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DEFINITIONS

Acute HIV infection:	The first 4-6 weeks after infection is a period when a person often has a high viral load and there is a greater likelihood of transmitting HIV to others compared with individuals in later stages of HIV infection. Individuals with acute HIV infection may test falsely negative on HIV tests if they are tested within the window period.
Health care provider:	(As per the Health Professions Act) An individual from a profession in which he or she exercises knowledge, skill, and judgment in, or provides a service related to, the preservation or improvement of the health of individuals, or the treatment or care of individuals who are injured, sick, disabled, or infirm.
High HIV transmission activities:	Activities that are associated with increased transmission or acquisition of HIV include: unprotected vaginal or anal sex; sex with an HIV infected person; sharing injection drug using equipment; sharing unprotected insertive sex toys; and acquisition of other sexually transmitted infections.
High prevalence populations:	Groups that have a higher incidence and prevalence of HIV infection in B.C. include men who have sex with men (MSM), people who use injection drugs, Aboriginal persons, incarcerated populations, sex workers and their clients.
Lot number:	The lot number is the 6-digit number which appears on the label on the outside of each box of 24 test kits. For quality control purposes, only the lot number on the outside of the box is to be used.
Point of Care (POC) HIV test:	POC HIV tests (or rapid HIV tests) are screening tests for antibodies for HIV, which are licensed by Health Canada for use by health care providers in clinical or laboratory settings, typically providing results within minutes.
Point of Care Site Lead:	The individual with the overall responsibility for ensuring that: the quality and technical aspects of POC HIV testing are conducted at each site; the ordering of test kits and supplies is completed; and the monthly reporting and ongoing training and competencies of staff are maintained.
Point of Care HIV Test, Invalid result:	An invalid or unacceptable result indicates that there is a problem either with the testing process, the control material, or the testing device.
Point of Care HIV Test, Non-reactive result:	If a client's point of care HIV test is **non-reactive (negative),** it is considered a final result and further testing is not required.

	For clients that may have a higher likelihood of being acutely infected with HIV and may be in the window period, standard HIV testing should also be offered (as standard testing has a higher sensitivity for detection of acute HIV infection).
Point of Care HIV Test, Reactive result:	If a client's POC HIV test result is **reactive**, it is considered a "**preliminary positive**". A venous blood sample must be collected for confirmatory testing by standard HIV testing. All preliminary positive results are reported to the local Medical Health Officer.
Quality assurance (QA):	All planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill the requirements for quality.
Quality control (QC):	The activities undertaken to verify the accuracy of a test result or the operational techniques and activities used to fulfill requirements for quality. Quality control materials (also referred to as quality control samples) are to be tested to ensure each lot or batch of POC HIV test kits is reacting and performing as expected.
Standard HIV test:	Standard HIV testing requires collection of a venipuncture sample for laboratory-based testing, which is a two-step protocol combining screening (i.e., enzyme-linked immunoassay, EIA) and confirmatory (i.e., Western Blot) testing. The result of standard HIV testing is considered final. Turnaround time for test results is typically within one week.
Voluntary HIV testing:	A confidential process that allows a person to discuss HIV acquisition and transmission with his or her health care provider, to decide whether to be tested, and to receive follow-up support upon receiving test results. Voluntary HIV Testing includes both provider- and client-initiated testing.
Window period:	The time between infection with HIV and the detection of HIV by a diagnostic test. The window period may vary between different HIV test products or protocols.

SECTION I: OVERVIEW AND INDICATIONS FOR POC HIV TESTING

1.0 BACKGROUND

Point of care (POC) HIV tests (also known as "rapid" HIV tests) are screening tests HIV antibodies which can be performed on-site while the client waits, and provide results within minutes. If reactive, the result is preliminary only and needs to be confirmed using standard serology. In Canada, one POC HIV test product has been licensed for use in health care settings: the INSTI™ HIV-1/HIV-2 Rapid Antibody Test (bioLytical Laboratories; hereafter referred to as the INSTI™ HIV Test). For more detailed information about this product, please refer to Appendix I – Summary of Test Properties.

In August 2010, the B.C. Centre for Disease Control (BCCDC), an agency under the Provincial Health Services Authority (PHSA) was asked by the Ministry of Health to introduce a centralized, province-wide HIV point of care (POC) testing, distribution, and quality assurance program. This program is funded through a provincial pilot project, Seek and Treat for the Optimal Prevention of HIV/AIDS (STOP HIV/AIDS). Through this program, BCCDC supplies POC HIV test kits to the regional health authorities and First Nations health agencies, to support HIV testing at designated POC testing sites.

2.0 PURPOSE

The purpose of this manual is to provide guidance regarding the implementation and use of POC HIV testing in B.C. for health care settings, in order to maximize the quality of POC HIV testing both within each site implementing POC HIV testing and for the province overall.

This manual outlines guidelines for programs or sites adopting POC HIV testing. Included in this manual are recommendations and procedures for the appropriate use of POC HIV test kits; and quality assurance components required for use with POC HIV test kits, such as staff training, documentation, and purchasing and inventory control.

This manual does not address pre- and post-test discussions surrounding POC HIV testing; these are separate guidelines located in Chapter 5 of the Communicable Disease Control Manual and can be found at www.bccdc.ca.

These guidelines are broadly applicable to any site in B.C. offering POC HIV testing. Some sections, such as purchasing and inventory control, and reports and documentation, are specific to sites receiving POC HIV test kits through the provincial program.

3.0 EPIDEMIOLOGY OF HIV INFECTION IN B.C.

The number of HIV tests performed in B.C. continues to increase. In 2010, over 180,000 tests were performed, of which approximately 25% were prenatal tests. The highest number of new positive HIV test results is reported in men who have sex with men (MSM), heterosexual populations, and people who use injection drugs (IDU). Aboriginal persons are over-represented among new positive HIV tests, particularly Aboriginal females. For the most recent data on recent trends in new positive HIV tests in B.C., please see the Annual Surveillance Reports (at http://www.bccdc.ca).

The Public Health Agency of Canada (PHAC) estimates that in B.C. in 2008, there were between 280-540 incident HIV infections (of which 50% were MSM, 25% were IDU, and 21% were heterosexual from non-endemic countries). The prevalence of HIV in B.C. was estimated at 11,400 persons (range 9,300–13,500 persons), of which 50% were MSM, 25% were IDU, and 25% were heterosexual. Nationally, an estimated 26% of HIV positive persons are unaware of their infection.

4.0 POLICY FRAMEWORK

Common objectives among HIV-related strategies in B.C. are the prevention of new HIV infections, reducing the number of HIV positive individuals who are unaware of their HIV status, and linkage of HIV positive individuals to care, treatment, and support services.

Expansion and increased availability of HIV testing is one strategy identified in B.C. at provincial and health authority levels to help achieve these objectives, and is a critical component of the STOP HIV/AIDS Pilot Project. Expansion of testing is considered one component of comprehensive HIV-related services, generally with emphasis on regional populations with a higher prevalence of HIV infection, and as a means of connecting people with HIV to appropriate care and support. Expansion of testing into rural and remote communities has also been identified as a priority. Other common themes include the importance of pre- and post-test discussions, and integration of HIV testing with testing for Hepatitis C (HCV) and other sexually transmitted infections. Testing to prevent perinatal transmission of HIV, and to a lesser extent occupational transmission of HIV, is also identified.

National strategies endorse HIV testing accompanied by pre and post-test discussions as an effective early intervention (by linkage to care) and an effective prevention strategy (by supporting the reduction of transmission in individuals with positive HIV tests).

HIV testing must be accompanied by three key elements: testing must be confidential, accompanied by pre- and post-test discussions, and conducted with informed consent.

5.0 COMPARISON OF POC & STANDARD HIV TESTING

- The INSTI™ HIV Test has similar sensitivity and specificity compared to standard HIV screening tests (Sensitivity, Specificity > 99%). While a non-reactive (negative) result is considered final (unless the person is tested early during the phase of acute infection and is in the window period), false reactive (positive) results can occur. False reactive results are more likely in a setting with a low prevalence of HIV (e.g., a setting where the population being tested for HIV has a low risk of infection).
- With standard HIV testing, confirmatory testing immediately follows positive screening tests in the lab and the result returned to the patient is final. With a reactive POC HIV test, the result is conveyed to the client as a preliminary result, and collection of a blood sample by venipuncture for confirmatory testing is required in order to provide the client with a final result at a later date.
- With standard HIV testing, a follow-up visit is required for receipt of results. The same applies to POC HIV testing if the result is preliminary reactive; however, if the POC HIV test is non-reactive, a follow-up visit is not required (if the client is outside of the window period).

- An individual with a non-reactive POC HIV test may be in the window period (i.e., prior to the development of a strong antibody response). Standard HIV screening tests are more sensitive than the INSTI™ HIV Test for detecting acute HIV infection, due to window period differences (see page 18 for more information).
- Typically, health care providers find POC HIV tests to be easy to use.
- Unlike machine-read results for standard HIV testing, interpretation of POC HIV tests is subjective. Inter-reader variability in test interpretation is low, although variability may be greater in early HIV infection when a reactive result may be faint and difficult to visualize.
- Unlike standard HIV testing, the health care provider and site administering the POC HIV test assumes the responsibility for quality assurance activities to ensure that the test is carried out correctly**.**
- With standard HIV testing, positive HIV results are reported to public health for partner notification through a routine, established surveillance system. With POC HIV testing, all preliminary positive POC HIV test results are to be reported to Medical Health Officers.

6.0 POTENTIAL BENEFITS OF POC HIV TESTING

- POC HIV testing is highly acceptable to, and preferred by, many clients presenting for testing as well as health care providers conducting testing.
- Use of POC HIV testing may result in increased uptake and volume of HIV testing.
- Individuals undergoing POC HIV testing are more likely to receive their test result, particularly if they are HIV negative. Receipt of a final HIV positive result may not differ from standard testing, although individuals may be more likely to present for receipt of confirmatory test results.
- The rapid turnaround time associated with POC HIV testing can guide urgent decision-making to prevent transmission of HIV infection or to improve patient care.
- POC HIV testing may be a viable testing option for individuals where venipuncture is difficult or has been unsuccessful.

