

# Quick Reference Instructions for use of the INSTI HIV-1 Antibody Test

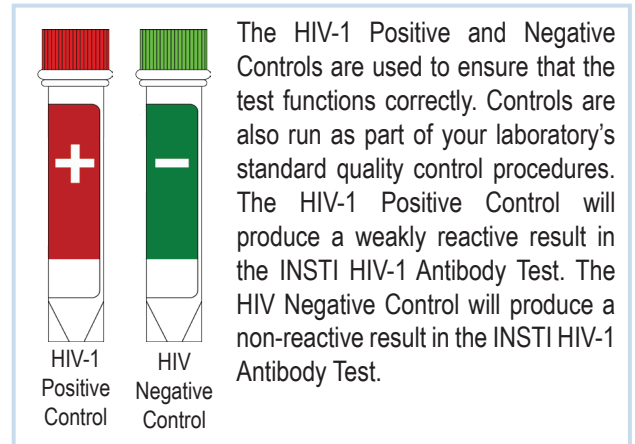
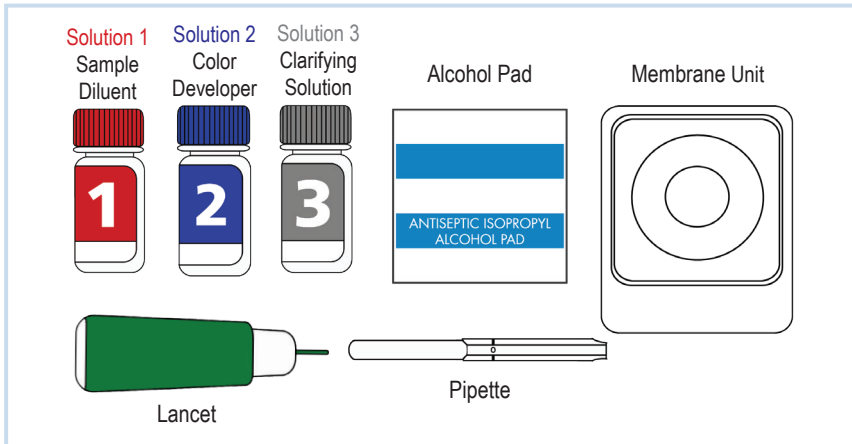
CLIA Complexity WAIVED for fingerstick blood. The instructions are only a Reference Guide. Before using the product read the INSTI HIV-1 Test Kit Package Insert completely

## Read this QUICK REFERENCE GUIDE completely before starting:

- First time user(s) must run the INSTI HIV-1 Antibody test with Control Material, before performing testing with fingerstick blood
- Cover the work space with a new, disposable, absorbent material
- Put on new disposable gloves
- Ensure temperature in the area of storage and testing is between 15-30°C (59-86°F)

If you have any questions or concerns contact technical assistance at:  
**1(866) 674-6784**

Before testing, all operators MUST be familiar with *Universal Precautions for Prevention of Transmission of HIV, Hepatitis B Virus and other Blood-borne Pathogens in Health Care Settings*. A *Certificate of Waiver* is required to perform this test in a CLIA Waived setting. This test is only waived for fingerstick whole blood specimens. Laboratories with a *Certificate of Waiver* must follow manufacturer's instructions when performing the test. Any modification by the user(s) to the manufacturer's test procedures will result in the test no longer meeting the requirements for waived classification.



## QUALITY CONTROL: INSTI Controls Preparation/SET-UP

For sampling of the controls with the provided single use short-stem bulb pipette, follow these instructions:

- Open an INSTI HIV-1 Antibody Test package by tearing the slit found along the side, or open a box of 24 INSTI HIV-1 Antibody Tests, and gather one of each kit materials required. See the diagram above.
- Open the individually wrapped membrane unit by tearing the slit located along the side. Make sure the membrane unit tab is facing towards you.
- Locate **Solution 1** and twist off the red cap, set cap and opened bottle in front of you.

## QUALITY CONTROL: Sample Collection

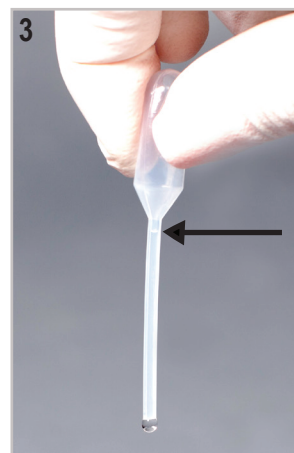
Positive and Negative Controls are to be tested individually with INSTI HIV-1 Antibody Tests



- Use a new pipette for each Control sample collection. Take the pipette and lightly depress the top bulb.



- Insert pipette tip into the clear liquid in the control vial. Slowly release the top bulb to completely fill the pipette stem.



