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## **SECTION 1: 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 for antibodies for HIV which can be performed on-site while the client waits, and provide results within minutes. 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 VIII – 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 requirements 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 currently being finalized, and will be located in Chapter 5 of the Communicable Disease Control Manual at [www.bccdc.ca](http://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

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 are common objectives among HIV-related strategies in B.C.

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 discussion 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 negative result is considered final (unless the person is tested early during the phase of acute infection and is in the window period), false positive results can occur. False positive results are more likely in a setting with a low prevalence of HIV (e.g., a setting where the risk of HIV infection is low).
- With standard HIV testing, confirmatory testing immediately follows positive screening tests and the result returned to the patient is final. With a positive POC HIV test, the result is conveyed to the client as a preliminary result, and collection of a blood specimen 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 positive; however, if the test is negative, a follow-up visit is not required (if the client is outside of the window period).
- An individual with a negative 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.
- 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 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 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 will be elaborated upon in subsequent sections of this manual:

- 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 in delivering HIV pre- and post-test discussions and trained how to use POC test kits.



- Capacity exists to provide additional support to individuals at the time of a preliminary positive POC HIV test and to facilitate standard confirmatory HIV testing.
- Clients are encouraged to test for other infections as appropriate (e.g., HCV, syphilis).
- Testing staff have knowledge of local care pathways and community resources available to individuals who test positive for HIV.
- Recommended quality assurance measures are in place (e.g., staff training, documentation and monitoring of test outcome, use of quality control test kits).
- Preliminary positive POC test results are reported to the local Medical Health Officer.
- Where feasible, clients presenting for HIV testing should be offered a choice of standard or POC HIV testing.

## 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 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 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.<sup>i</sup>

#### 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.<sup>ii</sup>

#### 9.1.3 Clinical diagnosis of acutely ill patients

<sup>i</sup> 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](http://www.bcwomens.ca/Services/HealthServices/OakTreeClinic/default.htm))

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



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 Voluntary HIV Testing Settings

The use of POC HIV testing is most indicated in settings where clients are expected to have a higher prevalence of undiagnosed HIV. 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. Examples of such settings include primary care clinics or outreach programs accessed by high prevalence populations. This is particularly of benefit for the two scenarios described below.

### 9.2.1 Settings accessed by high prevalence populations where not returning for test results is common among clients 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. Examples include clinics or outreach programs accessed by street-involved persons, or some sexually transmitted infection clinics.

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

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. Examples include emergency rooms, inpatient wards, corrections facilities, and detoxification centres.