7.0 POTENTIAL HARMS OF POC HIV TESTING

- POC HIV testing may lead to decreased uptake of testing for other infections (e.g., Hepatitis C, syphilis).
- As POC HIV testing is not laboratory-based or automated, there may be greater potential for user error or other site-specific factors to influence the quality of testing.
- Increased incidence of subsequent sexually transmitted infections has been reported in clients getting a POC HIV test in comparison to clients testing through standard protocols, possibly due to disinhibition on receipt of a negative test result or compression of pre- and post-test discussions into a single visit.
- With POC HIV testing there may be missed opportunities for partner discussion and referral (and prevention of further HIV transmission) if clients are lost to follow-up after receipt of a preliminary positive result (i.e., if follow-up confirmatory testing is not performed).

8.0 GENERAL REQUIREMENTS

The following are general requirements for health care settings adopting POC HIV testing. These points are further elaborated on in the Roles and Responsibilities section of this document located in Appendix II:

- POC HIV testing is confidential, accompanied by pre and post-test discussions, and conducted with informed consent.
- Testing is conducted by health care providers who have been trained to deliver HIV pre- and post-test discussions and how to use POC test kits.
- Recommended quality assurance measures are in place (e.g., staff training, documentation and monitoring of test outcome, use of quality control test kits).
- Where feasible, clients presenting for HIV testing should be offered a choice of standard or POC HIV testing.
- Clients are encouraged to test for other infections as appropriate (e.g., HCV, syphilis).
- Capacity exists within the organization to provide additional support to clients and testers at the time of a reactive POC HIV test and to facilitate standard confirmatory HIV testing.
- Testing staff have knowledge of local care pathways and community resources available to individuals who test positive for HIV.
- Preliminary positive POC test results are reported to the local Medical Health Officer.

9.0 INDICATIONS FOR POC HIV TESTING

The purpose of this section is to provide guidance regarding the appropriate use of POC HIV testing in B.C. In particular, this section suggests clinical scenarios and voluntary HIV testing settings where POC HIV testing is most indicated. These indications are based on the current epidemiology of HIV transmission in B.C., current policy frameworks for HIV testing, and a review of the evidence of impact and use of POC HIV testing.

9.1 Clinical Scenarios Where There is an Urgent Need to Determine HIV Status

As with standard HIV testing, providers need to use clinical judgment based on the history of risk exposure, potential for acute or early infection, and knowledge of the POC HIV test window period in acting on the result of POC HIV tests.

9.1.1 Pregnant women near term or in labour with undocumented HIV status or ongoing risk of HIV infection in pregnancy

The risk of transmission from a mother with HIV infection to her infant is substantially reduced if antiretroviral medications are administered to the mother during pregnancy, labour or delivery, or to the infant shortly after birth. POC HIV testing of women near term or in labour with undocumented HIV status or ongoing risk of HIV infection provides an enhanced opportunity for rapid identification of HIV infection and initiation of antiretroviral therapy to reduce the risk of HIV transmission to the newborn.[i]

[i] Refer to Oak Tree Clinic, B.C. Women's Hospital and Health Centre for guidelines regarding HIV testing and management in pregnancy (www.bcwomens.ca/Services/HealthServices/OakTreeClinic/default.htm)

9.1.2 Testing of the source individual during blood and body fluid exposures

Knowledge of the HIV status of source individuals during the evaluation of blood and body fluid exposures can guide decision-making regarding the administration of post-exposure prophylaxis. POC HIV testing of source individuals reduces the time to result availability and may avoid unnecessary post-exposure prophylaxis and anxiety in the exposed person.[ii]

9.1.3 Clinical diagnosis of acutely ill patients

Patients may present for emergency care where rapid knowledge of HIV status may improve quality of care by guiding further diagnostic workup or treatment (e.g., patients with a clinical presentation compatible with opportunistic infections).

9.2 HIV Testing Settings

There are no set criteria for determining whether POC HIV testing should be offered in a specific HIV testing settings (which can be broadly defined, including clinics, outreach programs, needle exchanges, etc). Rather, sites should be determined by Regional Health Authorities and First Nations communities according to local priorities for expanding and engaging populations in HIV testing, and with consideration at a regional level of sites where the potential benefits of POC HIV testing outweigh the potential harms (section 6.0, 7.0 above). A further consideration is whether voluntary testing settings have the infrastructure and resources required to adopt POC HIV testing (section 8.0 above; Appendix II).

Examples of voluntary HIV testing settings where POC HIV testing is expected to have the most benefit include:

[ii] Refer to BCCDC guideline "Blood and Body Fluid Exposure Management (March 2010)" in the CD Control Manual (www.bccdc.ca)

9.2.1 Settings accessed by populations where the prevalence of undiagnosed HIV is expected to be higher

Compared to other sites in the region. POC HIV testing may lead to increased uptake and volume of HIV testing. Use in these settings where the client population is known or suspected to have a higher prevalence of undiagnosed HIV may contribute to reducing the proportion of HIV positive individuals who are unaware of their HIV status.

9.2.2 Settings accessed by populations where not returning for test results is common among those tested

Receipt of a positive HIV result has been demonstrated to lead to a reduction in risk behaviour. POC HIV testing has been demonstrated to improve the receipt of final test results. In settings where a high proportion of clients are tested and do not return to find out their test results, POC HIV testing may be of benefit, particularly where failure to return is common among HIV positive individuals.

9.2.3 Settings accessed by populations where provision of a POC HIV test result will improve public health follow-up or connection to HIV clinical care

For example, presentation for medical care, admission to facilities, or other services may provide opportunities to engage individuals in testing. However, as the testing health care provider may not be the patient's primary health care provider, and rapid patient turnover within facilities is common, receipt of test results, follow-up by public health of positive results, and connection to HIV care may be difficult. In such settings, POC HIV testing with immediate identification of individuals with preliminary positive HIV results may improve follow-up and connection to care.

9.2.4 Settings accessed by populations with low rates of testing where of POC HIV testing may lead to increase uptake of testing

The convenience and ease of testing due to rapidity of result, and requirement for a single visit (if negative) may be appealing and lead to increased test uptake.

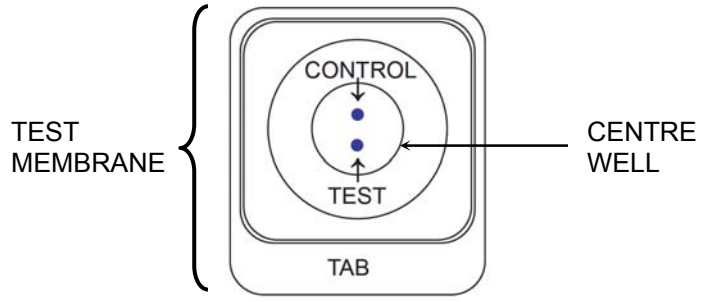
SECTION II: PERFORMING THE TEST

1.0 KEY INFORMATION ABOUT POC HIV TESTING

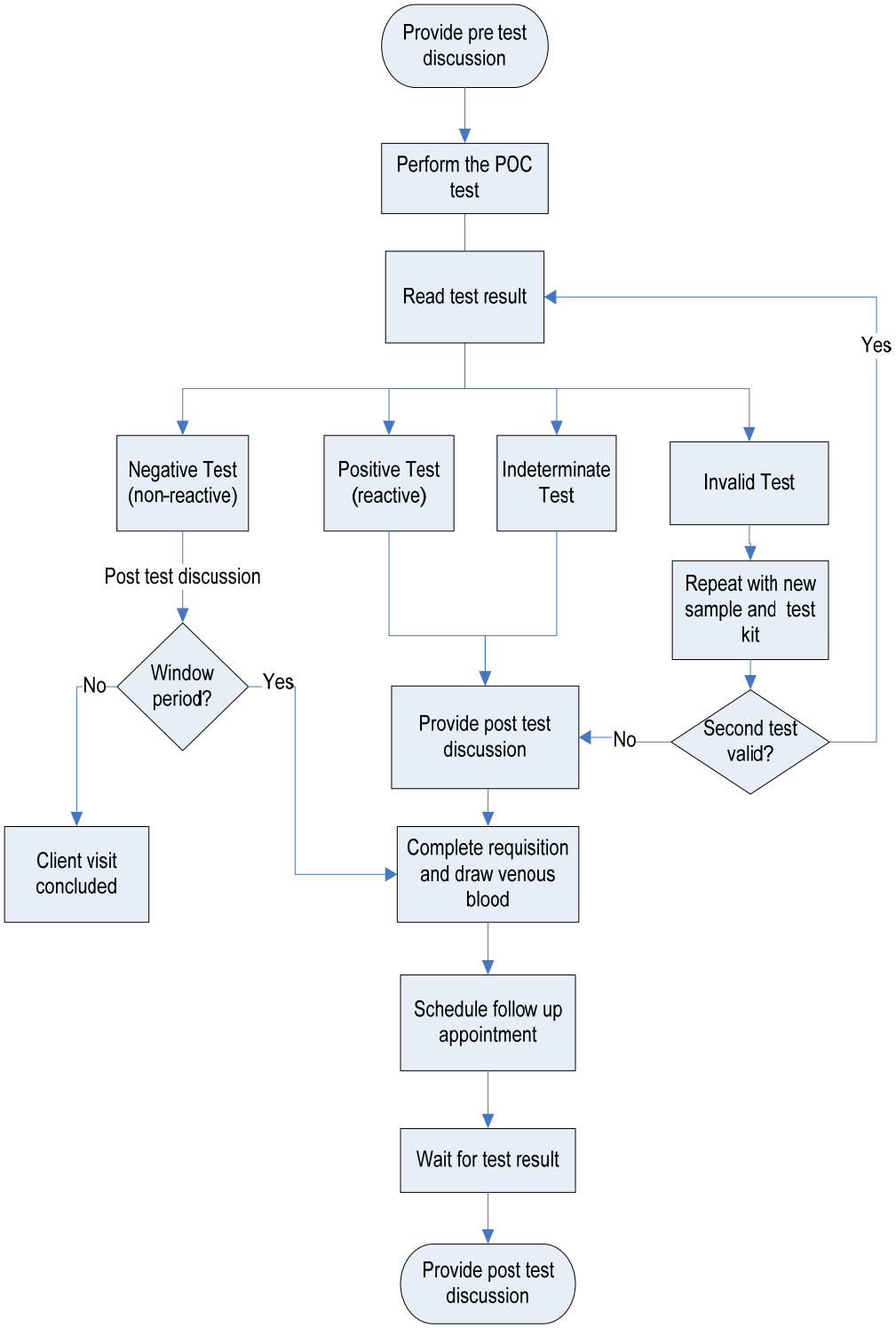
- The INSTI™ HIV Test is used to perform the initial screening for HIV antibodies in whole blood.
- POC HIV testing is confidential, accompanied by pre and post-test discussions, and conducted with informed consent. Guidelines for pre- and post-test discussions to accompany POC HIV testing are located in Chapter 5 of the Communicable Disease Manual (www.bccdc.ca).
- If a client's POC HIV test result is **reactive**, it is considered a "**preliminary positive**". A venous blood sample must be collected to confirm the POC HIV test result for confirmatory testing by standard HIV testing. All preliminary positive results are to be reported to the local Medical Health Officer and a plan should be made with the client to return for the confirmatory result.
- If a client's POC HIV test is **non-reactive (negative),** it is considered a final result and further testing is not required. For clients that may have a higher likelihood of being acutely infected with HIV and may be in the window period, standard HIV testing should also be offered (as standard testing has a higher sensitivity for detection of acute HIV infection).
- If a client's POC HIV test is **invalid**, the test should be repeated with a fresh sample using a new membrane unit, kit components, and support materials. If the client has a second invalid result, standard HIV testing should be performed and the POC Site Lead notified.
- If a client's POC HIV test is **indeterminate**, a venous blood sample must be drawn and forwarded to a laboratory for HIV standard testing.
- Where feasible, clients should be offered a choice of standard or POC HIV testing. Clients should also be encouraged to test for other infections such as syphilis or Hepatitis C as appropriate.
- Testing staff should have knowledge of local care pathways and community resources available to individuals who test positive for HIV.
- Quality Control testing of POC HIV test kits should be conducted according to recommendations (see Section III — Quality Assurance) prior to offering POC HIV testing.
- Any indication that POC HIV test kits are not performing properly should be reported to the POC Site Lead, the Provincial POC HIV Testing Program Manager and the manufacturer.
- All test results and other relevant information such as lot number and expiry date, should be documented (see Section III — Quality Assurance).

