130mm

210mm

The iCARE GONORRHEA FIELD USE RAPID TEST KIT <SWABS> is a rapid home test kit for direct detection of Gonorrhea. This product is for in vitro diagnostic use only and can be used at home.

Gonorrhea is a curable sexually transmitted infectious disease (STD), which is caused by the bacterium Neisseria gonorrhoeae. With our Gonorrhea Rapid home test kit, you can detect Gonorrhea on your own in 100% privacy. Our test kit is easy to use, and the result can be read at 15 minutes.

This test cannot be used more than once.

iCARE® ADVANCED

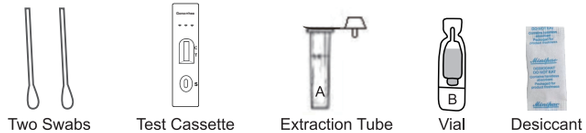
Gonorrhea Field Use Rapid Test Kit <Swabs>

PRECAUTIONS

1. This kit is for in vitro use only. Do not swallow.
2. All specimens should be treated as potential infectious diseases.
3. Discard after use. The test cannot be used more than once.
4. Do not use test kit beyond the expiration date.
5. Do not use the kit if the pouch is punctured or not well sealed.
6. Keep out of the reach of children.
7. **DISPOSAL OF THE DIAGNOSTIC**: The used device has the infectious risk. The process of disposing the diagnostic device must be done properly.

CONTENT OF THE KIT

1. One test in one pouch.
2. One pouch contains a test cassette, extraction tube (Pre-filled with Buffer A), 2 swabs and desiccant. The desiccant is for storage purposes only and is not used in the test procedure.
3. Leaflet with instructions for use (this one).
4. Buffer B (pre-filled in vial).
Please note: For the female procedure both swabs will be needed to collect the specimen. Only one swab is required for the male collection of the specimen.

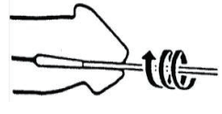


Two Swabs | Test Cassette | Extraction Tube | Vial | Desiccant

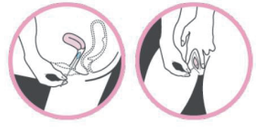
COLLECTING THE SPECIMEN

1. Use the swab to collect specimen in the following suggested method:

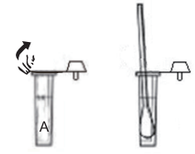
a) <u>For male patient</u>: Insert one swab into the urethra of the penis. Gently rotate with sufficient pressure to dislodge the epithelial cells. Allow the swab to remain inserted for a few seconds after rotation. Carefully remove the swab avoiding contact with any external surfaces.



b) <u>For female patient</u>: Use swab number 1 to remove discharges from the vaginal track opening. Then insert swab number 2 into vaginal track for half a minute and retrieve swab. Carefully remove the swab avoiding contact with any external surfaces.



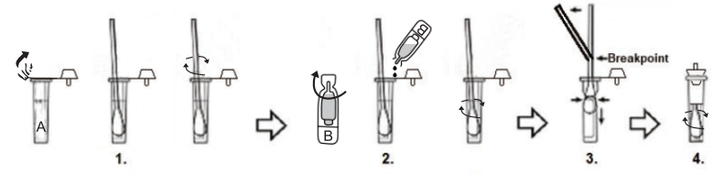
2. If the test is to be conducted immediately, tear the film of extraction tube (Pre-filled with Buffer A), put the swab into the extraction tube.



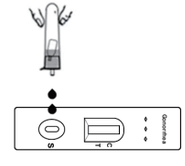
TEST PROCEDURE

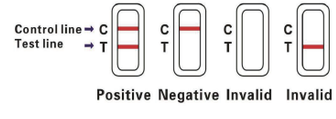
Before testing, open the package and equilibrate the test device, specimens and/or controls to room temperature(15-30°C).

1. Tear the film of extraction tube (Pre-filled with Buffer A), put the swab into the extraction tube, and rotate the swab against the tube for about 10 times and no less than 15 seconds.
2. Break the top of vial (Pre-filled with Buffer B), add all buffer B into the extraction tube and rotate the swab against the tube for about 10 times and no less than 15 seconds.
3. Break the swab at the break point and keep the swab head in the tube.
4. Install the dripper of the tube. Shake the extraction tube vigorously to mix the sample well. If the test is not to be conducted immediately, the extracted specimen should be stored at 2-8°C and tested within 24 hours.



5. Take out the test device from sealed foil pouch and place on a dry, clean, and level surface. Place the extraction tube in a tube holder or rack.
6. Hold the extraction tube vertically and add 2 drops of extracted specimens into the specimen well (S) making sure that there are no air bubbles. Start the timer immediately.
7. Wait for the colored line to appear. Read test results at 15-20 minutes.
NOTE: Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

Positive (+):
Rose-pink bands are visible both in the control region and the test region. The sample should be considered positive for Gonorrhea.
Negative (-):
A rose-pink band is visible in the control region. No color band appears in the test region. The sample should be considered negative for Gonorrhea.
Invalid:
No visible band at all, or there is a visible band only in the test region but not in the control region. Another test should be run to re-evaluate the specimen. If test still fails, please contact us for further instructions.