HIV 1/2, Urine-Based Home Test
(Tri-line) Test Cassette Manual 4th Generation
Home Screening Test for HIV 1 & HIV 2 + Subtype’s: (A, B, C, D, E, F, G, H and O)

- 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 urine 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 urinated for at least one hour prior to the specimen collection. The sample preform best if tested immediately after collection. If immediate testing is not possible, then 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
HOW TO INTERPRET THE RESULT

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

Positive (HIV infection):

Colored lines are visible in the control region and the test region. This means that infection by HIV is likely. As with a laboratory test it needs to be confirmed with a secondary test before a diagnosis can be made. Therefore, it is very important that, in case of a positive result, another test is made at a clinic.

*The intensity of the color of the lines varies due to different concentrations of HIV antibodies but also other blood values and therefore no meaning is attributed to line color intensity or width.*
**Negative (No HIV infection):**

One colored line is visible in the control region and no colored line in the test region. This means that no HIV infection was detected.

**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.