2.0 CONDUCTING THE INSTI™ HIV TEST

2.1 Test Schematic



2.2 Flow Diagram for HIV POC Testing During a Client Visit



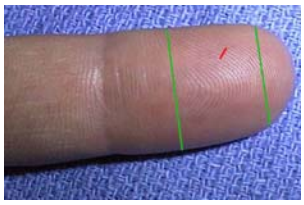
2.3 Procedure for Conducting the INSTI ™ Test

Prior to conducting the POC HIV test, check that the POC HIV test kits have not expired, and that that quality control testing has been done as per the guidelines in section 3.0.

Prepare for testing.

1. Wash or sanitize hands.
2. Prepare a testing area by disinfecting a non-porous level surface with an approved disinfectant. ***Note:*** *Alternately a new, clean, blue pad may be utilized to contain the testing materials.*
3. Gather the following materials:
   - INSTI™ HIV Test kit, which contains:
     - HIV test membrane
     - each of reagent solutions 1, 2 and 3
     - alcohol swab
     - single-use lancet
     - single-use pipette capable of dispensing 50 uL
   - gloves
   - gauze or cotton ball for post-puncture wound coverage
   - biohazard sharps/waste container
4. Select the finger to use for obtaining the blood sample.

   Note: *Avoid using the index finger or thumb because these two fingers are usually more calloused than the other three fingers. Similarly, avoid the tip of the finger.*



5. Massage and/or warm the selected finger to allow blood to flow to the surface.
6. Open alcohol swab, and the Solution 1 vial (do not discard the lid).
7. Open the pouch containing the membrane unit.
8. 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).

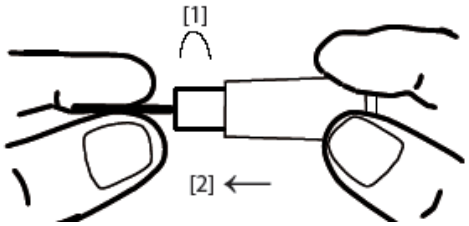
   Note: *If the centre well is touched, the HIV antigen molecules will be torn from the membrane and the test will not perform correctly.*
9. Put on gloves.

Collect finger prick

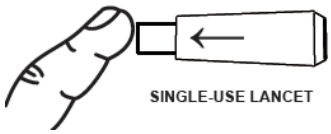
10. Wipe selected warmed finger thoroughly with alcohol swab and position hand at waist level or lower. Allow alcohol to dry before proceeding.

blood

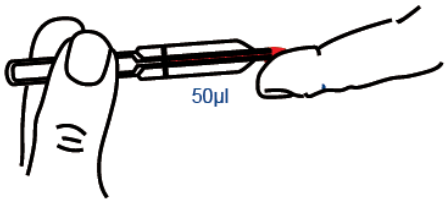
11. Twist off the protective cap from the lancet and then pull the cap straight off.



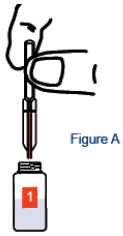
12. Position the lancet device against the finger. Holding lancet body, press the lancet firmly against the finger.

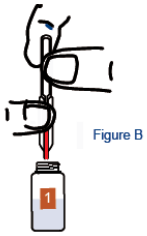


13. Dispose the lancet directly into a sharps container.
14. Hold the pipette horizontally and touch the tip of the blood drop to the tip of the pipette. ***Note:*** *The pipette will fill by capillary action;* ***<u>do not squeeze</u>*** *the pipette during filling.*



15. Fill the pipette to the fill line to obtain the required amount. ***Note:*** *It is very important to draw the correct amount of blood. If the puncture site does not yield a sufficient amount, a separate second puncture using a new lancet and pipette is required.*
16. Place gauze over the puncture site and ask the client to hold it against the puncture site and to elevate the hand.
17. Transfer the blood from the pipette into the sample diluent (Solution 1) vial by squeezing the bulb of the pipette to dispense the blood into the vial (figure A). ***Note:*** *If the blood does not expel from the pipette, hold the pipette vertically and slide a finger over the vent hole and squeeze the pipette bulb (figure B).*





18. Dispose the pipette in a biohazard waste container.
19. Recap the vial (Solution 1 + sample), mix by turning upside down a few times. ***Note:*** *Do not shake vigorously. Complete each of the following steps immediately.*
20. Carefully pour the entire contents of the Solution 1 vial into the membrane well.

Testing – Using solutions 1, 2, 3

Note: *If most of the solution has gone into the well but some has dripped on the side of the vial, 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.*

21. Wait until the solution is absorbed by the membrane (takes only a few seconds).
22. Mix the Colour Developer (Solution 2 vial) by slowly turning the vial upside down several times.

    Note: *This solution should appear evenly suspended prior to adding to the membrane.*
23. Open and add the entire contents of the colour developer (Solution 2) to the centre of the membrane unit. Wait until the solution is absorbed by the membrane (takes approximately 20 seconds).
24. Open and add the clarifying reagent (Solution 3 vial) to the centre of the membrane unit.

Interpret the results

25. Read the result immediately and record the result.

    Note: *If more than 5 minutes have passed since adding the clarifying solution (solution 3) the result is invalid.*

Clean up.

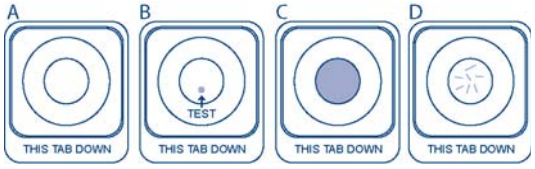
26. Discard the test membrane in a biohazard waste container.
27. Remove and discard gloves.
28. Decontaminate the work area with an approved disinfectant.

3.0 INTERPRETING THE TEST RESULTS

3.1 Procedure

1. Review the flowchart in section 2.2 (Flow Diagram for HIV POC Testing during a Client Visit) for information on interpreting the test result.
2. Read the test with the tab in the lower position from the membrane.
3. Interpret the test according to the instructions in the table on page 15.
4. Interpret the test and convey the result to the client.
5. Record the test result as per instructions in section III, 5.1.

3.2 Table: 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, 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). 	Test is valid Antibodies to HIV-1 or HIV-2 have been detected	A venous 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 positive result to local Medical Health Officer.
Indeterminate	One blue dot at the top. Faint background ring appears on the lower test dot. 	Test is valid Antibodies to HIV-1 or HIV-2 may have been detected	A venous sample should be drawn and sent for standard HIV testing.
Invalid	No blue dot at the top of the membrane; or blue specks appear; or there is a uniform blue colour across the membrane. 	Test is invalid Something may be wrong with the test kit or the testing process	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. Report invalid results to POC Site Lead. Use quality control samples to make sure that the test is operating properly

3.3 Notes and Limitations

- There is no correlation between the intensity of the blue colour control dot and the test result. The control dot may be a lot darker or lighter than the lower, client/test dot.
- When there is a problem reading the test (e.g., shadows or rings), then two individuals should read the test, if possible. The names of both people reading the test(s) should be documented.
- When more than 60uL of blood is used, the flow through the membrane may be obstructed and produce a uniform blue line across the entire membrane. It is extremely important to use the supplied capillary pipette to add the sample to solution 1.
- A client in the window period may have a false non-reactive test 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.
- A test that is performed using an insufficient sample, performed incorrectly or where a defective device is used, will give an **invalid** result and testing should be repeated. If the second POC HIV test performed is also invalid, quality control samples should be used to determine if the test kits are performing correctly. Notify the POC Site Lead after two consecutive invalid results. Venous blood samples should be drawn and sent to BCCDC 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), patients receiving HAART, and patients with elevated hemoglobin. Patients receiving HAART should not require POC testing. For patients with hypogammaglobulinemia, RNA or HIV antigen/antibody testing may be required.
- The INSTI™ HIV test has not been validated for detection of antibodies to HIV-1 Group O or N sub-groups.