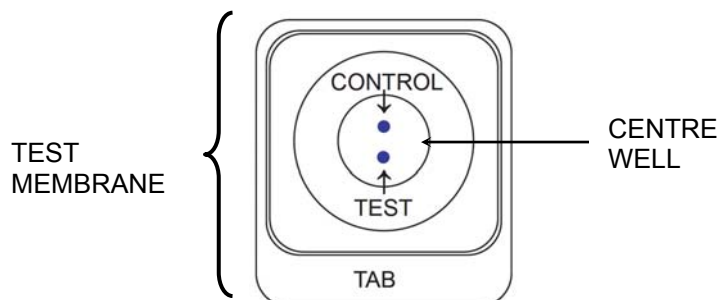
## SECTION II: PERFORMING THE TEST

### 1.0 KEY INFORMATION ABOUT POC HIV TESTING

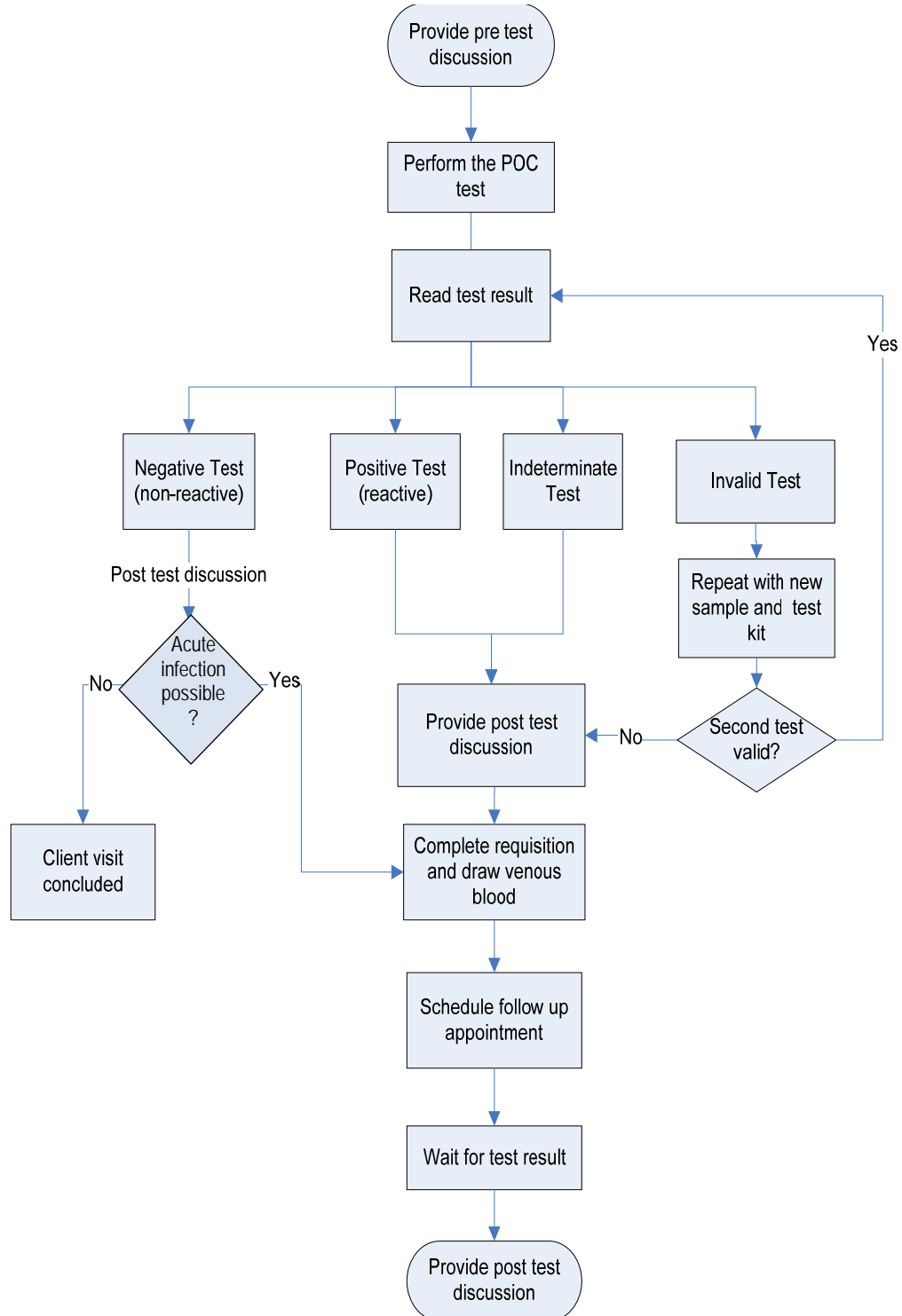
- The **INSTI™ HIV-1/HIV-2 Antibody Test** is used to perform the initial screening for HIV antibodies in whole blood.
- POC HIV testing is confidential, accompanied by pre- and post-test discussions, and conducted with informed consent. Guidelines for pre- and post-test discussions to accompany POC HIV testing are currently being finalized and will be located in Chapter 5 of the Communicable Disease Manual ([www.bccdc.ca](http://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 for confirmatory testing by standard HIV testing. All preliminary positive results should be reported to the local Medical Health Officer.
- 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 quality assurance supervisor 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 quality assurance supervisor, distributor and the Provincial POC HIV Testing Program Manager.
- 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 Testing Visit





### 2.3 Procedure for conducting the test

Prior to conducting the POC HIV test, ensure that the POC HIV test kits have not expired, and that quality control testing has been performed.

