



Gonorrhea Rapid Screen Test Instructions

WF1002F-GON (Field version) Swab

The iCare Gonorrhea Rapid Screen Test is a qualitative test for the detection of the gonorrhea antigen in urogenital specimen. Gonorrhea is a common sexually transmitted disease caused by the bacterium *Neisseria gonorrhoeae*. The bacterium can grow in warm moist areas of the reproductive tract, and also in the anus, throat, eyes and mouth. Most women and some men with gonorrhea do not have any symptoms. Possible symptoms include: burning sensation during urination, coloured (green, yellow, white) discharge from the penis or vagina, and pain or swelling of testicles. If left untreated, gonorrhea may lead to permanent damage of the reproductive organs and infertility, and spread to blood and joints and become life-threatening.

PRECAUTIONS

1. Do not use the test kit beyond the expiration date.
2. Do not use the kit if the pouch is punctured or not well sealed.
3. For in vitro use only. Do not swallow.
4. Do not mix the covers of Buffer A and Buffer B.
5. All specimens from the body should be treated as potentially infectious.
6. Contaminated swabs may give incorrect test results.
7. Discard after first use. The test cannot be used more than once.
8. DISPOSAL: The used-device has the risk of infection. Please dispose all used contents properly.

MATERIAL PROVIDED

1. A pack containing:
 - Test cassette
 - Desiccant (for keeping contents dry)

- Micro pipette (dropper)
2. Buffer A and Buffer B solution bottles
 3. Two swabs
 4. One mixing tube with cap
 5. Instruction sheet

Note: For the Male Specimen collection, only one swab is needed. For the Female Specimen collection, two swabs are needed.

TEST PROCEDURE

1. Add 300 μ l (about 6 drops) of Buffer A solution from bottle into the mixing tube.
2. Follow the instructions below to collect the specimen.

(SPECIMEN COLLECTION - MALE)

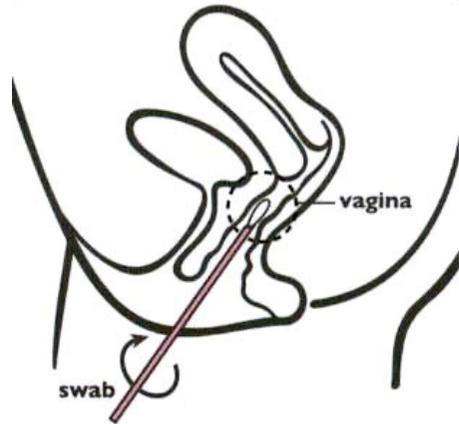
- (a) Insert one swab into the urethra of the penis.
- (b) Gently rotate swab with sufficient pressure for 3-5 seconds to collect epithelial cells.
- (c) Allow the swab to remain inserted for a few seconds after rotation.
- (d) Withdraw the swab carefully, avoiding any contact with any external surface to prevent contamination.



(SPECIMEN COLLECTION - FEMALE)

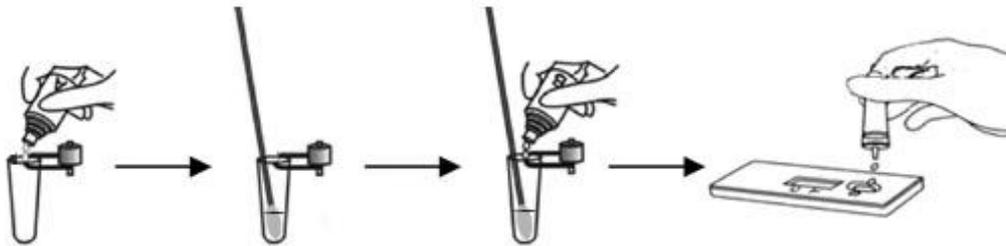
- (a) Use one swab to remove discharge at the vaginal opening, and discard the swab.
- (b) Insert the second swab into the vagina.
- (c) Rub and rotate the swab against the vagina for half a minute.
- (d) Withdraw the swab carefully, avoiding any contact with any

external surface to prevent contamination.



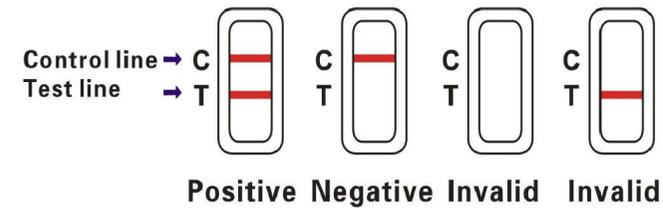
TEST PROCEDURE (Continued)

3. Insert the swab with the specimen into the mixing tube, and twirl briefly to mix the specimen into the solution. Keep swab immersed for 5 minutes.



4. Add 300 μ l (about 6 drops) of Buffer B solution from bottle into the mixing tube. The amount of Buffer B should be equal to Buffer A.
5. Twirl the swab vigorously for 10 seconds to mix the solution well.
6. Remove the swab and discard it.
7. Cap the mixing tube and mix the contents by gently swirling the tube.
8. Remove the testing cassette from the foil pouch and place it on a level surface.
9. Using the micropipette, draw 100 μ l (about 4 drops) of solution from the mixing tube and dispense it into the well of the test cassette.
10. Wait for 15 minutes and read results. Do not read after 20 minutes.

INTERPRETATION OF RESULTS



Positive (+) Result

Two rose-pink bands appear at “C” and “T”. The sample is considered positive for Gonorrhoea. Please visit a doctor or licensed medical facility for confirmation testing and treatment.

Negative (-) Result

Only one rose-pink band appears at “C”. The sample is considered negative for Gonorrhoea.

Invalid Result

No visible band at all, or there is a visible band only at “T”, but not at “C”. Repeat the test with a new test kit.

Product manufactured by:

JAL Innovation

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www.jalinnovation.com

Insert designed by:

LTLabs