3.4 Further Information

Please contact the Provincial POC HIV Testing Program Manager for further information about the test, interpretation of test results, or troubleshooting.

4.0 FOLLOW-UP TESTING

It is essential to confirm all reactive (preliminary positive) POC HIV test results with standard laboratory HIV testing. In addition, if a test results in two consecutive invalid results or an indeterminate result, a confirmatory lab sample should be drawn and sent for testing.

Clinical judgment remains important in HIV testing. If you receive a negative or indeterminate standard HIV test result for a client who you consider to have a high likelihood of having an HIV infection, you may contact a medical or clinical virologist at the PHSA Laboratory to review the case and to determine if additional tests are indicated.

Individuals (regardless of POC HIV test result) should be advised to get tested for other infections via standard blood testing where appropriate (i.e., syphilis, hepatitis B, hepatitis C).

As with standard HIV testing, if the serology done to confirm a POC preliminary positive results in a true positive result, a second blood test is recommended to confirm the diagnosis. This will

help to eliminate the low possibility of error that might result from sample handling such as mislabeling of submitted samples. Repeat testing is particularly recommended when the client's history suggests a low risk for exposure to HIV or the client does not undergo subsequent viral load testing or connect with HIV primary care follow-up.

4.1 Procedure for Follow-Up Testing

Samples can be collected on-site and transported directly to BCCDC Provincial Health Microbiology and Reference Laboratory for follow-up testing, or indirectly via another laboratory. Detailed instructions are available from the Point of Care Program Manager if needed.

General Instructions for All Collection Methods:

1. Obtain and complete a laboratory requisition according to established procedure (BCCDC serology requisition or other), indicating whether HIV testing is to be reported nominally or non-nominally.

2. Draw the appropriate samples (1 gold top and 1 EDTA top). See the appropriate Guide to Lab Services[iii] for current information.

3. Arrange for the sample to be transported to BCCDC Provincial Health Microbiology and Reference Laboratory for testing, per established process.

4. When the result of standard laboratory HIV testing is received, document the result in the client chart and the Daily Log of Client POC Test Results (if used; see Appendix IV). For clients with an initial reactive POC HIV test result, document the final POC HIV test result as **true positive** if standard HIV test confirms HIV infection or **false positive** if standard HIV test does not confirm HIV infection.

5. Notify client of confirmatory test result as per site policy.

Additional Steps for Testing Sites Sending Specimens Directly to BCCDC Provincial Health Microbiology and Reference Laboratory:

- Write "STAT" on the upper right corner of the BCCDC requisition. *(This alerts the staff who sort samples and run the tests that this sample goes first).*

- Write the POC test result in the comment section (e.g. If using the BCCDC Serology requisition form, write "POC reactive/non-reactive/invalid/indeterminate"). *Note: This information will facilitate tracking of test results and may assist BCCDC Laboratory in determining the appropriate standard HIV tests to perform.*

- Complete the FAX template and send fax to BCCDC to alert them that a sample is coming (See Appendix III). *This triggers a process in the lab so that they follow-up if the sample does not arrive when expected.*

[iii] Refer to PHSA Laboratories Guide to Programs and Services (http://www.phsa.ca/NR/rdonlyres/D632D356-8E8F-4917-BC3D-463EB5F8A14B/0/GuidetoProgramServices.pdf)

4.2 Ruling Out Acute HIV Infection

Some clients may be more likely to have an acute HIV infection; for example, individuals with symptoms of HIV seroconversion, or individuals who are likely to have ongoing or recent exposure to HIV. For these individuals, following a non-reactive POC HIV test, it is recommended to submit a blood sample for standard HIV testing. A standard HIV test can detect HIV antibodies as early as 2-3 weeks after infection; POC HIV testing may take a little longer but can detect HIV antibodies as early as 3-4 weeks after infection. For both POC and standard testing, approximately 95% of people will have a reactive HIV test by 6 weeks after infection (>99% by three months). Standard HIV laboratory screening tests are more sensitive than the INSTI™ HIV Test, due to window period differences. In the event that a reactive POC HIV test is followed by a negative standard laboratory test, further testing can be requested by the clinician.

For these clients, writing “HIV Ag/Ab combo” on the laboratory requisition form (i.e. in the “Other Tests” section of the PHSA Laboratory requisition) will ensure a test is performed that has the best capacity to detect acute HIV infection.

SECTION III: QUALITY ASSURANCE

1.0 OVERVIEW

The objective of quality assurance activities is to ensure the delivery of a high quality, accurate and efficient POC HIV testing process. Quality assurance activities must be in place at all times to ensure that test results are accurate and as reliable as possible, and to ensure confidence in the testing program and staff. For this reason, the overall responsibility for the quality and technical aspects of each site's POC HIV testing should be assigned to one individual (in this manual, this individual is referred to as the "POC Site Lead").

In B.C., quality assurance is a shared responsibility between staff conducting POC HIV testing, the POC Site Lead, the Provincial POC HIV testing program, the PHSA Laboratory, and the POC HIV test manufacturer (bioLytical).

While clinical health care settings (including hospital wards, clinics, or outreach programs) are not subject to the same standards for laboratory accreditation, the quality assurance activities described in this section of the manual are based on the same principles as those of laboratory accreditation.

1.1 Reporting Concerns Regarding the Quality of POC HIV Tests

Testers at sites using POC HIV tests and quality control samples may be the first to suspect issues with the quality of POC HIV test kits. Potential indications that POC HIV tests may not be performing as expected include:

- Increases in the number of clients with invalid, indeterminate, or false positive results.
- Incorrect POC HIV test results with the use of quality control samples.

Any concerns of this nature, including the lot number of the implicated POC HIV test kit or quality control test should be reported to:

- POC Site Lead; and
- **Dr. Sarah Fielden, Provincial POC HIV Testing Program Manager**:
  Tel: 604-707-5635 Fax: 604-707-5604 Email: sarah.fielden@bccdc.ca

These reports will be investigated to determine if the issue may be related to staff performance (e.g., incorrect procedure), impaired quality of the POC HIV test kit or quality control samples, or an expected variation.

2.0 STAFF TRAINING

The most important part of the program is to ensure that staff who conduct POC HIV testing are well-trained and can confidently perform and interpret the test. Records of staff training, competency and proficiency assessments should be maintained and be consistent with existing practice standards at each site.

2.1 Initial Training for POC HIV Testing

Core POC HIV education and POC HIV testing training sessions are held regularly by BCCDC and other health authority staff, in conjunction with bioLytical representatives. For more information, contact the Provincial POC HIV Testing Program Manager. Each site must define what additional observations or assessments, beyond the initial training sessions, must be met before a new tester is approved to offer POC HIV testing at that site.

Training for POC HIV testing may include a combination of education offered by BCCDC and by the POC Site Lead as follows:

BCCDC or Regional Health Authorities	• Pre- and Post-Test HIV discussion (as needed). • Completion of one 2–3 hour training program on the use of test kits and conducting quality assurance activities.
POC Site Lead	• Demonstration of competencies (see Appendix V –Direct Observation Checklist and Appendix VII- Training Completion Requirements).

Training addresses POC HIV testing competencies for providers (please refer to the table in Appendix VI —Training Competencies). Once training has been completed, each trainee should independently demonstrate, at a minimum, the competencies described in Appendix VII —Training Completion Requirements, in the presence of their POC Site Lead.

2.2 Continuing Education and Ensuring Ongoing Competency for Testers

Continuing education and ongoing competency assessment can be done by a variety of methods and should be scheduled for employees depending on their level of experience with POC testing by the POC Site Lead. Possible ways to provide continuing education related to POC and to ensure ongoing competency for testers are listed below:

- Interaction with Testers: Informal assessments can be done whenever the POC Site Lead is at the site, participating in, or observing, daily activities.
- Review of daily log of client POC test results (Appendix IV) and Quality Control Log (Appendix IX): It is recommended that the POC Site Lead review these documents at a minimum of once a month as an opportunity to assess how testers are performing and provide follow up as necessary.
- Direct observation of test usage: It is recommended that refresher training occur whenever there is a problem or issue identified or on a regular basis for staff, especially those who do not perform POC HIV tests regularly (see Appendix V –Direct Observation Checklist).
- Regular reviews with testers in a meeting setting: discussions with testers in a meeting setting can facilitate sharing of experiences with test kit usage and allow the POC Site Lead to gauge competency and comfort levels of testers and discuss learning needs.
- Investigation of errors: This is an opportunity to assess how testers are performing based on the findings of an error or near-miss event. These investigations are also an opportunity to discuss testing and to review documents.
- Proficiency Testing: See below.

2.3 Proficiency Testing

Proficiency Testing (PT) is conducted two to three times per year by an external provider who provides unknown testing materials to all testing sites. Testers at each site are expected to test the unknown materials and enter their result into an online database. Once all the results have been entered, each site will be able to identify if there are concerns with testing at their site and also be able to compare themselves to other sites (note: names of other sites participating in the PT program will not be visible to other users).

PT is highly recommended for each site participating in the provincial POC HIV testing program. It is an important tool that can be used by the site and the provincial program to verify the accuracy and reliability of POC HIV testing results in order to protect patient safety. PT differs from Quality Control (QC) testing as it assesses the entire testing process, involves the testing of unknown samples and anonymously compares the performance of all sites participating in the program.

The provincial POC HIV testing program will contract the services necessary for PT with an external provider on behalf of sites affiliated with the provincial program. Costs for PT are assumed by the provincial POC HIV testing program. The provincial program will be able to see the results from participating sites, but the identity of individual testers will not be included in the results database.

