

For In Vitro Diagnostic Use

**Rapid Test For Sexually Transmitted Disease
Trichomonas V./ C. albs (yeast) / Gardnerella V Ag Test
Triple (3 in 1) STD panel Rapid Test Kit
(Home Test)**

Cat No: JTCGV-3/1

[SUMMARY AND EXPLANATION]

Sexually transmitted infections (STIs) are among the most common cause of illness in the world and have far-reaching health, social and economic consequences for many countries. Sexual Transmitted Diseases (STDs) remain a public health problem of major significance in most parts of the world. The incidence of acute STDs is believed to be high in many countries. Failure to diagnose and treat STIs at an early stage may result in serious complications and sequelae, including infertility, fetal wastage, ectopic pregnancy, anogenital cancer and premature death, as well as neonatal and infant infections. The individual and national expenditure on STD care can be substantial. For the sexually transmitted diseases, also known as *hemophilus*, in females this infection causes an abnormal, foul-smelling, greyish vaginal discharge and sometimes redness or itching of vulva. Males may harbor the germs that causes this infection in their bodies, but they are usually asymptomatic. For Vaginitis, whether infectious or not, constitutes one of the most common problems in clinical medicine, and it is one of the main motives that lead women to seek out an obstetrician or gynecologist. Bacterial vaginosis, candidiasis and trichomoniasis are responsible for 90% of the case of infectious origin.

Bacterial vaginosis (BV) is characterized by the substitution of the vaginal flora, normally dominated by lactobacilli, by a complex and abundant flora of strictly or optionally anaerobic bacteria that are normally found in vagina (*Gardnerella vaginalis*, *Bacteroides* sp, *Peptostreptococcus*, *Mobiluncus* sp). Abundant foul – smelling vaginal secretions are the typical symptom of infection by ***Gardnerella vaginalis* (GV)**.

The symptomatic infection by ***Candida albs (yeast) (CA)*** arises when there is an excessive proliferation of this microorganism in the vaginal flora, ceasing its colonization and starting to achieve outright adherence to the vaginal cells, consequently causing infection. The patient presents thick, fetid vaginal secretions with a granular appearance and an itchy vulva. The vagina becomes hyperemic and the vulva erythematous, and there maybe excoriation and dyspareunia. ***Trichomonas vaginalis (TV)*** is a flagellate protozoan considered to be sexually transmittable and related to low socioeconomic levels. Typically a patient with trichomoniasis presents intense frothy yellow – greenish vaginal discharges, irritation and pain in the vulva, perineum and thighs, and dyspareunia and dysuria.

[Product usage]

Rapid Test For Sexual Transmitted Disease *Trichomonas V./ C. albs (yeast) / Gardnerella V Ag Test*
Triple (3 in 1) STD panel Rapid Test Kit
This is a single package box for women and men home test use.

[Test Box content]

1. One foil pouch: The pouch includes one **Triple (3/1), TV/ CA/GV Test Card** and 1 desiccant.
2. One dropper (0.5ml scale indication device)
3. One Urine cup
4. Purple Cap Sample Test Tube (Purple color of cap) within 0.5ml sample buffer. It contains: 0.01% Tris-saline, 0.05% Sodium Azide, 0.1% Tween-20/detergent. PH 7.5
5. Instruction manual

[Storage]

Please store it at a dry place with temperature between 2 to 30°C. Please avoid sunlight. Do not store it in the freezer.

[Preparation before the test]

1. Read the instruction manual carefully and thoroughly.
2. Prepare a timer.

[Test Procedures]

Collect urine:

1. To collect the first urine of the day for higher accuracy.
2. Open the test kit and take out the urine cup. Carefully place the urine into the cup then stand to wait for testing.

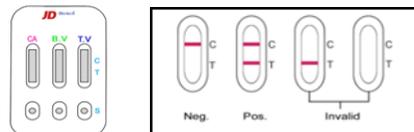
Test tube preparation:

1. Take out the Sample Test Tube from box.
2. Open the purple cap and stand vertical on table. Don't let the liquid be poured out.
3. Take out the 0.5ml dropper from box and suck up 0.5ml of urine liquid volume to scale of indication of dropper.
3. Put 0.5ml of Urine into the Sample Test Tube with 0.5ml of sample buffer.
4. Tightly close the cap and swirl the tube clockwise for about 5 seconds to mix the solution.

Test

1. Take out the **Triple (3/1), TV/ CA/GV Test Card** from foil pouch.
2. Break out the tip of the Purple Cap of Sample Test Tube (above Item 2.c)
3. Drip 3 to 4 drops of mixture urine liquid solution into the “S” region of the each Item test TV, CA, GV. then you will see the liquid starting to move upwards.
4. Place the test card under room temperature for **15** minutes reaction then read the result.