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 (supplied in a single use pouch or box of 24), 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.
  - Biohazardous 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 (keeping 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.
10. Wipe selected warmed finger thoroughly with alcohol swab and position hand at waist level or lower. Allow alcohol to dry before proceeding.
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 against the finger.
13. Dispose the lancet directly into a sharps container.
14. Obtain the pipette, hold it horizontally and touch the tip of the blood drop to the tip of the pipette. **Note:** *The pipette will fill by capillary action; do not squeeze the pipette during filling.*
15. Fill the pipette to the fill line to obtain the required amount. **Note:** *It is critical 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 elevate the hand.
17. Transfer the blood in the pipette into the sample diluent (Solution 1) vial by squeezing the bulb of the pipette to dispense the blood into the vial. **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.*
18. Dispose the pipette in a biohazardous waste container.
19. Recap the vial (Solution 1), mix by turning upside down a few times. **Note:** *Do not shake vigorously. The sample must be tested within 5 minutes of mixing blood with Solution 1.*
20. Carefully pour the entire contents of the Solution 1 vial into the membrane well. **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.
25. Read the result immediately and record the result. **Note:** *If more than 5 minutes have passed since adding the clarifying solution the result is invalid.*
26. Discard the test membrane in a biohazardous 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 1.0 (Key Information about POC HIV Testing) for interpreting the test. See also step 5 below.
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 13.
4. Record test result.

#### 3.2 Notes and limitations

- There is no correlation between the intensity of the blue colour control dot and the test result. The control dot can be a lot darker or lighter than the client or 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 this may 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 negative test result. Clients who may be more likely to be in the acute phase of HIV infection (i.e., have high likelihood of HIV infection) can be recommended to have blood drawn for standard HIV testing at the same visit.
- A test that is performed incorrectly or conducted using a defective device or insufficient sample will give an **invalid** result. If the second POC HIV test performed is also invalid, the quality assurance supervisor should be notified.
- False 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.

### 3.3 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 tests – and follow-up all indeterminate and invalid POC HIV tests – with standard laboratory HIV 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).

#### 4.1 Procedure

1. Obtain and complete a laboratory requisition according to established procedure, indicating whether HIV testing is nominal or non-nominal.
2. Note on the comment section of the requisition that a POC HIV test was performed and the result (e.g., “POC reactive/non-reactive/invalid/indeterminate”).  
**Note:** *This information will facilitate tracking of test results and may assist PHSA Laboratory in determining appropriate the standard HIV tests to perform.*
3. Draw the appropriate sample (1 gold top and 1 EDTA top). See applicable laboratory guide to services.



4. Send to testing laboratory according to established processes.
5. When the result of standard laboratory HIV testing is received, document the result in the client chart and the Daily Log of Test Results. For clients with an initial reactive POC HIV test result, document the final POC HIV test result as **true positive** (TP, if standard HIV test confirms HIV infection) or **false positive** (FP, if standard HIV test does not confirm HIV infection).


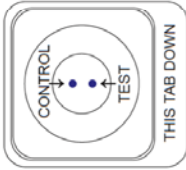
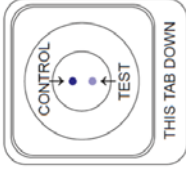

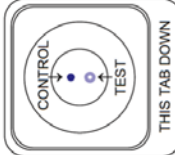



#### 4.2 Ruling out acute HIV infection

Some clients may be more likely to have 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 specimen for standard HIV testing. Standard HIV laboratory screening tests are more sensitive than the INSTI™ HIV Test, due to window period differences.

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.



**TABLE: INTERPRETATION OF TEST RESULTS**

<p><b>If the membrane reveals:</b>            Only one blue dot that is clearly visible at the top end farthest from the plastic tab.</p> 	<p><b>The test result is:</b>  <b>Non-reactive (Negative)</b>            No antibodies to HIV-1/HIV-2 were detected in the sample.</p>	<p><b>Next steps:</b>            Result is final.            If client may have acute HIV infection (e.g., symptoms or high risk), recommend standard HIV testing.</p>	
<p>Two blue dots are clearly visible. One dot may be darker than the other.</p>   	<p><b>Reactive (Preliminary positive).</b>            Must be confirmed by laboratory testing, due to chance of a false positive result.</p>	<p>A venous sample must be drawn and sent for standard HIV testing (confirmatory testing).            All preliminary positive results to be reported to local Medical Health Officer.</p>	
<p>Faint background ring appears on the test area.</p> 	<p><b>Indeterminate</b></p>	<p>A venous sample must be drawn and forwarded to lab for standard HIV testing.</p>	
<p>No dot at the top of the membrane, or only blue specks appear, or uniform tint across the membrane.</p>   	<p><b>Invalid</b></p>	<p>Repeat the test with a fresh sample using a new membrane unit, kit components, and support materials. If the second test yields an invalid result, draw a venous sample to send for standard HIV testing.</p>	

Images courtesy of BioLytical Laboratories (INSTI™ HIV-1/HIV-2 Antibody Test product monograph).