3.0 USING QUALITY CONTROL SAMPLES

Quality Control (QC) samples are produced by the manufacturer (bioLytical) and are used to evaluate the validity of the INSTI™ POC HIV test kits, to check whether the test kit has been used correctly and the results interpreted correctly, as well as to familiarize testers with the testing process and the appearance of a preliminary positive result. Each box of QC samples contains 36 vials, consisting of an equal number of: anti-HIV-1 positive control, anti-HIV-2 positive control and HIV negative control. Each vial should be sufficient to conduct to 4-5 tests (144-180 tests total/ box).The samples are shipped frozen and last up to one year if they remain frozen at -20ºC. Once thawed, they last 28 days when refrigerated at 2-8ºC. Samples are warmed to room temperature before use (approximately five minutes).

QC samples are considered to be a biohazard and there is a potential, but extremely low risk of HIV transmission associated with their use. Sites should follow biosafety rules regarding storage, handling and disposal of QC samples. Quality control samples should be stored in a freezer in the plastic container in which they are shipped and enclosed in a biohazard bag. Once thawed, vials can be stored in a refrigerator in a labeled, leak-proof container and enclosed in a biohazard bag.

When used on a regular basis, QC samples provide assurance that the HIV test results being given to clients are valid and accurate.

3.1 Frequency of Use

QC samples should be used at regularly scheduled intervals with a recommended **minimum of once per month**.

Sites must balance how often QC samples are used with the number of clients who would have to be retested in the event of a problem with the test kits. For sites doing few tests per month (0-25), the once per month minimum is reasonable as the number of clients that would need to be retested is minimal. For sites that do many (25 or more) tests per month, regular use of QC samples may be increased (e.g. once per week).

3.2 Other Indications for Use of QC Samples

In addition to the once per month minimum recommended use of QC samples, it is recommended that all sites participating in the Provincial POC HIV Testing Program perform QC testing as per the manufacturer's instructions as follows:

- for newly trained health care providers prior to actually using the POC HIV test kit on clients
- when a site receives a new shipment of POC HIV test kits
- when there is a change in test kit lot number
- when a site receives a new shipment of quality controls (usually once per year)
- if the temperature of the storage or testing area falls outside of the manufacturer's specified temperature range (less than 15°C or greater than 30°C)
- when two consecutive invalid results occur with the same client

When QC samples do not provide the expected results and it has been determined that there is a problem with the test kits, or QC failures are unresolved, none of the tests used since the last time QC samples were used with correct results can be considered valid. ***Contact the Provincial POC HIV Testing Program Manager immediately as client retests may be required.***

3.3 Overview of the Use of QC

When testing QC samples, use one set of controls (one each of anti-HIV-1 positive control, anti-HIV-2 positive control and negative control) and a separate pipette for each of the three controls (total of three POC HIV test kits and 3 **QC** pipettes). Ideally, a different person does QC testing each time, or, at a minimum, the same person should not always be conducting the QC testing, so that all testers are comfortable with the process. The staff person who performs QC testing should also perform POC HIV testing for clients. The positive control samples are intentionally weak positives to simulate a critical point in early infection, where antibody levels of the client may be barely high enough to be detected by the test kit.

When performing QC testing on a once per month basis, it is recommended that sites follow the "View or Do" model for quality control. The "View or Do" model encourages those performing QC testing once per month to show the results to their colleagues so that as many test kit users as possible have the opportunity to see what reactive and non-reactive results look like. Contact the Provincial POC HIV Testing Program Manager for suggestions as to how this may be done at a site.

3.4 Quality Control Failure

When the QC results seen on the test membrane do not agree with the expected result, QC is determined to have "failed" and an investigation into what caused the problem is

necessary. In the event of a QC failure, record the QC result and inform the POC Site Lead as soon as possible. Client POC HIV testing must be stopped immediately, until the cause of the failure is found and corrected.

It is important to review the testing environment for factors that could have caused the QC failure. Do not continue to use QC samples until you get a "correct result". It is a good practice to start an investigation by excluding more-common errors such as mix-up of control materials, reagents, pipettes and missed steps in the use of QC. Other important areas to investigate are:

- recent changes to the test or testing environment
- QC storage conditions
- QC expiry date/contamination
- pipette used for testing

3.5 Suggested Actions if QC Fails:

Repeat use of QC samples from the same vial. If QC fails again:

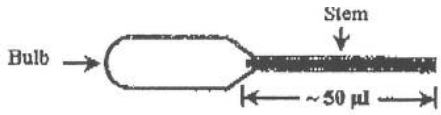
a. repeat test using a fresh vial taken out from the freezer. If QC fails again:
b. repeat test using a test kit from a newly opened box with the newly opened QC vial.
c. if QC fails again, there may be a problem with the test kit lot. STOP CLIENT TESTING. Notify the POC Site Lead and the BCCDC POC HIV Program Manager.

When QC samples do not provide the expected results and it has been determined that there is a problem with the test kits, or QC failures are unresolved, none of the tests used since the last time QC samples were used with correct results can be considered valid. This means that all clients tested since the last use of QC samples with correct results will need to be called back and retested (unless a confirmatory test was ordered).

4.0 PERFORMING A QUALITY CONTROL TEST

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

Preparation	1.	Remove one HIV-1 positive, one HIV-2 positive and one negative QC vial from fridge or freezer and bring to room temperature (approximately 5 minutes).
	2.	Document the QC test information (lot number, expiry date) on the appropriate log. ***Note:*** *vials expire 28 days after thawing if stored in the refrigerator.*
	3.	Wash or sanitize hands.
	4.	Prepare a testing area by disinfecting a non-porous level surface with an approved disinfectant. ***Note:*** *Alternately a new, clean blue pad may be utilized to contain the testing materials.*
	5.	Gather the following materials: • three INSTI™ HIV Test kits (one for each of the positives and negative control) • three quality control pipettes • gloves • biohazardous sharps/waste container
Prepare test membrane	6.	Open one pouch containing the first membrane unit.
	7.	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, HIV-2 positive) using a black or blue marking pen and place the membrane on a level surface.
Testing	9.	Put on gloves. ***Note:*** *All control samples should be handled as if capable of transmitting infectious diseases*.
	10.	Gently agitate the 3 QC sample vials by inverting, or flicking, a few times. Tap the bottoms of the vials a few times on a hard surface to bring all the material from the cap back into the body of the vial.
	11.	Remove, **and retain**, the cap from the solution 1 vial.
Pipette a sample	12.	Unscrew the cap of the negative QC sample.
	13.	Carefully push a small amount of air out of the pipette provided for quality control testing (do not use the capillary pipette). Hold the pipette vertically above the sample vial, and aspirate the QC sample from the vial. Fill the pipette just to the neck of the bulb.



Solution 1	14.	Set down the QC vial, and pick up the opened solution 1 vial. Position the pipette with sample above the opened solution 1 vial. Transfer the QC sample from the pipette into the sample diluent (solution 1) vial by squeezing the bulb of the pipette to dispense the sample.
	15.	Discard the pipette in a biohazard sharps/waste container. Recap the QC vial.
	16.	Recap the solution 1 vial, mix by inverting the vial a few times. Carefully pour the entire contents of the solution 1 vial into the membrane well. Wait until the solution is absorbed by the membrane (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 vial, 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	17.	Mix the color developer (solution 2 vial) by slowly turning the vial upside down several times. ***Note:*** *This solution should appear evenly suspended prior to adding to the membrane.* Open and add the entire contents of solution 2 to the centre of the membrane unit. Wait until the solution is absorbed by the membrane (takes approximately 20 seconds).
Solution 3	18.	Open and add the clarifying solution (solution 3 vial) to the centre of the membrane unit. Wait until the solution is absorbed by the membrane (takes approximately 20 seconds).
Record results	19.	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.*
	20.	Discard the test membrane into a biohazard sharps/waste container.
Repeat for HIV-1 control	21.	Open and label a new membrane and repeat from step 12 with the second quality control (HIV-1).
Repeat for HIV-2 control	22.	Open and label a new membrane and repeat from step 12 with the third quality control (HIV-2).
Clean up	23.	Remove and discard gloves.
	24.	Decontaminate the work area with an approved disinfectant.
	25.	Check that the lids are tight on all QC vials. Store in labeled container with the expiry date (28 days after thaw) and put in biohazard bag labeled with expiry date if not already done. Place into refrigerator for storage.

5.0 PROGRAM REPORTS AND DOCUMENTATION

Managing the whole POC HIV testing process is critical to its success. It is recommended that testing sites develop and maintain standard operating procedures related to POC HIV testing, which are based on these guidelines and consistent with existing practice standards. Testing sites should retain all POC HIV test records according to their agency's policy on retention of clinical records (or a minimum of two years if no such policy exists).

This section outlines the minimum information that needs to be collected for the individual undergoing POC HIV testing, for quality control testing, and for monthly summary reporting. This information may be recorded and retrieved in a variety of different formats depending on the testing site (e.g., electronic charts, paper charts, testing logs). Templates of tools for this documentation are provided in the appendices of this document. Word versions of the templates are available from the Provincial POC HIV Testing Program Manager, and can be adapted for use as required.

With the exception of the monthly summary report forms, other documents used do not need to be sent to the Provincial POC HIV Testing program. However, these documents may be used by the site and the Provincial POC HIV Testing Program in the event of a critical incident such as a quality control or proficiency testing failure.

5.1 Documentation of Test Results for POC HIV Tests

For each client undergoing POC HIV testing, the following minimum information should be documented in the client chart or record:

- Date of POC HIV test
- Client identifying information including contact information
- Identification of provider conducting the test
- POC HIV test lot number and expiry date (found on the outside of the box of 24 kits)
- POC HIV test result (i.e., reactive, non-reactive, invalid, indeterminate)
- Whether a venipuncture for HIV serology was collected (or requisition for HIV serology given, if sample collection not available on site)
- Standard HIV serology result (i.e., reactive, non-reactive, invalid, indeterminate)
- Final classification of a reactive POC HIV test:
  - 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)

Testing sites are required to establish processes to:

- Monitor that clients with a reactive POC HIV test result have standard HIV serology performed, and that these results are received and reviewed by the site and with the client.
- Follow up when standard HIV serology and POC HIV test results are not the same.
- Rapidly identify all clients tested with a POC HIV test from a specific lot number, or that have a specific type of POC HIV test result (e.g. non-reactive, reactive, invalid) in case of a quality issue requiring investigation or re-testing.

