1. Decide to test

The HIV POC Test happens within the context of a client visit/encounter, so clinical judgment is a critical part of the client/provider discussion. Written informed consent is not required for the BC Program – an informed consent discussion and agreement to be tested is sufficient. It is recommended that the discussion include STI risks and additional STI testing if indicated. For clients at high risk of HIV, testing for TB may also be discussed. Additional supports or discussions may occur in the visit/encounter.

2. Do a Client Test

Detailed instructions to do the INSTI™ test are available on the BC Program webpage – Education and Training section – Written Instructions subsection.

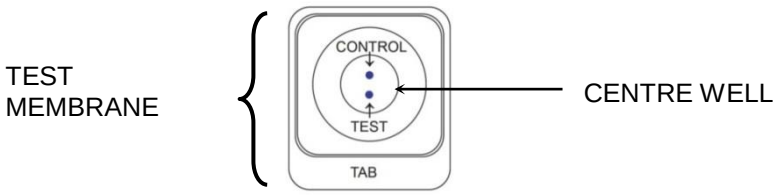
Finger-stick Blood Collection

Blood collection is likely the most challenging activity when doing the point of care test.
Practice and mentor advice are invaluable to improve your skills.

Documents and links are available on the BC Program webpage (Education and Training section –Job Aides) to provide information, tips and links to provide more information.

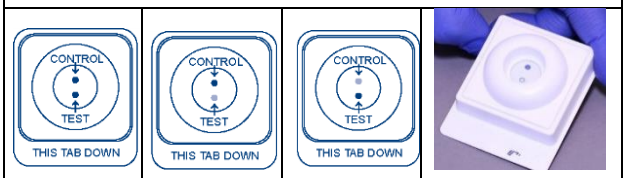
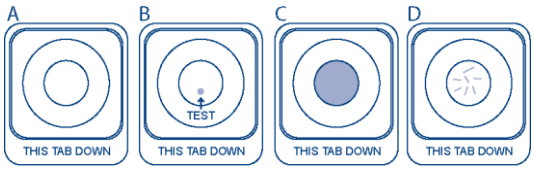
3. Determine the Results

Test Schematic



1. Read the test with the tab in the lower position from the membrane (ie tab is closest to you).
2. Interpret the test to convey the result to the client.
3. Record the test result.
4. Discuss additional actions to be taken based on these results.

Interpretation of HIV Point of Care Test Results (INSTI™)

Result	If the membrane shows:	Interpretation:	Next Steps:
Non-reactive (negative)	Only one blue dot at the top (farthest from the plastic tab): 	Test is valid. Antibodies to HIV-1 and HIV-2 **have not** been detected	Result is final. If client has signs or symptoms of acute HIV infection, a blood sample should be drawn and sent for standard HIV testing.
Reactive (preliminary positive)	Two blue dots appear, one above the other. One dot may be darker than the other, or appear as a ring. 	Test is valid. Antibodies to HIV-1 or HIV-2 have been detected	A venous blood sample must be drawn and sent for standard HIV testing (to confirm the result and to rule out the possibility of a false positive result). **Report (preliminary) reactive POCT result per location instructions to local Medical Health Officer, or HIV/CD intake nurse.**
Invalid	No blue dot at the top of the membrane; or blue specks appear; or there is a uniform blue colour across the membrane **OR – solution 3 was added more than 5 minutes before the membrane is read.** 	**Test is invalid.** **There is NO CLIENT RESULT.** Something may be wrong with the test kit or the testing process, or there is an underlying client IgG deficient health condition.	Repeat with a fresh sample and new test kit making sure that sufficient sample has been collected for testing. If the second test is also invalid, a venous sample should be drawn and sent for standard HIV testing. Expand underlying client health discussion to see if there is an underlying condition or treatment that results in low IgG levels. Use quality control samples to make sure that the test is operating properly. Report invalid results X2 to BC Program.

4. Document the Test Results

If information is manually written, it is recommended that it be as legible as possible. A template for a paper-based Client Log is available on the webpage – Resources-Worksheets section. Recording all results on a single document makes it easier to identify who has been tested if a specific test kit lot is recalled, or found to be faulty. Information on the Client Log is entered into the Monthly Inventory Report that is sent to the BC HIV POCT Program. This report captures what happens to every kit, so if a kit is discarded, that information must be captured, and the Client Log is often the easiest way to do this.

For each client undergoing HIV POC testing, the following minimum information should be recorded in the client chart and on the Client Test Log:

- Date of HIV POC test
- Client identifying information including contact information (2 unique identifiers are needed). Test locations using electronic record-keeping may be able to use a chart number as identification on the test log.
- Test provider identification
- HIV POC test lot number and expiry date (found on the outside of the test kit packet)
- HIV POC test result/outcome (reactive, non-reactive, invalid, waste or expired)
- Next steps as indicated by result

For a reactive (preliminary positive) result, record the following:

- Whether a venipuncture for HIV serology was collected (or requisition for HIV serology was given, if sample collection is not available at test location) OR not done.
- **REPORT the preliminary positive HIV POCT result to the MHO or HIV/CD intake nurse for your area, per local practice.**
- Record the standard HIV serology result (i.e., reactive, non-reactive, indeterminate) when it comes back. **Remember to send ALL confirmatory results to the MHO or HIV/CD intake nurse for your area, per local practice.**
- Record the final classification on the client record and on the Client Result Log (or site-specific document for capturing kits used for client testing)
    - Preliminary positive (i.e., no standard serology performed, lost to follow-up)
    - True positive (i.e., standard serology is reactive)
    - False positive (i.e., standard serology is non-reactive)

Client results that will be recorded as "Waste" for the monthly report:
The Client Log template includes a section at the bottom related to kit use coded as waste for data information purposes. This change enables us to report how many clients were tested (assuming 1 kit per client) and that a reactive result is new and is followed up.

