Candida albicans/ Trichomonas vaginalis/ Gardnerella vaginalis antigen Combo Test Kit (LFIA)

FOR PROFESSIONAL USE ONLY
FOR *IN VITRO* DIAGNOSTIC USE ONLY.
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.

Instructions For Use

Test Kit Contents


Test Cassette


Sampling swab


Dilution buffer and dropper


Instructions for use

REF	Components / Specification	Test Cassette	Sampling swab	Dilution buffer and dropper	Instructions for use
012113-01-01	1 pc/Box	1	1	1	1
012113-20-01	20 pcs/Box	20	20	20	1

Test cassette contains test strip, plastic cassette, desiccant. The test strip contains anti-Candida albicans antibody labeled with latex microsphere, anti-Gardnerella vaginalis antibody labeled with latex microsphere, anti-Trichomonas vaginalis antibody labeled with latex microsphere. Another anti-Candida albicans antibody, anti-Gardnerella vaginalis antibody and anti-Trichomonas vaginalis antibody are fixed on the CA line, GV line and TV line respectively. The CA line/GV line/TV line and control line (C line) are in the detection window on the nitrocellulose membrane.

Intended Use

Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit (LFIA) is a Latex microsphere immunochromatography for the rapid qualitative detection of Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis in female vaginal swab samples in vitro.
This test kit is suitable for women with clinical symptoms of gynecological inflammation or suspected gynecological inflammation.

Introduction

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 predominated 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.

Test principle

Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit (LFIA) uses a double antibody sandwich method to detect Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis by Latex microsphere 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 Latex microspheres 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 Gardnerella 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.

Storage Instructions

The test kit should be stored away from direct sunlight at 2℃ to 30℃ with a shelf-life of 24 months. Do not freeze.

Sample requirements

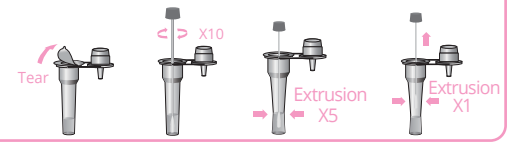
1. Secretions were obtained from the posterior vaginal fornix with sampling swabs.
2. Sample should be transferred into the dilution buffer provided in this kit as soon as possible after collection.
3. Samples should be tested immediately after collection. If the sample cannot be detected immediately, it can be placed at 2-8°C for 72h. For long-term storage, it can be stored at -20°C for 6 months.

Testing Procedure

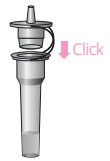
1 Read instructions carefully.

2 A sampling swab is used to collect the vaginal discharge from the posterior vagina.

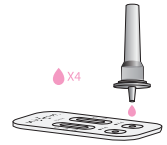
3 Tear the seal of the dilution buffer, and insert the swab (after collection) into the dilution buffer. Rotate the swab against the inner tube wall 10 times. Squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer, then move the swab up until it is resting on the sample solution, squeeze the swab from the outer tube wall in order to leave the sample in the tube as much as possible.



4 Remove and discard the swab, cover the tube with the dropper.



5 Open the aluminum foil pouch, take out the test cassette and lay it on a clean flat surface, add 4 drops processed sample extract into each of the 2 sample wells.



6 The result should be observed within 15-20 minutes. Result observed after 20 minutes is invalid.

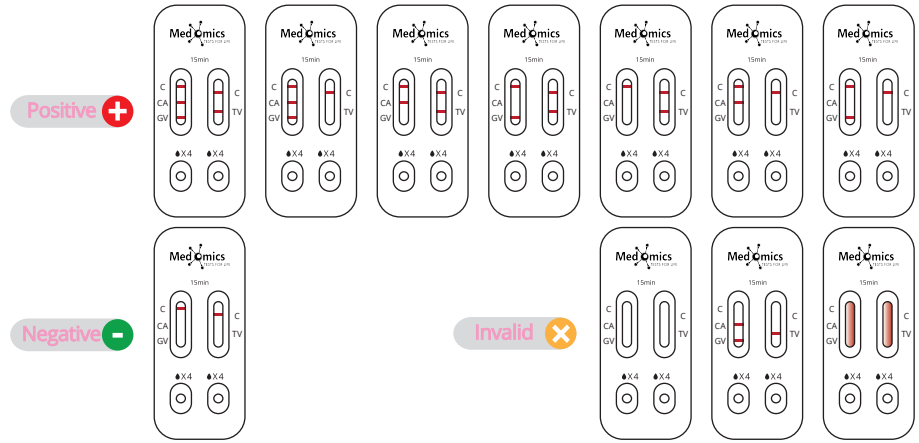
Remark: Additional required but not provided equipment: Timer

Test method 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 or proper training.

Interpretation of Test Results

"C": Control Line "CA": Candida albicans Test Line "GV": Gardnerella vaginalis Test Line "TV":Trichomonas vaginalis Test Line



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Display of Results/Expected Values

Negative result: If only the quality control C line appears and the detection 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, 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.