- Extract information on key POC HIV test program indicators for reporting on a monthly basis (see section 5.2 below).

While some testing sites may be able to use existing clinical information systems to meet the above requirements, an alternate approach is to establish a testing log. This testing log should be maintained in a central location and completed for all POC HIV tests conducted at the testing site, and can be reviewed as required to meet the above requirements. A testing log template is provided in Appendix IV — Daily Log of Client POC Test Results.

5.2 POC HIV Test Monthly Summary Reports

In order to maintain an appropriate regional and provincial supply of POC HIV test kits, and to monitor the performance of POC HIV test kits at regional and provincial levels, testing sites are required to provide a monthly summary report to the Provincial POC HIV Testing Program Manager which includes the following information:

- The number of POC HIV test kits (and their expiry dates), in inventory at the start and end of the month
- The number of clients tested by POC HIV test kits:
  - Number of clients with non-reactive POC HIV test results
  - Number of clients with reactive POC HIV test results (total number, and numbers with final result being preliminary positive, true positive, and false positive based on standard serologic testing)
  - Number of clients with invalid POC HIV test results
  - Number of clients with indeterminate POC HIV test results
- The number of POC HIV test kits used for quality control testing
- The number of POC HIV test kits used for training and proficiency testing
- The number of test kits wasted
- The number of test kits expired and discarded

This information is to be sent to the appropriate regional health authority contact person(s) and the Provincial POC HIV Testing Program Manager, by the **end of the first week of the subsequent month**. A template of a reporting form for this purpose is provided at Appendix VIII — Monthly Summary Report.

5.3 Documentation of Quality Control Results

Testing sites are required to document the results of all quality control tests performed, including:

- The type of quality control material (e.g., negative, HIV-1 positive, HIV-2 positive)
- Quality control lot number and expiry date on vial
- POC HIV test lot number (on the box of 24 test kits)
- POC HIV test result (reactive, non-reactive, invalid, indeterminate)

This documentation should be maintained in a central place and reviewed monthly by the POC Site Lead to ensure that quality control testing is performed at the recommended frequency (see 3.0 above).

Quality control testing can be documented directly on a testing log (for example, see the Daily Log of Client POC Test Results template in Appendix IV). Alternately, a separate Quality Control Log can be maintained (template provided in Appendix IX).

5.4 Incident Reporting

Any staff identifying an incident involving POC HIV testing at a testing site should report the incident to the POC Site Lead and according to local practice standards. The purpose of incident reporting is to be able to monitor and document unexpected or unintended outcomes so that a problem can be identified and corrected before client results are affected.

Examples of incidents include:
- Unexpected results using quality control samples
- Inaccurate interpretation of POC HIV test results
- Temperature where test kits stored is higher or lower than requirements
- Use of expired test kits, or expired quality control materials

Testing sites may have established methods for incident reporting that can be used in these situations. Alternately, an incident log can be maintained to document all POC HIV test-related incidents, which can be periodically reviewed by the POC Site Lead (see template in Appendix X). The POC Site Lead may determine that additional support and training may be required, and are recommended to contact the Provincial POC HIV Testing Program Manager in this regard.

6.0 PURCHASING AND INVENTORY CONTROL

6.1 INSTI™ HIV Test Kits

Under the Provincial POC HIV Testing Program, the Provincial Program Manager arranges for the purchase of the requested volume of POC HIV test kits for participating Health Authorities and First Nations Health Agencies in B.C. These POC HIV test kits are provided free of charge and orders are placed on a quarterly basis up to a set allotment. Through the Provincial POC HIV Testing Program, test kits are ordered in boxes of 24 (i.e., supplies to conduct 24 POC HIV tests). Individually packaged POC HIV test kits are not purchased through the provincial program.

Health Authorities and First Nations Health Agencies who require more POC HIV test kits than their allotment will be required to purchase these test kits independently. All questions regarding ordering POC HIV test kits can be directed to the Provincial POC HIV Testing Program Manager.

6.2 Quality Control Materials and Other Supplies

Quality control samples and related supplies are provided free of charge by and ordered through the Provincial POC HIV Testing Program Manager as required by each participating Health Authority and First Nations Health Agency. Other testing supplies such as extra lancets, quality control storage materials and temperature monitors can also be ordered through the Provincial POC HIV Testing Program Manager.

6.3 Inventory Control

POC HIV test kits are shipped to participating sites designated by the Health Authority or First Nations Health Agency. It is the responsibility of each Health Authority or First Nations Health Agency to reconcile the number of test kits received against the number of tests performed.

When test kits and quality control samples are received, it is recommended that each site notify the Provincial POC HIV Testing Program Manager of the following:

- Number of POC HIV tests or quality control samples received.
- Lot number and expiry dates of test kits and quality control samples.
- ***Note****: POC HIV Kits come in boxes of 24 and each has a lot number and expiry date on the outside of the box. While the separate components of the test kits each have their own lot numbers, only the lot number and expiry date on the outside of the box needs to be recorded.*
- Status of supplies (i.e. any damage).

Unsuitable supplies include those that are expired, improperly stored, or damaged. Contact the Provincial POC HIV Testing Program Manager to request pick-up/return/disposal of unsuitable supplies. Please refer to the Returning Unsuitable Supplies table in section 6.4.

6.4 Returning Unsuitable Supplies

Determine the supply destination according to the table below.

If supply involves:	**Action:**
Expired INSTI™ HIV Test kits or quality control samples	• Notify the Provincial POC HIV Testing Program Manager with number and consult to prevent recurrence. ***Note:*** *Kits can be transferred to a high use location prior to expiry through the Provincial POC HIV Testing Program Manager.*
Improperly stored INSTI™ HIV test kit or quality control samples	• Quarantine the materials at the correct storage temperature while investigation is underway. • Report incident to the POC Site Lead and Provincial POC HIV Testing Program Manager. • Consider additional staff training or competency assessment.
Defective materials in kits or quality control samples	• Report incident to the POC Site Lead and the Provincial POC HIV Testing Program Manager. • Save the original material(s) in the event it needs to be sent to the Provincial POC HIV Testing Program Manager.

Improperly shipped/received or damaged materials	• Report incident to POC Site Lead. • Contact the Provincial POC HIV Testing Program Manager for instructions on how to proceed.
Recalled INSTI™ HIV Test kits or quality control samples	• Quarantine affected supplies. • Report incident to POC Site Lead and Provincial POC HIV Testing Program Manager. • Complete recall form and fax to Provincial POC HIV Testing Program Manager. • Follow Provincial POC HIV Testing Program instructions for return or disposal.

6.5 Monitoring Storage Temperature of INSTI™ HIV Test Kits

Temperature monitoring is required to ensure that the INSTI™ HIV Test kits are stored between 15 °C and 30°C. A temperature monitor that measures maximum and minimum temperatures over a given period of time should be stored with the POC HIV test kits, and a temperature monitoring log should be maintained (a sample temperature monitoring log is provided in Appendix XI).

If the temperature monitor indicates that the ambient temperature has increased or decreased outside of the specified range, test kits should be moved to an alternate location for storage and the POC Site Lead should be notified. If test kits have been kept outside of the recommended temperature range (15 – 30°C) overnight or for extended periods in unmonitored locations/spaces, it is recommended that kits be quarantined, moved to a temperature monitored area, quality control samples used and the incident reported to the POC Site Lead. After using the quality controls and receiving valid results, the kits may be used for client testing.

7.0 OUTREACH AND MOBILE SITES

The quality assurance recommendations in this section (i.e., use of quality control samples, training, documentation) apply equally to outreach and mobile sites. For these sites, the following should be considered.

7.1 Transporting / Storing Supplies

Quality assurance requirements must be maintained wherever kits are stored (e.g., temperature monitoring). Kits should not be stored overnight or for extended periods in unmonitored locations/spaces (e.g., vehicles).

7.2 Testing Space

A flat level surface must be available for testing staff to conduct the test on to avoid spillage (i.e., flat, level surface such as a carrying case and clipboard). The surface must be able to be decontaminated with a bleach solution or alternative method of maintaining a clean work surface that is not capable of transmitting infectious substances.

7.3 Waste Disposal

Mobile sites must have biohazard waste disposal capability (i.e., biohazard waste or sharps containers).

7.5 Venipuncture Capability

Outreach and mobile sites should either:

a) be equipped and staffed to provide clients with venipuncture to obtain a sample for standard HIV laboratory testing if the POC HIV result is reactive, indeterminate or invalid, and/or if the client may have acute or early HIV infection.

b) establish a procedure to ensure that a venipuncture sample is collected (e.g., accompany clients to a nearby laboratory with a completed requisition for HIV testing).

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APPENDICES

APPENDIX I — Summary of Test Properties

<table>
<tr><td colspan="2">INSTI™ HIV-1 / HIV-2 Antibody Test Kit
Supplier: bioLytical Laboratories Inc.
License Issue Date (Class IV Medical Device): October 25, 2005</td></tr>
<tr><td colspan="2">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</td></tr>
<tr><td colspan="2">SPECIMEN TYPE:
Fingerstick blood, EDTA-treated whole blood or plasma, serum.</td></tr>
<tr><td colspan="2">VALIDATION FOR USE:
Validated for HIV-1, HIV-2 antibodies. Not validated for detection of antibodies to HIV-1 Group O or N subtypes.</td></tr>
<tr><td colspan="2">TEST PERFORMANCE:</td></tr>
<tr><td>Sensitivity
Specificity</td><td>Fingerstick whole blood ♥ :
Sensitivity 99.6% [95% CI 98.9-99.9%],
Specificity 99.7% [95% CI 99.4-99.8%]</td></tr>
<tr><td>Positive Predictive Value (PPV)</td><td>Fingerstick whole blood: PPV varies according to HIV prevalence.
<table><tr><th>HIV Prevalence</th><th></th><th>PPV</th></tr><tr><td>0.1%</td><td>(1 in 1000)</td><td>12.5%</td></tr><tr><td>0.2%</td><td>(1 in 500)</td><td>22.2%</td></tr><tr><td>1.0%</td><td>(1 in 100)</td><td>58.9%</td></tr><tr><td>10.0%</td><td>(1 in 10)</td><td>94.0%</td></tr></table></td></tr>
<tr><td>Low Antibody Titer</td><td>Performance equivalent to standard HIV testing protocols using commercial low titer performance panels.</td></tr>
<tr><td>Window period</td><td>When compared to standard HIV testing 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%].</td></tr>
<tr><td colspan="2">PRECAUTIONS:
False negative or invalid test results may be obtained in patients with severe hypogammaglobulinemia conditions (e.g., multiple myeloma), patients receiving HAART, and patients with elevated hemoglobin.</td></tr>
<tr><td colspan="2">STORAGE:
Storage temperature 15-30 °C, shelf-life 12 months.</td></tr>
<tr><td colspan="2">EXTERNAL QUALITY CONTROL:
In place (August 2007)</td></tr>
</table>

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

APPENDIX II — Roles and Responsibilities

This section of the guidelines summarizes the roles and responsibilities of the Tester, the Health Authority/Site, the BCCDC Provincial POC Program and service providers such as bioLytical and the proficiency testing service provider. Collaboration of all of these groups is critical to the success of a POC HIV testing program. The BCCDC Provincial Point of Care Testing program has created the Point of Care Guidelines for Health Care Settings; sites/Health Authorities are responsible for adapting and implementing these guidelines to their specific needs and operational policies/procedures.

