

One-Step Gonorrhoea Home Test Kit (Tri-line) Test Cassette Manual

Screening Test Cassette (Urine or Swab) for Neisseria Gonorrhoeae infection.



- One individual sealed pouch containing:
- Test device
- One bottle diluent 1 (A)
- One bottle diluent 2 (B)
- Alcohol pad
- Instructions

Material Required but not provided

- Urine collector container 30ml
- Time or Watch capable of timing 10 to 30 minutes
- Clean, Disposable, Absorbent Workspace Cover
- Biohazard Waste Container

PRECAUTIONS

- Carefully follow the instructions exactly.
- Only use the included pipette.
- This kit is for in vitro use only. Do not swallow.
- Contaminated blood may cause erroneous results.
- Discard after first use. The test can only be used once.
- Do not use test kit beyond the expiration date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of children's reach.

STORAGE AND STABILITY

- Store at 4°C to 30°C in the sealed pouch up to expiration date.
- Keep away from sunlight, moisture and heat.
- Use the test shortly after opening the pouch.
- Do not freeze.

URINE SPECIMEN COLLECTION AND PREPARATION

Collect 20-30 ml of first catch urine in a clean sterile container (not provided) without any preservatives.

Not: You should not have urinate for at least one hour prior to the specimens' collection. The sample perform best if tested immediately after collection. If immediate testing is not possible. The sample should be stored at 2°C-8°C for up to 24 hours. Do not freeze.

TEST PROCEDURE URINE SAMPLE

- If the test or urine sample has been stored in a cold place, wait for it to reach room temperature (10°C - 30°C).
- Add 5 drops of urine in micro tube (diluent 1) and mix well.
- After 5 minutes, add 3 drops of diluent solution 2 in to the micro tube (diluent 1), and mix well.
- Remove the test cassette from its sealed foil pouch by tearing at the notch.
- Dispense 4 drops of specimen solution into the sample well of the test device.
- Wait for the color bands to appear. Read the result at 10-15 minutes.
- Do not read test result after 30 minutes

ENDOCERVICAL SPECIMEN COLLECTION AND PREPARATION WITH SWAB

Females Endocervical sample.

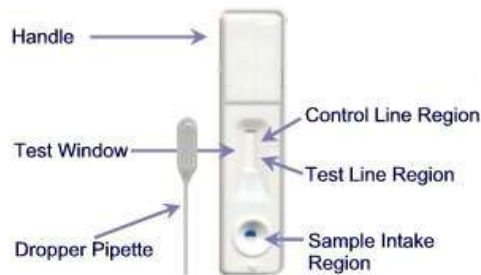
Remove any excess mucus from the potentially infected site with the first swab, and then discard it. Insert the second swab into the endocervical canal until most of the tip is no longer visible; Rotate the swab for 15-30 seconds. Carefully withdraw the swab without touching the vaginal surface.

Males Endourethral sample.

Insert the swab into the urethra of the penis and rotate for 3-5 seconds and withdraw.

TEST PROCEDURE ENDOCERVICAL SAMPLE

- When the test has been stored in a cold room, wait for it to reach room temperature (10°C - 30°C).
- Place the specimen swab in the micro tube (diluent A / 1)
- Swirl the swab 2-3 times for a few seconds during the extraction step, pressing it against the wall of the tube to expel the liquid and insure thorough contact of reagents and specimen.
- Thoroughly remove as much extract from the swab as possible by raising it above the liquid level and squeezing the extraction tube.
- Remove swab and then add 3 drops of diluent B / 2 solution in to the micro tube (A / 1), and mix well.
- The extract can remain at room temperature for up to 30 minutes without affecting the test results.
- Remove the test cassette from its sealed foil pouch by tearing at the notch.
- Dispense 4 drops of specimen solution into the sample well of the test device.
- Wait for the color bands to appear. Read the result at 10-15 minutes.
- Do not read test result after 30 minutes



HOW TO INTERPRET THE RESULT

Results can be read at 5-20 minutes. 20 minutes should be allowed to confirm a negative result.

Note: There is no meaning attributed to line color intensity or width.

Positive (Gonorrhea infection):

Rose-pink bands are visible both in the control region and the test region. The sample should be considered positive for *Neisseria Gonorrhoeae* infection.

Negative (No Gonorrhea infection):

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 *Neisseria Gonorrhoeae* infection.

Invalid:

There are no colored lines or only a colored line in the test region. The most common reason for an invalid test result is that the test procedure was not carried out properly.