The following situations will be changed to "waste" for the monthly report:

- Client has tested previously with a positive result.
- Client requested a retest (second test is recorded as waste for the monthly report).
- Client refused after a test membrane was opened (kit will have to be discarded).

Is this result recorded as Invalid or Waste?
Sometimes you have challenges with blood collection or you spill one of the solution bottles, and you're not sure if this is waste or an invalid result.

The key question is "**Did you finish the procedure**?"

If yes Interpret the reaction based on the control and the test spot appearance. If there is no blue colour in the control spot area, then this is INVALID.

If no This is waste – reason is "blood collection problem" or "vial spill".

Recording this information on the Client Log will help the person who does the Monthly Report.

Notes and Limitations of the test

- The control dot may be darker or lighter than the lower, client/test dot.
  - There is acceptable variation in spot colour, size and appearance between different master lots of test kits.
  - Please contact the BC Program if you are unsure if what you are seeing is within acceptable limits.
  - If possible, take a picture of the test membrane with a smart phone and attach it in an email to the BC Program.
- When there is a problem reading the test (e.g., shadows or rings), two individuals should read the test, if possible. The names of both people reading the test(s) should be recorded.
  - Remember that results read more than 5 minutes after the addition of solution 3 are considered to be "invalid".
- Sometimes when a client has a **high hematocrit** or **more than 60uL of blood** is used, the flow through the membrane may be slowed and may produce a uniform blue colour across the entire membrane (an **invalid** result). Sometimes the result is a **false positive** when confirmatory testing is done.
  - The supplied capillary pipette will collect the necessary 50 uL to add to solution 1.
  - The high hematocrit client may be a consideration if the client tests as false positive on more than one occasion.
- A client in the **window period** may have a **false non-reactive test (false negative) result**.
  - Clients who are more likely to be in the acute phase of HIV infection (i.e., have high likelihood of HIV infection) should be encouraged to have blood drawn for standard HIV testing at the same visit.
  - Clinical judgement will indicate whether both a POC and a standard HIV test should be done at this time for this client.
- A test that is performed using an **insufficient sample**, **performed incorrectly** or where a **defective device** is used, may give an **invalid** result and testing should be repeated.
  - If the second HIV POC test performed is also invalid, quality control samples should be tested to determine if the test kits are performing correctly.
  - Notify the POC Test Location Lead and the BC Program Lead after two consecutive invalid results on the same client.
  - Venous blood samples should be drawn and sent to BCCDC PHL for standard laboratory HIV testing.
- **False non-reactive (negative) or invalid test results** may be obtained from clients with **hypogammaglobulinemia** conditions (e.g., multiple myeloma) or clients receiving long-term **HAART**.
  - Clients receiving HAART should not require POC (HIV Antibody) testing. The viral load test (HIV NAAT) is a better indicator of their status.
  - For patients with hypogammaglobulinemia, RNA NAAT or HIV antigen/antibody testing may be required.
- The INSTI™ HIV test has **not been validated** for detection of antibodies to **HIV-1 Group N** sub-group.

Summary of Test Properties

INSTI™ HIV-1 / HIV-2 Antibody Test Kit

Supplier: bioLytical Laboratories Inc.
License Issue Date (Class IV Medical Device): October 25, 2005

Components	INSTI™ membrane unit contains HIV-1 (gp41) and HIV-2 (gp36) recombinant proteins (which capture HIV-1 and HIV-2 specific antibodies), and a procedural control (protein-A treated spot) which detects the presence of IgG antibodies normally present in blood and blood components
Sample Type	Fingerstick blood, EDTA-treated whole blood or plasma, serum.
Validation for Use	Validated for HIV-1, HIV-2 antibodies. Not validated for detection of antibodies to HIV-1 N subtype.

Test Performance:

Sensitivity Specificity	**Finger-stick whole blood ♥** : Sensitivity 99.6% [95% CI 98.9-99.9%], Specificity 99.7% [95% CI 99.4-99.8%]
Positive Predictive Value (PPV)	Finger-stick whole blood: PPV varies according to HIV prevalence.

HIV Prevalence		PPV
0.1%	(1 in 1000)	12.5%
0.2%	(1 in 500)	22.2%
1.0%	(1 in 100)	58.9%
10.0%	(1 in 10)	94.0%

Low Antibody Titer	Performance equivalent to standard antibody serological HIV test protocols using commercial low titer antibody performance panels.
Window period	When compared to standard antibody serological HIV tests on 25 established commercial seroconversion panels the INSTI™ HIV Test was reactive: • at the same time (14/25, 56%) or • up to eight days later than standard testing (9/25, 36%). In the remaining two panels (8%), the INSTI™ HIV Test was not reactive by the last bleed in the seroconversion panel. **The sensitivity of the INSTI™ HIV Test for detection of acute HIV infection is 69.4% [95% CI 54.6%-81.8%].**

Precautions:
False negative or invalid test results may be obtained in clients with severe hypogammaglobulinemia conditions (e.g., multiple myeloma), patients receiving HAART, and patients with elevated hemoglobin.

Kit Storage:
Storage temperature 2-30°C (Aug 2018) shelf-life 15 months (Feb 2016).

External Quality Control:
In place (August 2007)

♥ See product insert for sensitivity and specificity using other sample types.