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Industry Provider: bioLytical (manufacturer of INSTI test kit)
Testing Process	• Provide pre and post discussions, including informed consent, to clients according to established process and procedures. • Perform client testing and interpret results according to established procedures. • Deliver test results to client according to established procedures. • Obtain venous blood sample for confirmatory testing as applicable and arrange for follow up with client regarding confirmatory test results. • Record usage and results of each test kit on client testing log used at site (including those used for quality controls, wasted, training etc.) • Follow site policies regarding confidentiality of records. • Report concerns/problems with the test kit performance to POC site lead and provincial program manager as	• Allocate sufficient clinic, material and human resources to implement, operate, review and maintain the use of POC HIV testing within each site. • Ensure necessary equipment available for testing (i.e. gloves, sharps containers, Band-Aids). • Report all reactive results to Medical Health Officer according to established regional procedures for communicable disease reporting. • Collaborate with testers to ensure appropriate implementation of POC HIV testing. • Report concerns/problems with the test kit performance to provincial POC HIV	• Prepare, maintain and report budget status and requirements to the appropriate committees and management teams. • Provide monthly summaries of POC test kit usage by Health Authority and provincially to the appropriate committees and management teams. • Provide data regarding test kit usage to Health Authority/Site as requested. • Provide support to sites performing POC HIV testing including training, procurement, distribution and trouble shooting. • Follow up with sites on abnormal results (i.e. invalid, indeterminate, false negative, false positive). • Report concerns/problems with the test kit performance to appropriate BCCDC managers and to bioLytical.	• Provide advice regarding usage and specifications of test kit. • Follow up on concerns/problems related to test kit performance and provide direction on the use of kits.

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Industry Provider: bioLytical (manufacturer of INSTI test kit)
	applicable. • Participate in the evaluation of the POC HIV testing program.	testing program manager. • Participate in the evaluation of the POC HIV testing program.	• Collaborate with testers, Health Authority/site to ensure optimal implementation of POC HIV testing at site, health authority and provincial levels. • Disseminate product information and feedback to Health Authorities/Sites if concerns have been raised and subsequently addressed by bioLytical. • Evaluate the POC HIV testing program and report findings from the evaluation to the appropriate committees and management teams.	

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Service Provider: bioLytical (manufacturer of INSTI test kit)
Training • **Competency** • **Continuing education/ refresher training**	• Participate in POC as well as HIV pre and post test discussion training programs. • Successfully complete competency assessment before testing clients in collaboration with POC site lead. • Participate in periodic refresher training and continuing education.	• Schedule staff training in collaboration with provincial program. • Verify that trained staff members have successfully completed competency assessment before testing clients. • Retain training and competency records for all staff (tracked, filed and retained for 10 years). • Schedule periodic refresher training and continuing education for testers.	• Develop training materials such as presentations, checklists etc. • Coordinate, participate and deliver content for training as requested by and in collaboration with Health Authorities/sites. • Develop continuing education materials and coordinate continuing education sessions in collaboration with Health Authority/Site as needed.	• Participate in initial training as available. • Provide competency assessment panels as requested and as available.

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Service Provider: bioLytical (manufacturer of INSTI quality control samples)
Quality Control Samples	• Store and use quality control samples according to manufacturer's instructions. • Use quality control samples as per provincial program guidelines: o on each new test kit lot o when test kits are received o monthly o as needed for training purposes • Record quality control sample results and notify POC site lead of any unexpected results. • Contact POC site lead/provincial program manager if quality control samples fail to give the result expected.	• Order quality control samples through the provincial POC HIV testing program. • Assume responsibility for integrity of quality control samples in health authority/site. • Ensure quality control samples are stored as per manufacturer's instructions and contact provincial POC HIV testing program manager if there is a concern with storage. • Review POC HIV test kit usage log sheets and take corrective action as required. • Contact provincial POC HIV testing program in the event of a problem with quality control samples.	• Purchase quality control samples for sites. • Provide guidance around the use of quality control samples and training. • Act as a resource for quality control sample problems/concerns. • Contact the manufacturer as needed.	• Manufacture and ship quality control samples. • Respond to any issues related to quality control samples.

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Service Provider: bioLytical (manufacturer of INSTI test kit)
Inventory	• Track test kit usage on daily log of client POC test results. • Report when kit inventory is low or close to expiration date to POC site lead. • Store test kits and materials as indicated in provincial guidelines.	• Collaborate with provincial POC HIV testing program manager to order test kits and required supply inventory. • Assume responsibility for test kits at site/in health authority. • Forward testing Monthly Summary Report (see Appendix IX) to provincial POC HIV testing program manager. • Participate in kit redistribution to optimize utilization and eliminate wastage in such instances as kits being near expiration date.	• Initiate renewal of contract with kit vendor. • Order test kits on behalf of sites and organize distribution and delivery. • Verify Certificate of Analysis for each lot number received. • Retain the original *Certificate of Analysis* for each kit lot number and provide a copy to testing sites on request. • Order and distribute supplies such as quality controls, extra lancets, pipets and temperature monitors. • Disseminate information regarding inventory changes to sites in a timely manner. • Coordinate redistribution of limited date kits in collaboration with Health Authorities/sites to enhance utilization.	• Inform the POC HIV Program Manager of any product updates or changes related to test kits, quality controls samples or other associated testing materials in a timely manner. • Supply test kits and quality control samples with the maximum expiry date possible. • Provide the Certificate of Analysis for each kit lot with each shipment

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Service Provider: bioLytical (manufacturer of INSTI test kit)
Storage of INSTI Test Kits	• Complete daily temperature logs for all areas where test kits are stored, and notify POC site lead of any temperature outside the accepted range.	• Ensure temperature logs are maintained regularly for all areas where test kits are stored and take corrective action as required. • Assume responsibility for storage of test kit materials and supplies.	• Provide sites with temperature monitors as needed or recalibrate existing monitors as scheduled.	
Documentation and Reference Material	• Complete all documentation as outlined in the provincial program guidelines. • Use most recent version of provincial program guidelines and manufacturer's instructions. • Provide feedback to provincial program on suggestions for new documents, or revisions of current documents.	• Maintain all documentation as required. • Ensure the most recent version of provincial program guidelines and manufacturer's instructions are being used by testers.	• Liaise with testers and Health Authority/Site supervisors to update documents and reference materials as required.	• Notify provincial program manager regarding changes to product documents.

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Service Provider: bioLytical (manufacturer of INSTI test kit)
Risk Management	• Report abnormal/unexpected outcomes to the POC site lead.	• Retain and store clients log sheets in case of need to communicate problem with test kit to clients. • Investigate unexpected outcomes, record actions and ensure implementation of corrective actions. • Report abnormal/unexpected results to the provincial POC HIV testing program.	• Discuss abnormal/unexpected results with Health Authority/site supervisors. • Report to advisory and steering committees as required. • Relay information on changes or problems with test kits to all sites as applicable. • Report abnormal/unexpected results to appropriate BCCDC management and to bioLytical as applicable.	• Respond to any concerns regarding kit performance and provides guidance as to how to proceed.
Recall Process	• Respond to recall alert messages from Provincial Program. • Review current stock for recalled product. • Quarantine recalled product and follow instructions from Site Lead and contact Provincial Program Manager regarding outcomes. • Re-test clients as recommended by Provincial Program Manager.	• Ensure recalled product has been identified and quarantined for all sites • Communicate with sites, Provincial Program Manager and bioLytical throughout entire process. • Lead process for client retesting as necessary. • Retain all documents related to the recall event	• Facilitate communication between POC Site Leads/sites and bioLytical. • Determine if client retest is needed and facilitate process as needed	• Initiate recall process. • Liaise with Provincial Program Manager throughout the recall process. • Provide clear instructions of expectations to Provincial Program and sites.

Activity	Tester	Site (Health Authority)* **Items included in this column may be the responsibility of the Health Authority or site and is to be determined at a regional level.**	Provincial Program	Service Provider: Proficiency Testing provider	Service Provider: bioLytical (manufacturer of INSTI test kit)
Proficiency Testing	• Participate in proficiency testing as requested.	• Work with provincial program manager to enroll sites in proficiency testing program. • Schedule staff participation in proficiency testing events. • Review proficiency testing results with staff, and follow up concerns accordingly. • Maintain proficiency testing records.	• Initiate and manage contract with proficiency testing provider on behalf of the sites. • Act as the contact for sites if concerns or questions arise. • Analyze provincial proficiency testing data results in aggregate form and report on results as part of the Provincial POC HIV Testing program evaluation. • Offer support/assistance (i.e. training) for those sites that discover errors as a result of their participation in the proficiency testing program.	• Manufacture and distribute the proficiency testing materials to sites. • Respond to issues regarding shipments or testing schedule. • Analyze data from all participating sites. • Create and distribute reports to participating sites.	• Respond to any proficiency testing issues related to kit performance.

