LIMIT–HPV INSTI HIV-1 Antibody Test Procedure

**To be used by the research nurses for HIV-negative participants.

The nurse will conduct a rapid HIV test at the enrolment/baseline and at the exit visit using the INSTI HIV-1 Antibody Test Kit. This test involves using a lancet to obtain a drop of the participants blood through a finger prick.

This will be used to monitor the patient's HIV infection status throughout the clinical trial.

Be sure to read the INSTI HIV-1 Antibody Test Kit package insert before performing test.

Check test kit expiration date.

Test collection materials:

- Personal Protective Equiptment - Disposable gloves and protective eyewear
- Alcohol swab
- INSTI HIV-1 Antibody Test Kit – includes: membrane unit, sample diluent, colour developer, and clarifying solution
- Single-use Lancet
- Single-use Pipette
- Cotton Guaze

Procedure:

1. Gather materials including: alcohol swab, lancet, pipette, one sealed test pouch containing INSTI membrane unit, and one vial each of the sample diluent, colour developer and clarifying solution.
2. Wash and dry hands.
3. Put on pair of disposable gloves and protective eyewear.
4. Select a finger to perform the test. Avoid using a finger that is calloused or injured in any way. Choose a bare finger since a ring can constrict circulation.
5. Massage the finger to allow the blood to move to the surface (fingertip will become pink). The hand must be positioned at waist level or lower.
6. Clean the test area with an alcohol swab. Allow area to dry thoroughly before perfoming test.
7. As soon as the finger is dry, twist off the green protective cap from the lancet and pull it straight out. (See figure A on package insert)
8. Press the finger firmly at the point just below where the lancet will be applied.
9. Use your other hand to hold the lancet by the body and press the lancet body firmly against the finger to activate the device and to make a small puncture on the side of the test finger. (See figure B on package insert)
10. Discard the lancet in a sharps container.
11. Apply slight pressure to the distal (far end) of the finger to produce a large drop of blood.

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12. Hold the pipette horizontally and touch the tip of the pipette to the blood sample. The blood will automatically flow to the fill line and then stop. Never squeeze the tube while filling. (See figure C on package insert)
13. If you do not get enough blood to reach the fill line, gently apply intermittent pressure near the puncture site. If blood amount is inadequate, perform a second puncture using a new lancet.
14. Use guaze to have the participant apply gentle pressure to the puncture site to stop the bleeding.
15. Transfer the blood in the pipette to the Sample Diluent vial by aligning the tip of the pipette with the vial. Squeeze the pipette bulb to dispense the blood. Note: If the blood will not expel, hold the pipette vertically and slide a finger over (without pressing) the vent hole. Then squeeze the bulb. (See figure E on package insert)
16. Recap the Sample Diluent vial and mix the contents with inversion.
17. Dispose of pipette in biohazard container.
18. Tear open the pouch and carefully remove the Membrane Unit without touching the center well. The tab of the Membrane Unit can be labelled with the participants name or study ID number.
19. Place the unit on a level surface.

NOTE: At this point it is important that the following steps be performed immediately and in sequence

20. Remix the Sample Diluent/blood mixture and pour the entire contents in the center of the Membrane Unit well. NOTE: this needs to be done **within 5 minutes** of adding the blood to the Sample Diluent vial contents. The sample should be absorbed through the membrane within 30 seconds (times may vary).
21. Take the Colour Developer and slowly invert to mix the solution thoroughly.
22. Open the Colour Developer and add the entire contents to the center of the Membrane Unit well. This coloured solution should absorb through in about 20 seconds.
23. Open the Clarifying Solution and add entire contents to the center of the Membrane Unit well. This will lighten the background colour and help with reading the results.
24. Immediately read the results while the membrane is still wet. Do not allow more than 5 minutes to pass after adding the Clarifying Solution before reading results.
25. Discard all specimens and materials used for the test in a biohazard waste container.
26. Thoroughly wash hands.

Reading Results:

Please refer to the INSTI HIV-1 Antibody Test Kit package insert for diagrams and how to interpret results.

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A BLUE dot in the control spot indicates that the procedure was performed correctly and will appear on all valid tests.

Possible results include:

1. **Non Reactive (Negative)** result: only one blue dot appeas on the memberane at the Control Spot. No dot should be visible in the Test Spot (below the Control Spot).

2. **Reactive (Preliminary Positive)** result: two blue dots appear on the membrane at both the Control and Test spots. This means that the specimen contained HIV-1 antibodies. One dot may be darker than the other.

3. **Invalid Results:** (test performed incorrectly or there is a problem with the sample or device). Invalid test results need to be repeated using all new test collection materials.
    a. No dot appears on the membrane
    b. The test dot appears without the control dot
    c. There is a uniform tint across the membrane
    d. Only blue specks appear on the membrane

4. **Intermediate Results:** a faint background ring appears at the Test Spot along with the blue control dot.

If the INSTI HIV-1 Antibody test result is REACTIVE or INDETERMINATE:

Notify the participant of the test result and explain that this is a preliminary result. Another blood test will be performed and confirmed by a laboratory once he is seen by a physician.

The participant is to be referred **immediately** to Dr de Pokomandy (at MUHC Chronic Viral Illnesse Service) for follow-up.

It is important that we ensure that Dr. de Pokomandy responds and a follow-up appointment is made. (MUHC Chronic Viral Illnesses Service, tel: (514) 934-1934 Ext. 32146 - Karène Proulx-Boucher, research coordinator at the Glen site).

Explain to the participant that it is advisable to abstain from sexual activities or to use protection when engaging in sexual activities until the result can be confirmed.

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