Medomics
TESTS FOR LIFE

CANDIDA ALBICANS/TRICHOMONAS VAGINALIS/ GARDNERELLA VAGINALIS

ANTIGEN COMBO TEST KIT (LFIA)

INFECTIOUS DISEASE

Specification
1 pc/Box/20 pcs/Box

Storage condition
2-30°C

Testing time
15 minutes

Shelf life
24 months

Description

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.

Sample female vaginal swab

Specification 1pc/box, 20pcs/box

Storage condition 2℃-30℃, keep dry, away from direct sunlight

Shelf life 24 months, single use

Precaution Use within 1 hour after opening the inner packaging

Test Kit Contents


Test Cassette


Sampling swab

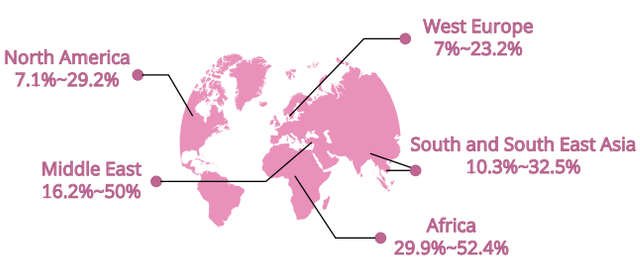

Dilution buffer and dropper


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

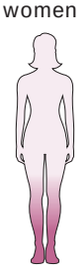
Epidemiology

Bacterial vaginosis (B.V.)
When the number of lactobacilli which produce hydrogen peroxide in the vagina decrease or disappear, the facultative anaerobic bacteria and anaerobic bacteria increase, which lead to vaginal infections. Then common pathogens include facultative aerobic bacteria (Gardnerella Vaginals), anaerobic bacteria (Prevotella, Activity Campylobacter, Bacteroides, Atropa vaginalis) and Ureaplasma ureaplasma, Mycoplasma hominis, etc.



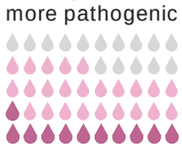
B.V. morbidity

Vulvovaginal Candidiasis (V.V.C.) refers to vaginal inflammation caused by Candida infection. 75% of women suffer from V.V.C. at least once in their life time, and 40% to 45% of women experienced recurrent infections.


Mobidity rate is about 23% in China, 11.6% of gynecological outpatient clinics, 0.58% for R.V.V.C.


Mobidity rate from 29% to 49% in Europe and USA, 9% for R.V.V.C.

Mixed vaginitis is inflammation of the vagina caused by two or more pathogenic microorganisms.


Internal mobidity rate of V.V.C + B.V. is 20.95%-74.89%


External mobidity rate of V.V.C + B.V. is 14.9%

Advantages

On-site screening &
Quick results in 15 min

Low professional requirement
Low training requirement

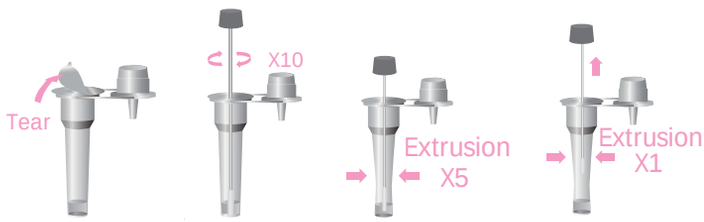
Unaffected by medication
Obtain pathogen antigen, high specificity

Operation process

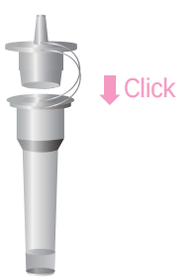
1 Read instructions carefully.

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

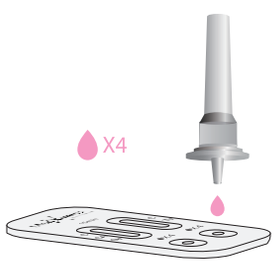
3 Tear the seal of the dilution buffer, and insert the swab (after collection) into the dilution buffer. Rotate the swab against the inner tube wall 10 times. Squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer, then move the swab up until it is resting on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



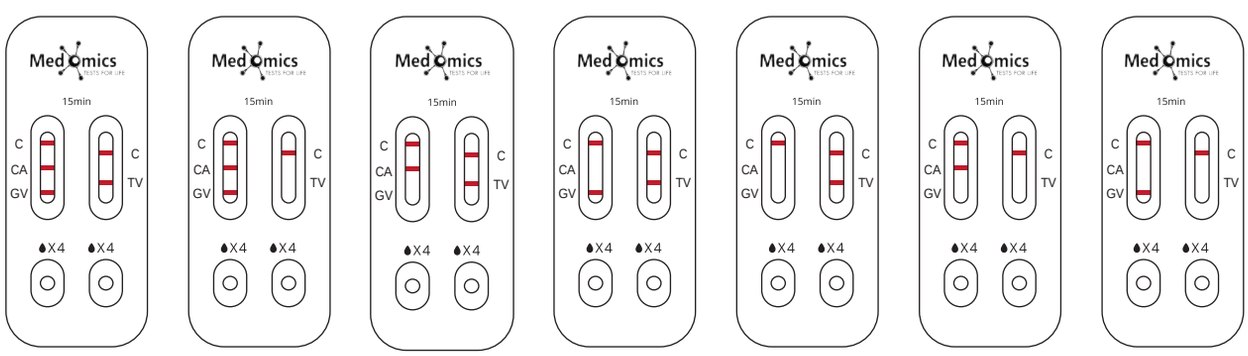
6 The result should be observed within 15-20 minutes. Result observed after 20 minutes is invalid.

Remark: Additional required but not provided equipment: Timer

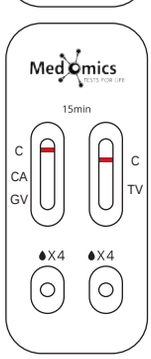
Interpretation of Test Results

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

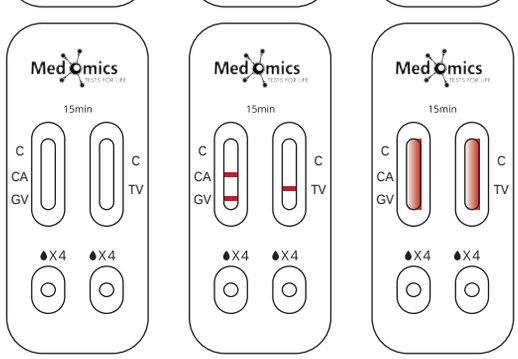
Positive +



Negative -



Invalid ×



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 interval			
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 interval			
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 interval			
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	