QUICK REFERENCE INSTRUCTIONS

FOR USE OF THE INSTI® HIV-1/HIV-2 ANTIBODY TEST

CLIA COMPLEXITY WAIVED FOR FINGERSTICK WHOLE BLOOD. THE INSTRUCTIONS ARE ONLY A REFERENCE GUIDE.
BEFORE USING THE PRODUCT READ THE INSTI HIV-1/HIV-2 TEST KIT PACKAGE INSERT COMPLETELY

READ THIS QUICK REFERENCE GUIDE COMPLETELY BEFORE STARTING:

- First time user(s) must run the INSTI® HIV-1/HIV-2 Antibody test with Control Material, before performing testing with fingerstick whole 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 2 – 30°C (35.6 – 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 FINGER STICK 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

Positive and Negative Controls are to be tested individually with INSTI® HIV-1/HIV-2 Antibody Test.

INSTI® CONTROLS

HIV-1 POSITIVE CONTROL

HIV-2 POSITIVE CONTROL

HIV NEGATIVE CONTROL

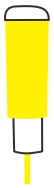
THE HIV-1 POSITIVE, HIV-2 POSITIVE AND HIV NEGATIVE CONTROLS ARE USED TO ENSURE THAT THE TEST FUNCTIONS CORRECTLY. CONTROLS ARE ALSO RUN AS PART OF YOUR LABORATORY'S STANDARD QUALITY CONTROL PROCEDURES. THE HIV-1 AND HIV-2 POSITIVE CONTROLS WILL PRODUCE A WEAKLY REACTIVE RESULT IN THE INSTI® HIV-1/HIV-2 ANTIBODY TEST. THE HIV NEGATIVE CONTROL WILL PRODUCE A NONREACTIVE RESULT IN THE INSTI® HIV-1/HIV-2 ANTIBODY TEST.

INSTI® HIV-1/HIV-2 ANTIBODY TEST

SOLUTION 1
Sample Diluent

SOLUTION 2
Colour Developer

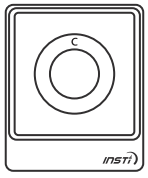
SOLUTION 3
Clarifying Solution



LANCET

PIPETTE

ALCOHOL PAD

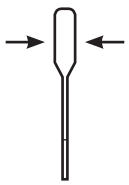


MEMBRANE UNIT

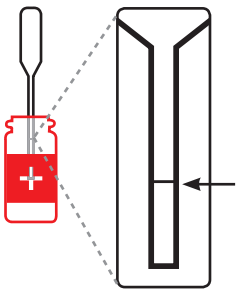
- Open an INSTI® HIV-1/HIV-2 Antibody Test package by tearing the slit found along the side. (See components pictured above)
- Open the individually wrapped membrane unit by tearing the slit located along the side. Make sure the membrane unit tab is facing towards you.
- Locate **SOLUTION 1** and twist 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/HIV-2 Antibody Test.



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



2. 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** the fill line as indicated to the left.

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

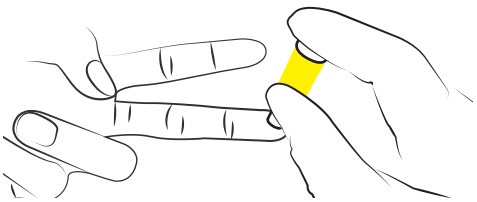
Run remaining INSTI® procedure steps outlined in the **TEST PROCEDURE** and **INTERPRETATION OF RESULTS** sections.

PERFORMING THE INSTI® HIV-1/HIV-2 ANTIBODY TEST

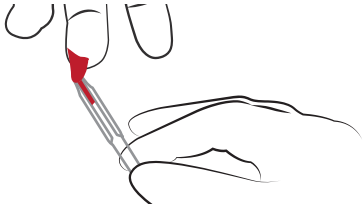
INSTI® HIV-1/HIV-2 ANTIBODY TEST PREPARATION /SET-UP - FOR PREPARATION/SET UP, FOLLOW THE INSTRUCTIONS AS DESCRIBED IN THE QUALITY CONTROL SECTION (TURN OVER) OF THIS GUIDE.

FINGERSTICK BLOOD SAMPLE COLLECTION

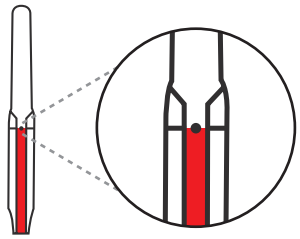
Read these instructions completely before starting fingerstick blood collection



- Clean fingertip with alcohol swab, **ALLOW FINGER TO DRY**.
- Twist and pull the yellow 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 OR BELOW HORIZONTAL** 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:

1. 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.
2. Re-cap **SOLUTION 1**, and invert a few times.

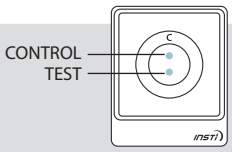
3. **POUR SOLUTION 1** with specimen into the center of the membrane unit well. **ALLOW TO ABSORB COMPLETELY**, then immediately proceed to the next step.

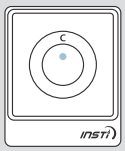
4. **INVERT SOLUTION 2** a few times before pouring into the centre of the membrane unit well. **ALLOW TO ABSORB COMPLETELY**, then immediately proceed to next step.

5. **POUR SOLUTION 3** into the centre 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.

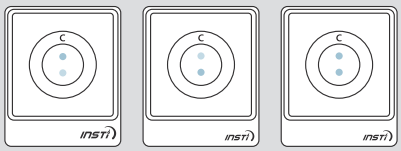




NON-REACTIVE

Only 1 blue control dot appears on the top.

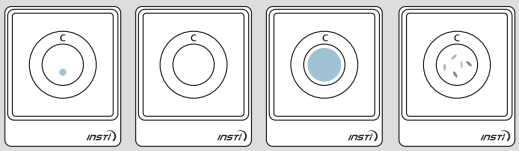
A NON-REACTIVE TEST RESULT MEANS THAT HIV ANTIBODIES WERE NOT DETECTED IN THE SPECIMEN. THE TEST RESULT IS INTERPRETED AS NEGATIVE FOR HIV ANTIBODIES. HOWEVER, THIS DOES NOT EXCLUDE POSSIBLE INFECTION WITH HIV.



REACTIVE

2 blue dots appear, one control and one test dot.
(Note: One dot may be darker than the other.)

A REACTIVE TEST RESULT MEANS THAT HIV ANTIBODIES HAVE BEEN DETECTED IN THE SPECIMEN. THE TEST RESULT IS INTERPRETED AS **PRELIMINARY POSITIVE** FOR HIV ANTIBODIES.



INVALID

A missing control dot is an invalid result.

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.