- Ensure that the liquid in the stem reaches ONLY to the fill line as indicated above.



- Transfer the liquid to the uncapped **Solution 1** bottle by completely squeezing the bulb.
- After placing the control liquid into **Solution 1**, re-cap **Solution 1** and invert several times.

Run remaining INSTI HIV-1 Antibody Test procedure steps outlined in the TEST PROCEDURE and INTERPRETATION OF RESULTS sections

# PERFORMING THE INSTI HIV-1 ANTIBODY TEST

## INSTI HIV-1 Antibody Test Preparation/Set-up

For preparation/set-up, follow the instructions as described in the Quality Control section (turn over) of this Guide.

### Fingerstick Blood Sample Collection

Read these instructions completely before starting fingerstick



- Clean fingertip with alcohol swab, **allow for alcohol to dry**
- Twist and pull the green tip out of the lancet
- Place the lancet on the fingertip slightly off center, press firmly until you hear a click to puncture the skin



- Squeeze the finger to create a bead of blood
- Place the pipette tip horizontally into the blood bead. Do not squeeze the pipette bulb; pulse the finger to keep a bead of blood forming.



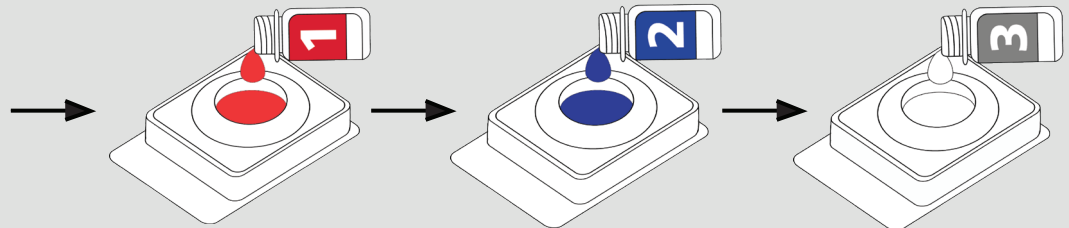
- To fill the pipette, capillary action will automatically draw the blood to the black fill line
- Be sure to not cover the air hole between the black line with your fingers
- Depending on how the subject bleeds, you may need to continuously pulse the fingertip

### TEST PROCEDURE to follow after sample collection

NOTE: It is important that the following steps be performed immediately after collection and in the sequence as shown:



- When the pipette is filled, transfer the specimen (blood) into Solution 1 by squeezing the pipette bulb
- If it does not release, cover the air hole on the black line with your fingers and squeeze again
- Re-cap Solution 1, and invert a few times



Pour **Solution 1 with specimen** into the center of the membrane unit well. **Allow to absorb completely**, then immediately proceed to the next step

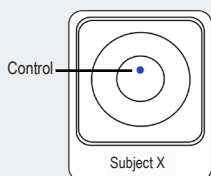
Pour **Solution 2** into the center of the membrane unit well. **Allow to absorb completely**, then immediately proceed to the next step

Pour **Solution 3** into the center of the membrane unit well. **Allow to absorb completely**, then interpret the results

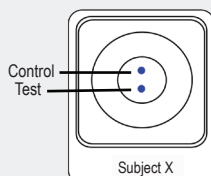
### INTERPRETATION OF THE RESULTS: Read results immediately

Results must be interpreted within five minutes of completing the procedure. Make sure the patient identifier tab on the membrane unit is facing towards you.

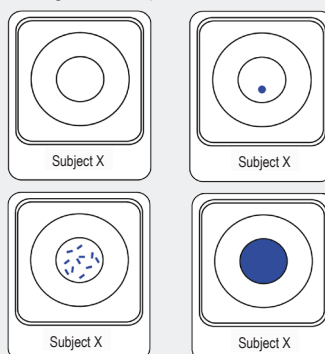
**NON-REACTIVE**  
Only one blue control spot appears on top



**REACTIVE**  
Two blue spots appear, one control and one test spot  
**NOTE:** one spot may be darker than the other



**INVALID**  
A missing control spot is an INVALID result



A **NON-REACTIVE** Test Result means that HIV-1 antibodies were not detected in the specimen. The test result is interpreted as negative for HIV antibodies. However, this does not exclude possible infection with HIV.  
A **REACTIVE** Test Result means that HIV-1 antibodies have been detected in the specimen. The test result is interpreted as **Preliminary POSITIVE** for HIV-1 antibodies.  
An **INVALID** Test Result means that the test was run incorrectly or insufficient specimen was added. **Repeat the test once** with a new sample collection and INSTI test. If the second test result is also invalid, contact technical assistance at:

1 (866) 674-6784

Follow CDC guidelines to inform the test subject of the test result and its interpretation