

4th Generation

HIV 1/2, Whole Blood-Based Home Test (Tri-line) Test Cassette Manual

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
- Alcohol pad
- Instructions

Material Required but not provided

- 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.

TEST PROCEDURE

- When the test has been stored in a cold room, wait for it to reach room temperature (10°C - 30°C).
- Wash the hands thoroughly to avoid contamination of the specimen.
- Open the pouch and place the cassette on a level surface.
- Clean the area to be lanced with the alcohol pad.
- Wait for the area to dry completely (do not blow on it).
- Use the safety lancet and pipette. The safety lancet can only be used once.



Twist off the protective cap, and then pull it straight out.

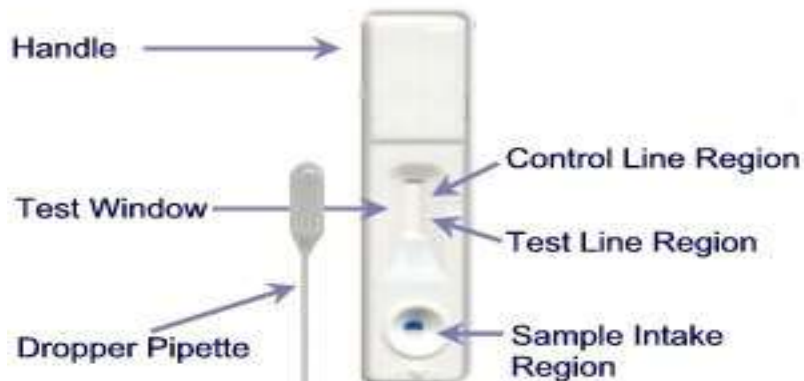


Press the lancet firmly against the puncture site to activate the device.



Gently apply intermittent pressure near the puncture site to obtain the required blood volume

- Squeeze the pipette together and collect blood by slowly releasing the pressure.
- Add One drop of blood, from the pipette, to the round well of the cassette.
- Wait 20 seconds.
- Add Two drops of diluents solution, from the bottle, to the round well of the cassette
- If the liquid is not moving across the membrane within one minute, add one more drop of buffer solution to the round well of the cassette.



HOW TO INTERPRET THE RESULT

Read the result 15 minutes after adding the buffer solution. Do not read the result after 20 minutes.

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.