Result reading:



Please read the test card in 15 minutes, if the reading time is after 30 minutes from testing, the test will be considered as a failure.

Negative result. (Not infected)

A red/purple line shown at the [C] control region while no lines appeared at [T] Test region.

Positive result: (infected):

A clear red/purple line appeared on both “ [C] Control region and the [T] Test region or light / purple line appeared on [T] region. The line color at [T] Test region may vary depending on the degree of infection.

Result is false or failed:

No line appeared on either [C] Control region or [T] Test region, or only [T] Test region had a line shown will be considered as a fail test.

[Accuracy]

Compared with wet mount microscope and culture method.

[Attention]

Do NOT collect urine sample containing blood as it can affect the test reading.

1. Please use the **Triple (3/1) C.A/T.V/G.V test card** within 1 hour after opening the package to prevent humidity from affecting the accuracy of the test.
2. The test tube contains neutral buffer. If it gets in contact with eyes or skin, please wash the area with tap water for 1 to 2 minutes to avoid possible allergies.
3. It is unnecessary to strongly mix the urine sample with the buffer inside the test tubes. If there are too many bubbles floating on the surface of the liquid after mixing, put the test tube aside for 3 to 5 minutes to let some bubbles diminish, then apply the test.

[Product limits]

1. This product is for Home Test to determine possible *Candida Albicans (Yeast)* and *Trichomonas Vaginalis* or

Test Product	Specificity	Sensitivity
<i>Candida albicans</i> Antigen Test Kit	98.4%	95.5%
<i>Trichomonas Vaginalis</i> Antigen Test Kit	99%	100%
<i>Gardnerella Vaginalis</i> Antigen Test Kit	98.62%	98.46%

Gardnerella V. infection.

2. The product is for “In Vitro Diagnostic” use.
3. The product is for one time use ONLY. Please discard the test when it is done.
4. Do NOT use an expired test card.
5. Do NOT use the test card if any damages are discovered on a sealed test kit.
6. Please place the test kit out of reach from children.

[Question and Answer, Q&A]

For Candida Albicans (Yeast) Test

Q1: Does the urine sample have to be collected in the morning for test purposes?

A1: No, the urine can be collected at any time. However, the first urination in the morning will have higher concentration which aids the test accuracy.

Q2: Can the “blood urine” be used as the test sample for test?
 A2: No, the blood urine contains red blood cells which can alter the reading since the reaction line for this test is also red-purple.

Q3: When adding the urine sample, will it affect the test determination if sample was added more than 4 drops?

A3: It is suggested to add no more than 6 drops of urine into the test tube to mix with the buffer. For test purpose, it is better to add no more than 6 drops as it may leak out of the Sample well (S well) and affect the reading.

Q4: Can the test result be allowed if the waiting time takes more than 30 minutes to react?

A4: The test reading cannot be longer than 30 minutes because the negativity detected may become positive as time gets longer due to air oxidation. The result will not be accurate and cannot be taken as a final record.

Q5: If the background color becomes light purple-red color during the analysis, will it affect the final result.

A5: The depth of color will vary depending on subject’s urine composition, temperature difference, and humidity. The background color can be purple, red, or close to white.

The test is effective as long as the line appeared on the “C” Control zone.

Q6: What are the symptoms of Candida infection?

A6: **Women**

6.1. There are cases wherein some have yeast infections more often than others because they are not careful about their own body. It is true that prevention is better than cure.

6.2 A vaginal infection caused by the presence of *Candida albicans* is known as yeast infection. Several symptoms of this type of infection are redness, dryness, burning, and itching.

6.3 Some causes of yeast infection are the kind of clothing worn and even stress can set off an outbreak. A lot of women have claimed that yeast infection was developed when they started to have their menstrual cycle.

6.4 Even if it is frequently seen to infect women’s vagina’s, it is sometimes seen in the oral cavity, men’s foreskins, folds of the skin, and in babies diapered areas.

Men:

Yeast infection in males rarely happens. In cases when men develop this infection it is frequently called Balanitis which is found in the penile head of uncircumcised men.

For Trichomonas Vaginalis Test

Q7: What are the symptoms of a Trichomonas infection?

A7: Women

Vaginal discharge is common. This is typically greenly-yellow, and may be 'frothy'. The discharge usually has an unpleasant or fishy smell. Your vagina and vulva may be itchy and uncomfortable. The irritation may extend into the groin. Sex may be painful. It may be sore when you pass urine. No symptoms occur in up to half of infected women. However, you can still pass on the infection even if you have no symptoms.

