the concentrations listed below. Test the listed items in the absence or presence of Candida albicans,Trichomonas vaginalis, and Gardnerella vaginalis. No interference was observed.

Potential Interfering Substances	Concentration
Whole blood	50ul/mL
Mucin	0.3mg/mL
Urine	50ul/mL
Mycostatin	5mg/mL
Miconazole	5mg/mL
Tinidazole	5mg/mL
Metronidazole	5mg/mL
Jieeryin (lotion)	2.5ul/mL
Fuyinjie (lotion)	20ul/mL
Hemoglobin	10mg/mL

Sensitivity and Specificity

The clinical research was evaluated by comparing the FRENOVO Candida albicans / Trichomonas vaginalis / Gardnerella vaginalis antigen Combo Test Kit with Gram staining for Candida albicans, Microscopic examination for Trichomonas vaginalis and Nugent scoring for Gardnerella vaginalis respectively, to evaluate the clinical sensitivity and specificity of the Candidate Kit. The Clinical Test results of the test kit and the reference method are summarized in the 2×2 table below:

Candida albicans antigen test study		Gram staining		Total Results
FRENOVO Candida albicans/ Trichomonas vaginalis/ Gardnerella vaginalis antigen Combo Test Kit	Results	Positive	Negative	
	Positive	120	3	123
	Negative	2	108	110
Total Results		122	111	233

Clinical sensitivity=98.36% (94.20% ～ 99.80%)
Clinical specificity=97.30% (92.30% ～ 99.44%)
Accuracy=97.85% (95.06% ～ 99.30%)

Trichomonas vaginalis antigen test study		Microscopic examination		Total Results
FRENOVO Candida albicans/ Trichomonas vaginalis/ Gardnerella vaginalis antigen Combo Test Kit	Results	Positive	Negative	
	Positive	135	1	136
	Negative	2	112	114
Total Results		137	113	250

Clinical sensitivity=98.54% (94.83% ～ 99.82%)
Clinical specificity=99.12% (95.17% ～ 99.98%)
Accuracy=98.80% (96.53% ～ 99.75%)

Gardnerella vaginalis antigen test study		Nugent scoring		Total Results
FRENOVO Candida albicans/ Trichomonas vaginalis/ Gardnerella vaginalis antigen Combo Test Kit	Results	Positive	Negative	
	Positive	116	3	119
	Negative	1	146	147
Total Results		117	149	266

Clinical sensitivity=99.15% (95.33% ～ 99.98%)
Clinical specificity=97.99% (94.23% ～ 99.58%)
Accuracy=98.50% (96.19% ～ 99.59%)

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		

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