Product Performance

· 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 10^4CFU/mL; the LoD of Trichomonas vaginalis is 10^4cells/mL; the LoD of Gardnerella vaginalis is 10^5CFU/mL.
· Cross Reactivity
Cross reactivity and potential interference of Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit (LFIA) 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.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Neisseria gonorrhoeae	1.0×10^6CFU/mL	No
Mycoplasma hominis	1.0×10^6CFU/mL	No
Chlamydia trachomatis	1.0×10^6CFU/mL	No
Acinetobacter	1.0×10^6CFU/mL	No
Ureaplasma urealyticum	1.0×10^6CFU/mL	No
α-Hemolytic streptococcus	1.0×10^6CFU/mL	No
γ-Streptococcus	1.0×10^6CFU/mL	No
Proteus vulgaris	1.0×10^6CFU/mL	No
Enterococcus faecalis	1.0×10^6CFU/mL	No
Pseudomonas aeruginosa	1.0×10^6CFU/mL	No
Staphylococcus epidermidis	1.0×10^6CFU/mL	No
Escherichia coli	1.0×10^6CFU/mL	No
Shigella dysenteriae	1.0×10^6CFU/mL	No
β-Hemolytic streptococcus	1.0×10^6CFU/mL	No
human papillomavirus	1.0×10^5PFU/mL	No
Staphylococcus aureus	1.0×10^6CFU/mL	No

• Interfering Substances Effect
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 Medomics Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit (LFIA) at the concentrations listed below. Test the listed items in the absence or presence of Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis.

Potential Interfering Substances	Concentration	Interference (Yes/No)
Whole blood	50ul/mL	No
Mucin	0.3mg/mL	No
Urine	50ul/mL	No
Mycostatin	5mg/mL	No
Miconazole	5mg/mL	No
Tinidazole	5mg/mL	No
Metronidazole	5mg/mL	No
Jieeryin (lotion)	2.5ul/mL	No
Fuyinjie (lotion)	20ul/mL	No
Hemoglobin	10mg/mL	No

Clinical results

The clinical research was evaluated by comparing the Candida albicans/Trichomonas vaginalis/Gardnerella vaginalis antigen Combo Test Kit (LFIA) manufactured by Jiangsu Medomics Medical Technology Co., Ltd with Nugent scoring for BV, Microscopic examination for Trichomonas vaginalis and Gram staining for Candida albicans 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:

	Nugent Scoring Result		
Medomics Gardnerella vaginalis antigen test result	Positive	Negative	Total
Positive	363	33	396
Negative	3	884	887
Total	366	917	1283
*95% Confidence Interbal			
Sensitivity: 99.18% (97.62%～99.83%) Specificity: 96.40% (94.98%～97.51%)	PPV: 91.67% (88.50%～94.19%) NPV: 99.66% (99.02%～99.93%)		Accuracy: 97.19% (96.14%～98.03%) Kappa value: 0.9328

	Gram staining Result		
Medomics Candida albicans antigen test result	Positive	Negative	Total
Positive	360	28	388
Negative	8	887	895
Total	368	915	1283
*95% Confidence Interbal			
Sensitivity: 97.83% (95.76%～99.06%) Specificity: 96.94% (95.61%～97.96%)	PPV: 92.78% (89.74%～95.15%) NPV: 99.11% (98.25%～99.61%)		Accuracy: 97.19% (96.14%～98.03%) Kappa value: 0.9325

	Microscopic examination Result		
Medomics Trichomonas vaginalis antigen test result	Positive	Negative	Total
Positive	247	0	247
Negative	1	1035	1036
Total	248	1035	1283
*95% Confidence Interbal			
Sensitivity: 99.60% (97.77%～99.99%) Specificity: 100.00% (99.64%～100.00%)	PPV: 100.00% (98.52%～100.00%) NPV: 99.90% (99.46%～100.00%)		Accuracy: 99.92% (99.57%～100.00%) Kappa value: 0.9975

Warnings and Precautions

1. Please read the manual carefully before operation, and please test in strict accordance with the requirements of the manual.
2. This test kit is used for in vitro diagnosis only.
3. This test kit should be used within 1 hour after opening the foil pouch.
4. Bring the kit contents to room temperature before testing.
5. Do not re-use the test kit.
6. Do not use the test kit if the pouch is damaged, the seal is broken or the test cassette is wet or polluted.
7. Do not use the test kit contents beyond the expiration date printed on the outside of the box.
8. Do not mix with kit components from other kits.
9. Test kit solutions should only be used as directed.
10. Avoid contact with skin and eyes;If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.
11. After the test, the used test cards, etc. should be disposed of as medical waste.
12. Do not move the test cassette around during the test.

Reference

1. François L Mayer, Duncan Wilson, Bernhard Hube. Candida albicans pathogenicity mechanisms. Virulence. 2013 Feb 15;4(2):119-28.
2.Van Der Pol B. Clinical and Laboratory Testing for Trichomonas vaginalis Infection. J Clin Microbiol. 2016 Jan;54(1):7-12.
3.António Machado and Nuno Cerca. Influence of Biofilm Formation by Gardnerella vaginalis and Other Anaerobes on Bacterial Vaginosis. J Infect Dis. 2015 Dec 15;212(12):1856-61.

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