Men:

Discharge from the penis is common. It may be sore when you pass urine. You may pass urine frequently (due to irritation inside the penis). No symptoms occur in up to half of infected men. However, you can still pass on the infection even if you have no symptoms.

Q8: What should I do when my result is positive?

A8: Please make an appointment with a doctor for further personal advice and attend any possible clinical tests. Doctors will provide detailed information and suggestions for the test positive subjects.

Q9: What should I do when my result is negative?

A9: This indicates that the subject does not have Trichomonas Vaginalis infection. However, it is strongly suggested to do the test with a sex partner because male may not have any symptom while infected and other partner may be infected through intercourse.

For Gardnerella Vaginalis Test

Q1: Does the urine sample have to be collected in the morning for test purposes?

A1: No, the urine can be collected at any time. However, the first urination in the morning will have higher concentration which aids the test accuracy.

Q2: Can the "blood urine" be used as the test sample for test?

A2: No, the blood urine contains red blood cells which can alter the reading since the reaction line is also red-purple.

Q3: When adding the urine sample, will it affect the test determination if sample was added more than 4 drops?

A3: It is suggested to add no more than 6 drops of urine into the test tube to mix with the buffer. For test purpose, it is better to add no more than 6 drops as it may leak out of the Sample well (S well) and affect the reading.

Q4: Can the test result be allowed if the waiting time takes more than 30 minutes to react?

A4: The test reading cannot be longer than 30 minutes because the negativity detected may become positive as time gets longer due to air oxidation. The result will not be accurate and cannot be taken as a final record.

Q5: If the background color becomes light purple-red color during the analysis, will it affect the final result?

A5: The depth of color will vary depending on subject's urine composition, temperature difference, and humidity. The

background color can be purple, red, or close to white. The test is effective as long as the line appeared on the "C" Control zone.

Q6: What are the symptoms of Bacteria Vaginosis (Gardnerella V) infection?

A6: While there are many possible symptoms of Gardnerella vaginitis, there are a large percentage of women (and men) who do not have any symptoms. If Gardnerella is not treated in a timely manner, the bacteria can transfer to the urethra and also cause a urinary tract infection. The bacteria may also cause an abnormal Pap smear result, but treating the infection should result in a negative test result (pending there are no other issues).

Q7: What should I do when my result is positive?

A7: Please make an appointment with a doctor for further personal advice and attend any possible clinical tests. Doctors will provide detailed information and suggestions for the test positive subjects.

Q8: What should I do when my result is negative?

A8: This indicated that the subject did not have Bacteria Vaginosis (Gardnerella V) infection. However, it is strongly suggested to do the TEST with a sex partner because male will have no symptom while infected by Bacteria Vaginosis (Gardnerella V) and other partner may be infected through intercourse.

REV. JTCGV-3/1-OTC-IFU-EN
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CE Mark



Consult instruction for use



Temperature limitation



Do not reuse



Caution, irritating



In vitro diagnostic medical device

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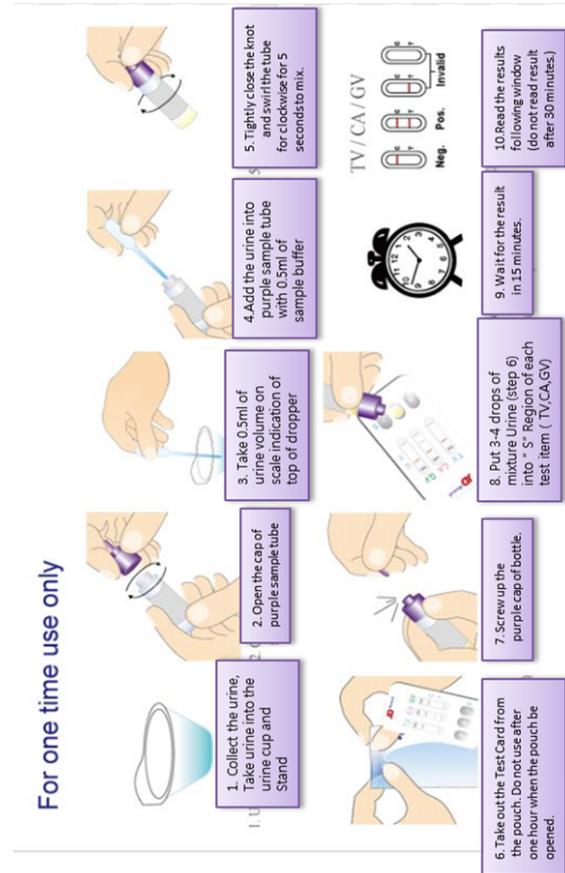
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EC REP



For one time use only