APPENDIX III — Daily Log of Client POC Test Results

Testing site: _____ **POC Test Lot Number (on Box):** _____
Reviewer's signature: _____ **Expiry Date (on Box):** _____

Date of Test *dd/mm/yyyy*	**Tester Initials**	**Client Identifier 1*** *(ie Name, Chart Number, DOB)*	**Client Identifier 2***	**POC Test Result** *Reactive Non-reactive Invalid Indeterminate*	**HIV Serology Collected or Requested** *(Yes, No)*	**HIV Serology Result** *Reactive Non-reactive Indeterminate Not Done*	**Reactive POC Test Final Result** *PP – Prelim Pos^ FP – False Pos TP – True Pos*	**Notes / Comments** *(# of test kits left)*

* A minimum of two client identifiers is recommended for accuracy of client information.
^ In this context, Preliminary Positive refers to individuals having a reactive POC test result but are lost to follow-up and serology is not performed.

APPENDIX IV — Fax Template Form

INSERT your LOGO FAX

STAT HIV POC Confirmatory Testing is Required

Please complete this form and FAX it to the BBCDC HIV Testing Lab when samples are ready to be sent (or when information is known) so that the lab is aware that samples are to be arriving for confirmatory HIV testing. The lab can follow up with the testing site if the samples do not arrive when expected, and the samples will be given priority when they arrive in the lab.

Please see attached requisition with client information.

DATE			
TO	BCCDC HIV Testing Lab	**FAX**	(1) 604-707-2407
FROM		**FAX**	
PHSA Client # (if applicable)			
THIS IS PAGE 1 OF ___ (if any pages are missing, please call _____)			

Transport Details:

Transport Mode:	Drop off ☐ Bus ☐ Other ☐ Identify: Taxi ☐ Air ☐ Local Courier ☐
Transport Courier:	
Flight Number: (if applicable)	
Date of Shipment:	
Expected Date/Time of Delivery	
Waybill Number:	

Site Contact Information for Results:

Name:		Email:	
Phone:	Secure FAX:	— — None ☐	
Best Day to contact Is:	☐Monday to Friday OR	Specify Day:	
Best Time is: ☐ AM ☐ PM	OR	Specify Time:	

Does client have a previous positive HIV test result? ☐ No ☐ Yes

Comments:	

APPENDIX V — Direct Observation Checklist for POC HIV Testing

Test Provider: _____ Observer: _____

Did the test provider:		**YES**	**NO**
1.	Check to ensure Quality Control has been performed according to requirements prior to testing the client sample?		
2.	Obtain informed consent for the test?		
3.	Offer standard laboratory HIV testing or POC testing to the client?		
4.	Record the client and test information on the testing log sheet?		
5.	Record or check the lot number and expiry date of the test kit?		
6.	Provide a clean area on which to perform testing?		
7.	Wash/sanitize hands prior to starting the testing process?		
8.	Remove the membrane from the pouch without touching the centre well?		
9.	Wear gloves to perform the test?		
10.	Wipe client's selected finger thoroughly with alcohol swab prior to puncture?		
11.	Dispose of the used lancet directly into a sharps container?		
12.	Fill the pipette to the fill line to obtain the required amount of blood?		
13.	Transfer the blood in the pipette into the solution 1 vial by squeezing the bulb of the pipette to dispense the blood into the vial?		
14.	Dispose of the used pipette directly into a biohazard waste container?		
15.	Mix the blood in solution 1 vial by gentle inversion?		
16.	Test the sample within 5 minutes of mixing blood with solution 1?		
17.	Mix solution 2 by gently turning it upside down and ensuring contents mixed?		
18.	Add the entire contents of solution 2 to the centre of the membrane unit and allow time to absorb?		
19.	Add the entire contents of solution 3 to the centre of the membrane unit and allow time to absorb?		

20.	Read the result within 5 minutes of adding the clarifying solution (solution 3)?		
21.	Remove and dispose of gloves into biohazard waste container?		
22.	Record the result on the testing log sheet?		
23.	Discuss and advise testing for HIV using venous blood collection for clients who tested negative with POC test but may be in the window period?		
24.	Draw venous blood when POC test was reactive, invalid (a second time), indeterminate or if an acute HIV infection is suspected?		
25.	Label the venous blood in the presence of the client with all required identifiers?		
26.	Complete the laboratory requisition as required?		
27.	Provide client an opportunity to express degree of satisfaction with the testing process (via web link card or printed survey)?		

Number of test kits used under observation: _____

Observer: _____ Date: _____

Follow-up issues identified? YES _____ NO _____

Comments:

_____

_____

_____

Review of direct observation by trainer/assessor

The test provider has demonstrated competence YES _____ NO _____

Observer: _____ Date: _____

Note that it is recommended that POC HIV Testing competencies are reviewed once per year.

APPENDIX VI — Training Completion Requirements

The following completion requirements specifically pertain to the use of the POC HIV test. It is expected that learners attending POC training have knowledge of the following prerequisites:

- HIV Pre- and Post-Test discussions
- Legal and professional requirements and practice standards for obtaining informed consent
- Legal and professional requirements and practice standards for maintaining confidentiality

To successfully complete the POC HIV testing training, the learner must attend a two- to three-hour POC testing workshop and at completion of the training workshop independently demonstrate at minimum the following competencies:

POC HIV Testing Initial Testing and Quality Assurance Training — Competencies	Trainer Initials
1. Demonstrate the appropriate use and interpretation of the POC HIV test.	
2. Demonstrate the procedures for using quality control samples.	
3. Demonstrate a client-centered approach when obtaining informed consent, for maintaining confidentiality, and when providing client education.	
4. Demonstrate a client-centered approach when interpreting and providing the POC test result and when discussing next steps and follow-up.	
5. Demonstrate how and when to report POC test results.	
6. Describe potential errors and measures to reduce errors related to use of the POC test kit and quality control materials.	
7. Describe follow-up and referral process for confirmed HIV positive standard lab tests.	

By signing below, the learner and trainer are declaring that the learner has competently, ethically, and safely demonstrated the above completion requirements. It is recommended that POC HIV Testing competencies are reviewed once per year.

Learner Name: _____ Learner Signature: _____

Trainer Name: _____ Trainer Signature: _____

Date: _____

Completed form to be retained by the POC Site Lead.

APPENDIX VII — Training Competencies

Core POC HIV Test Provider Competencies			
Knowledge of:	**Skill in:**	**Judgment regarding:**	**Attitude that:**
• legislation, confidentiality, and informed consent related to HIV testing • HIV infection and window period and the impact on testing • HIV diagnostic tests and appropriate use • how to implement and sustain quality assurance activities • education and communication techniques • documentation and reporting requirements	• obtaining informed consent • describing the diagnostic test options available • using POC test kit and running quality controls • collecting POC test sample • interpreting test results and providing appropriate follow-up and determining next steps based on results • collecting or referral for collection of venous sample • providing appropriate client education • collecting and documenting data for surveillance, reporting, and case management	• choosing the appropriate HIV diagnostic product (i.e. standard or POC testing) • client follow-up and referral based on HIV test results • referring clients to appropriate services (i.e. treatment, counseling)	• respects client's choices and beliefs • demonstrates self awareness of own beliefs, values, and practice limitations • demonstrates sensitivity regarding impact of HIV diagnosis, reporting, and partner notification • respects and supports the adherence to quality assurance activities

APPENDIX VIII — Quality Control Log

Testing site: _____

Date of Quality Control *dd/mm/yyyy*	**Tester Initials**	**Quality Control Material** *(Negative, Positive HIV-1 Positive HIV-2)*	**Quality Control Lot Number** *(On Vial)*	**POC Test Lot Number** *(On Box)*	**POC Test Result** *Reactive Non-reactive Invalid Indeterminate*	**POC Test performs as expected** *(Yes, No)*	**Notes / Comments**	**Supervisor Initial**

APPENDIX IX — Monthly Summary Report

Testing Site: _____ Reporting period: _____ to _____

A. INVENTORY TRACKING:

Number of POC HIV test kits in inventory at start of period	
Number of POC HIV test kits in inventory at end of period	
Expiry date of Kits: *If multiple expiry dates please specify number of kits due to expire at each date*	
Number of POC HIV test kits removed from inventory during period and transferred to another testing site *Name of other testing site:*	

B. USE OF POC HIV TESTS FOR DIAGNOSTIC TESTING:

Number of clients with:

1. Non-reactive POC HIV test results		
2. Reactive POC HIV test results		
a. Preliminary positive *(serology not performed)*		
b. True positive *(serology performed & reactive)*		
c. False positive *(serology performed & non-reactive)*		
3. Invalid POC HIV test results		
4. Indeterminate POC HIV test results		

C. USE OF POC HIV TESTS FOR OTHER REASONS:

Number of test kits used for quality control testing	
Number of test kits used for training and/or proficiency testing	

D. DISPOSAL OF POC HIV TEST KITS:

Number of test kits wasted *Please explain:*	
Number of test kits expired and discarded	

Report completed by: _____

Fax Report to Provincial POC HIV Testing Program Manager: (604) 707-5604

APPENDIX X — Incident Summary Form

Site: _____

							To be completed by Supervisor		
Date, Time	**Description of Incident**	**Type**	**Immediate Actions Taken**	**Date and time reported**	**Reported to**	**Reported by**	**Follow-Up Actions**	**Root Cause Required ?**	**Supervisory Review**

Occurrence Types:

QC: QC failure
QA: QA non conformance
TP: Test kit or procedure
O: Other (specify)
CT: Complaint
PF: Process failure
NC: Policy not followed
DF: Documentation failure

APPENDIX XI — Temperature Monitoring Log

Room Temperature Log for INSTI Kit Storage

Site: _____ **Month:** _____ **Year:** _____

Notify POC Site Lead when temperature is:
less than 15 ^{0}C more than 30 ^{0}C

Day	Time	# Kits	Monitor Record					
	hh:mm		Temp ^{0}C	Minimum	Maximum	Acceptable? Yes/No	Initials	Not Acceptable? Actions
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								
25								
26								
27								
28								
29								
30								
31								

Reviewed by: _____ **Review Date:** _____

Comments: