

Quality Control (QC) Test Procedure (Using INSTI™ HIV POC Test Kit)

- Preparation**
1. Remove HIV-1 positive and negative QC bottles from the fridge and bring to room temperature (approximately 5 minutes).
 2. Record the QC test information (lot number, expiry date) on the appropriate log.
Note: bottles are OK for use up to the expiry date on the bottles, as long as they are stored in the fridge.
 3. Wash or sanitize hands.
 4. Prepare a testing area by disinfecting a non-porous level surface with an approved disinfectant.
Note: Or, use a new, clean blue pad or paper towel (in case of spills)
 5. Gather the following materials:
 - two INSTI™ HIV Test kits (one for each of the controls)
 - two quality control pipettes
 - gloves
 - biohazardous sharps/waste container

Prepare test membrane



6. Open one test kit packet.
Retain the blood collection supplies with other such supplies.
7. Open the pouch containing the membrane unit.
Remove the test membrane from the pouch without touching the centre well. Position the test membrane on the level surface with the tab down (facing you).
Note: If the centre well is touched, the HIV antigen molecules will be torn from the membrane and the test will not perform correctly.
8. Label the membrane with the type of control (i.e., HIV negative, HIV-1 positive) and place the membrane on a level surface.

Mix samples

9. Put on gloves.
Note: All control samples should be handled as if capable of transmitting infectious diseases.
10. Gently mix the 2 QC sample bottles by inverting a few times.
Tap the bottoms of the bottles a few times on a hard surface to bring all the material from the cap back into the bottle.

Pipette a 50 uL sample

11. Unscrew the cap of the negative QC sample, and retain it.
Unscrew the cap of solution 1, and retain it.
Hold both opened bottles in one hand, noting which one is the sample.

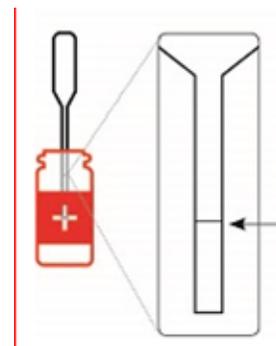


12. Squeeze the bulb of the **QC pipette** very gently to push a small amount of air out of the pipette (do not use the blood collection pipette).

Hold the QC pipette vertically above the QC bottle, lower the pipette into the bottle, then slightly release the pressure on the bulb to draw the QC sample up.

Fill the pipette just to the black line and maintain pressure to hold the sample in the pipette.

If you draw sample above the black line, squeeze the bulb gently to push the sample back to the black line.



Solution 1



13. Move the pipette with sample above the opened solution 1 bottle. Squeeze the bulb of the pipette to dispense the sample into solution 1.
14. Discard the pipette in a biohazard sharps/waste container. Recap the QC bottle sample.
15. Recap the solution 1 bottle, mix by gently inverting the bottle 5 to 10 times. Carefully pour the entire contents of the solution 1 bottle into the membrane well.

Wait until the solution is absorbed. (takes only a few seconds).

Note: *If most of the solution has gone into the well but some has dripped on the side of the membrane unit, continue the test. If the control dot appears the test can be interpreted. The test is built to ensure sufficient sample has been added when the control dot appears.*

Solution 2



16. Mix the color developer (solution 2 bottle) by slowly turning the bottle upside down several times.

Note: *Look at the bottom of this bottle as there should be nothing sticking to the bottom if mixed correctly.*

Open and add the entire contents of solution 2 to the centre of the membrane well.

Wait until the solution is absorbed. (takes approximately 20 seconds).

Solution 3



17. Mix, open, and add the clarifying solution (solution 3 bottle) to the centre of the membrane well.

Wait until the solution is absorbed. (takes approximately 20 seconds).

Record results

18. Read the result immediately and record the result.

Note: *If more than 5 minutes have passed since adding the clarifying solution*

the result is considered invalid.

19. Discard the test membrane into a biohazard sharps/waste container.

**Repeat for
HIV-1 pos
control**



20. Open a new test packet, retain the blood collection supplies and open the test membrane envelope as before.
Label this membrane and repeat from step 11 with the second quality control (HIV-1 positive).

Clean up

21. Check that the lids are tight on both QC bottles Place in labeled container and store in refrigerator.
 22. Decontaminate the work area with an approved disinfectant.
 23. Remove and discard gloves.
 24. Retain unused blood collection supplies (blood collection pipette, lancet and alcohol pad) from the kit for use in case of future blood collection challenges.
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