## 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 "quality assurance supervisor").

In B.C., quality assurance is a shared responsibility between staff conducting POC HIV testing, the quality assurance supervisor, the Provincial POC HIV testing program, the PHSA Laboratory, the distributor, and the POC HIV test manufacturer.

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

Providers at testing sites using POC HIV tests and QC panels may be the first to suspect issues with quality of POC HIV testing. 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 test results with quality control materials.

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

- The quality assurance supervisor
- **Dan Barnetson, Territory Manager, Somagen Diagnostics Inc.**  
Tel: 780-702-9521 or 1-800-661-9993 ext. 9521 Email: [dan.barnetson@somagen.com](mailto:dan.barnetson@somagen.com)
- **Bobbi Brownrigg, Provincial POC HIV Testing Program Manager:**  
Tel: TBD Fax: 604-707-5604 Email: [bobbi.brownrigg@bccdc.ca](mailto:bobbi.brownrigg@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 materials, 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 training sessions are held regularly by BCCDC and other health authority staff, in conjunction with bioLytical and/or Somagen representatives (for more information, contact the Provincial POC HIV Testing Program Manager).

Training for POC HIV Testing includes:

- Pre- and Post-Test HIV discussion.
- Completion of one 2–3 hour training program on the use of test kits and conducting quality assurance activities as per the POC HIV Test Guidelines.
- Demonstration of competencies (see Appendix III –Direct Observation Checklist).

Training addresses core POC HIV testing competencies for providers (please refer to the table in Appendix I —Training Competencies). At completion of the initial training, the provider should independently demonstrate at minimum the competencies described in Appendix II — Quality Assurance Training Completion Requirements.

Quarterly refresher training is recommended for staff who conduct fewer than 20 POC tests per month.

## 2.2 Schedule Existing Staff for Ongoing Competency Challenges

Each site will enroll in a proficiency testing program (using blind specimens presented with a client case history) provided by PHSA Laboratories. The purpose of the proficiency testing program is ensure that testers are using the test kits and controls properly, and to help test providers think about how they would handle cases they may not run in to on a daily basis. Proficiency testing allows comparison of the results you get on unknown samples with the results of the same samples from your peer test providers. It allows you to see "how you are doing" and provides the opportunity to correct issues before they become critical.

Proficiency testing will be conducted twice a year (approximately every 6 months) by PHSA Laboratories, and the same sample types will be sent to all testing sites. There are usually 2–3 samples to test and send back results on. The data will show if there is a problem with one site or many. A problem with many sites indicates that there may be a problem with the system, the sample material or the kits used in testing. Proficiency testing is not just a test of the ability of one person to get the right result, but it can also help identify procedural or rather an indicator of issues that may arise during testing or with testing kit quality/storage.

The Quality Systems Lead and the Provincial POC HIV Testing Program Manager will coordinate proficiency testing with site quality assurance supervisors. Any errors in proficiency will be investigated immediately and corrective action must be taken and documented. Each site will maintain proficiency testing records.



### 3.0 USING QUALITY CONTROL PANELS (QC KITS)

Quality Control Panels (QC kits) are produced by the manufacturer (bioLytical) and are used to evaluate the performance of the POC HIV test kits and to check whether the health care provider is using the test kits correctly. This testing confirms that the test system is working correctly and must be done even though each test kit has an internal control.

When conducting a quality control panel, both a positive and negative control are tested (i.e., using two POC HIV test membrane units and bulb pipettes). Ideally a different person does QC testing each day, or, at a minimum, it should not always be the same person conducting the QC testing. The person who performs quality control testing should also be performing POC HIV testing for clients.

Control panels contain vials of known HIV antibody positive and negative specimens. The panels are shipped frozen and last up to one year if they remain frozen at  $-20^{\circ}\text{C}$ . Once thawed, they last 28 days in refrigeration at  $2-8^{\circ}\text{C}$ . *Each box of controls contains 10 vials each of positive and negative controls; each vial should be sufficient to conduct to 8 tests (80 test total/ box).*

Quality control kits should be used under the following circumstances:

- By the newly trained health care provider prior to actually using the POC HIV test kit on clients.
- By the health care provider who infrequently uses the POC HIV test kits on clients.
- Whenever a new shipment of POC HIV test kits is received.
- Whenever there is a change in lot number.
- If the temperature of the storage or testing area falls outside of the manufacturer's specified temperature range.
- At periodic intervals as determined by the testing site.

Testing sites need to determine the optimal frequency for running controls based on their testing volume. How frequently each site will run quality control panels depends on the volume of point of care testing at each site and the experience of the tester. General guidelines for frequency of running quality controls are:

- If a site conducts  $> 24$  POC HIV tests per day, the controls should be run every day
- If a site conducts  $\leq 24$  POC HIV tests per day, the controls should be run approximately once per 24 specimens, but no less than once a week.
- If a site does no POC HIV tests in a given week, controls do not have to be run that week, but controls must be run prior to conducting a client test, if it has been a week or more since the last controls were run.

A site is defined as where the kits are stored with temperature monitoring and therefore, is not always determined by where testing takes place.



## 4.0 PERFORMING A QUALITY CONTROL TEST

### 4.1 Procedure

1. Remove one positive and one negative control vial from fridge and bring to room temperature. **Note:** *If control is not refrigerated, obtain new control from freezer storage if applicable. Control vial lids are color coded for ease of selection.*
2. Document the quality control test information (lot number, expiry date).
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:
  - Two INSTI™ HIV Test kits (one for each of the positive and negative controls)
  - Gloves
  - Biohazardous waste container
6. Open one pouch containing the first membrane unit, and open the Solution 1 vial (keeping the lid).
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., positive or negative) using a black or blue marking pen and place the membrane on a level surface.
9. Put on gloves. **Note:** *All control samples should be handled as if capable of transmitting infectious diseases.*
10. Unscrew the cap of the first QC sample (i.e., positive or negative control).
11. Use the pipette provided for quality control testing, hold it vertically and aspirate the withdrawn QC sample from the QC vial. **Note:** *Carefully push air out of the pipette prior to placing the tip into the vial. Fill the pipette to the neck of the bulb.*
12. 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 into the vial.
13. Discard the pipette in a biohazardous waste container.
14. Recap the vial (Solution 1), mix by inverting the vial a few times. **Note:** *The sample must be tested within 5 minutes of mixing the QC sample with solution 1.*
15. Carefully pour the entire contents of the Solution 1 vial into the membrane well. **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.*
16. Remove the cap and pour the entire contents of the vial (solution 1) into the membrane well. Wait until the solution is absorbed by the membrane (takes only a few seconds).



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.*
18. Open and add the entire contents of the color developer (solution 2) to the centre of the membrane unit. Wait until the solution is absorbed by the membrane (takes approximately 20 seconds).
19. Open and add the Clarifying solution (Solution 3 vial) to the centre of the membrane unit.
20. Read the result immediately and record the result. **Note:** *If more than 5 minutes have passed since adding the clarifying solution the result is invalid.*
21. Discard the test membrane in a biohazardous waste container.
22. Remove and discard gloves.
23. Repeat with the second quality control (i.e., positive or negative control).
24. Decontaminate the work area with an approved disinfectant.

#### **4.2 Notes on the Quality Control Test**

If reading the QC tests is more than 5 minutes since adding the clarifying solution, the result is **invalid** and the test should be repeated.

If the QC result is not as expected (i.e., the POC HIV test does not react to a positive QC test control, or reacts to a negative QC test control), the result is **invalid** and the test should be repeated. If the issue persists, the incident should be reported to the quality assurance supervisor, and the Provincial POC HIV Testing Program Manager and Distributor should be informed. **Do not test clients using that INSTI™ HIV test kit lot number until the investigation has been conducted and the issue resolved.**

#### **5.0 PROGRAM REPORTS AND DOCUMENTATION**

Managing the whole POC HIV testing process is critical to its success. Testing sites should 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 seven 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 and can be adapted for use as required.

With the exception of the monthly summary report forms, these documents do not need to be sent to the Provincial POC HIV Testing program. However, these documents may be used for periodic clinical practice audits by the quality assurance supervisor, or the Provincial POC HIV Testing Program Manager or Quality Systems Lead.



## 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 specimen for HIV serology was collected (or requisition for HIV serology given, if specimen 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.
- 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., invalid, non-reactive, reactive) 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 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 Test Results, and is also available electronically.

## 5.2 POC HIV Test Monthly Summary Reports

In order to maintain an appropriate regional and provincial supply of POC HIV testing, 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 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 designated regional POC HIV Test Coordinator, and the Provincial POC HIV Testing Program Manager, by the **end of the second week of the subsequent month**. A template of a reporting form for this purpose is provided at Appendix V — 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, positive)
- Quality control lot number
- POC HIV test lot number
- POC HIV test result

This documentation should be maintained in a central place and reviewed monthly by the quality assurance supervisor 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 Test Results template in Appendix IV). Alternately, a separate Quality Control Log can be maintained (template provided in Appendix VII).

### 5.4 Incident Reporting

Any staff identifying an incident involving POC HIV testing at a testing site should report the incident to the quality assurance supervisor 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 corrective action can be undertaken (e.g., further training). Examples of incidents include:

- Unexpected results using quality control panels
- Inaccurate interpretation of POC HIV test results
- Temperature higher or lower than requirements
- Expired kits
- Testing procedures or processes followed incorrectly

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 quality assurance supervisor (see template in Appendix VI). The quality assurance supervisor may determine that additional support and training may be required, and can 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 POC HIV Testing, Distribution, and Quality Assurance Program, the Provincial POC HIV Testing Program Manager purchases a set number of POC HIV test kits for the Health Authorities and First Nations Health Agencies in B.C. on a quarterly basis. These POC HIV test kits are provided free of charge. Reminder emails for ordering test kits will be sent to the POC HIV Testing contact for each Health Authority and First Nations Health Agencies on a quarterly basis. Through the Provincial POC HIV Testing Program, test kits are ordered in boxes of 24 (i.e., supplies to conduct 24 POC HIV tests). Individual POC HIV test kits are not purchased.

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

Quality Control materials are ordered through the Distributor (Somagen).

### 6.3 Inventory Control

The POC test kits are shipped to a central location designated by the Health Authority or First Nations Health Agency, where they are later distributed to various sites. It is the responsibility of each Health Authority to document the number of kits received against the number of tests performed.

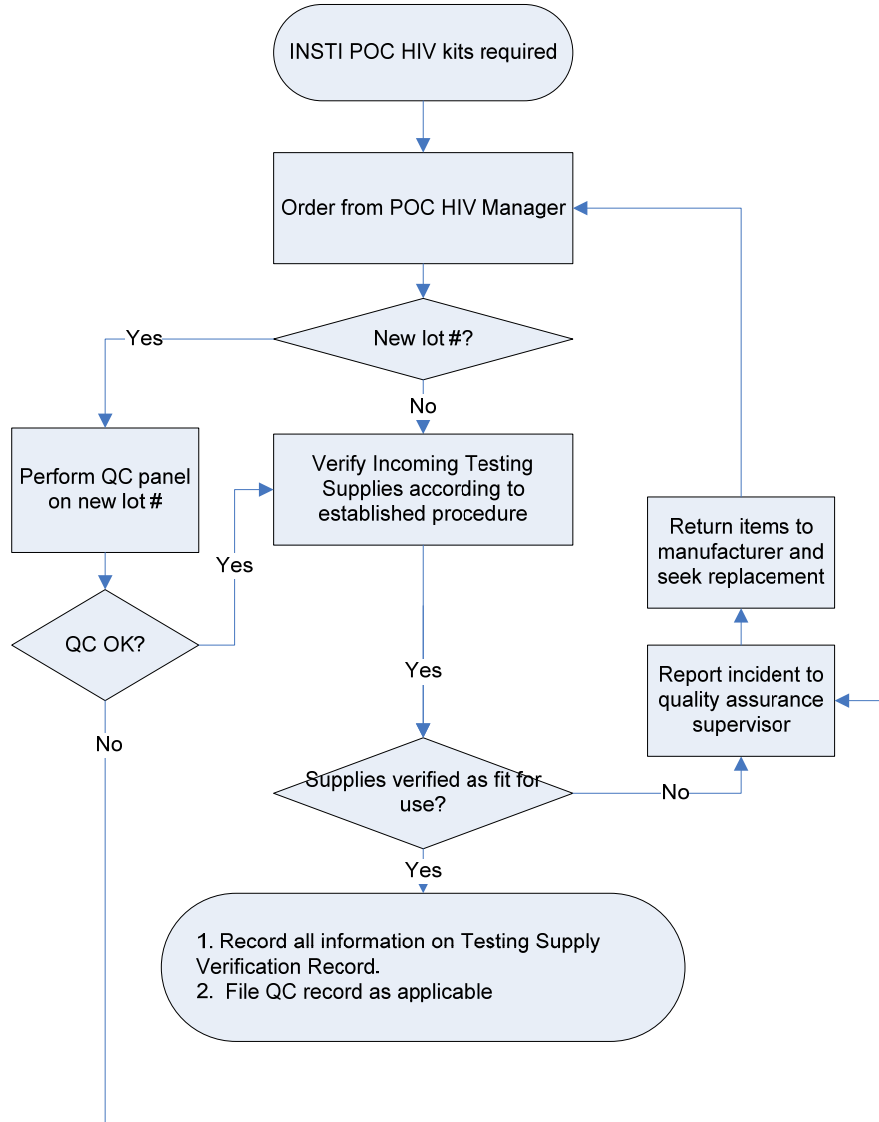
It is recommended that each site prepare an incoming verification form to receive POC test kits, which documents (a sample Testing Supply Verification Record is provided in Appendix IX):

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

Unsuitable supplies include those which are expired, improperly stored, or damaged. Please refer to the Returning Unsuitable Supplies table in section 6.5. Test kits and supplies used for quality control, training, or proficiency testing should be tallied in the Monthly Summary Report (see Appendix V). Contact Somagen, the distributor, to request collection of unsuitable supplies.

*Note: Positive and negative quality controls should be conducted on kits from each new shipment.*

**6.4 Flow diagram for Purchasing and Verification of Incoming Supplies**





## 6.5 Returning Unsuitable Supplies

Determine the supply destination according to the table below:

If supply involves:	Action:
Recalled Kits or quality control panels	<ul style="list-style-type: none"> <li>• Quarantine affected supplies.</li> <li>• Report incident to quality assurance supervisor and Provincial POC HIV Testing Program Manager.</li> <li>• Attach photocopy to the Testing Supply Verification Record (see Appendix IX).</li> <li>• Complete recall form and fax to Somagen.</li> <li>• Follow Somagen instructions for return or disposal.</li> </ul>
Expired INSTI™ HIV Test kit or QC materials	<ul style="list-style-type: none"> <li>• Can be used for new staff training or competency assessment.</li> <li>• Notify the Provincial POC HIV Testing Program Manager with number and consultation to prevent recurrence. <i><b>Note:</b> Kits can be transferred to a high use location prior to expiry through the Provincial POC HIV Testing Program Manager.</i></li> </ul>
Improperly stored INSTI™ HIV Test kit or QC materials	<ul style="list-style-type: none"> <li>• Quarantine the materials at the correct storage temperature while investigation is underway</li> <li>• Report incident to the quality assurance supervisor</li> <li>• Consider additional staff training or competency assessment.</li> </ul>
Defective materials in kits or quality control panels	<ul style="list-style-type: none"> <li>• Report incident to the quality assurance supervisor and the Provincial POC HIV Testing Program Manager.</li> <li>• Submit the original materials to the Provincial POC HIV Testing Program Manager and attach a photocopy to the Testing Supply Verification Record (see Appendix IX).</li> </ul>
Improperly shipped/received or damaged materials	<ul style="list-style-type: none"> <li>• Report incident to quality assurance supervisor.</li> <li>• Submit the original materials to the Provincial POC HIV Testing Program Manager and attach a photocopy to the Testing Supply Verification Record (see Appendix IX).</li> <li>• Contact Somagen and explain the problem</li> <li>• Follow Somagen instructions for return or disposal.</li> </ul>

## 6.6 Monitoring the Storage Temperature

Temperature monitoring is required to ensure that the INSTI™ HIV Test kits are stored between 15 and 30°C. A temperature monitor that monitors 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 X).

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 quality assurance supervisor should be notified. See 7.3 below for test verification before further use of the tests for clients. Consider using these improperly stored test kits or controls for new staff training or competency assessment.

## **7.0 OUTREACH AND MOBILE SITES**

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

### **7.1 Transporting/storing supplies**

QA 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 (i.e., 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 Control testing**

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 panels run and the incident reported to the quality assurance supervisor. After performing controls and receiving valid results, the kits may be used for client testing.

### **7.4 Waste disposal**

Mobile sites must have bio-hazardous waste disposal capability (i.e., bio-hazardous waste and sharps container, and for disposal of used test kits).

### **7.5 Venipuncture capability**

Outreach and mobile sites should 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. If this capacity is not available, each site should establish a procedure for ensuring that a venipuncture specimen is collected (e.g., accompany clients to a nearby laboratory with a completed requisition for HIV testing).



## DEFINITIONS

**Acute HIV infection:** The first 4-6 weeks after infection which 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.

**Indeterminate test result:** The test is indeterminate if a faint background ring appeared on the test area.

**Invalid test result:** An invalid or unacceptable result indicates that there is a problem either with the testing process, the control material, or the testing device.

**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. Each component of the test kit will have its own lot number. Please log only the lot number on the outside of the box for quality control purposes.

**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. Results that are negative are considered final (relative to the window period), while a positive test is considered a preliminary positive result and a blood sample obtained by venipuncture must be collected for confirmation by standard HIV testing.

**Quality control (QC):** QC can be defined as the activities undertaken to verify the accuracy of a test result or the operational techniques and activities used to fulfill requirements for quality. These control materials (also referred to as panels) are to be tested to ensure each lot or batch of test kits is reacting and performing as expected.

**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 Assurance Supervisor:** The individual with the overall responsibility for ensuring the quality and technical aspects of POC HIV testing conducted at each site.

**Standard HIV test:** Standard HIV testing requires collection of a venipuncture specimen 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.



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**APPENDIX I — Training Competencies**

<b>Core POC HIV Test Provider Competencies</b>			
<b>Knowledge of:</b>	<b>Skill in:</b>	<b>Judgment regarding:</b>	<b>Attitude that:</b>
<ul style="list-style-type: none"> <li>• legislation, confidentiality, and informed consent related to HIV testing</li> <li>• HIV infection and window period and the impact on testing</li> <li>• HIV diagnostic tests and appropriate use</li> <li>• how to implement and sustain quality assurance activities</li> <li>• education and communication techniques</li> <li>• documentation and reporting requirements</li> </ul>	<ul style="list-style-type: none"> <li>• obtaining informed consent</li> <li>• describing the diagnostic test options available</li> <li>• using POC test kit and running quality controls</li> <li>• collecting POC test sample</li> <li>• interpreting test results and providing appropriate follow-up and determining next steps based on results</li> <li>• collecting or referral for collection of venous sample</li> <li>• providing appropriate client education</li> <li>• collecting and documenting data for surveillance, reporting, and case management</li> </ul>	<ul style="list-style-type: none"> <li>• choosing the appropriate HIV diagnostic product</li> <li>• client follow-up and referral based on HIV test results</li> <li>• referring clients to appropriate next-level services</li> </ul>	<ul style="list-style-type: none"> <li>• respects client's choices and beliefs</li> <li>• demonstrates self awareness of own beliefs, values, and practice limitations</li> <li>• demonstrates sensitivity regarding impact of HIV diagnosis, reporting, and partner notification</li> <li>• respects and supports the adherence to quality assurance activities</li> </ul>



**APPENDIX II — Quality Assurance 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 Education
- Legal and professional requirements for obtaining informed consent
- Legal and professional requirements for maintaining confidentiality

To successfully complete the HIV point of care (POC) 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 procedures for performing and interpreting the POC test.	
2. Demonstrate the procedures for quality assurance activities.	
3. Demonstrate appropriate use of POC test kit.	
4. Describe the relationship of HIV infection and window period in relation to HIV testing.	
5. Demonstrate a client-centred approach when obtaining informed consent, for maintaining confidentiality, and when providing client education.	
6. Demonstrate a client-centred approach when interpreting and providing the POC test result and when discussing next steps and follow-up.	
7. Demonstrate how and when to report POC test results	
8. Describe potential errors and measures to reduce errors related to use of the POC test kit and quality control materials.	
9. 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. This certification of competency is valid until \_\_\_\_\_.

Learner Name: \_\_\_\_\_

Learner Signature: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Completed form to be retained by quality assurance supervisor.**



**APPENDIX III — 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 biohazardous 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 gentle 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 biohazardous waste container?		
22. Record the result and time read on the testing log sheet?		



	YES	NO
23. Discuss and advise venous blood collection for HIV high risk clients who tested negative with POC test?		
24. Draw venous blood when POC test was reactive, invalid or indeterminate?		
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 times observed: \_\_\_\_\_

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: \_\_\_\_\_



**APPENDIX IV – DAILY LOG OF TEST RESULTS**

Testing site: \_\_\_\_\_ POC Test Lot Number: \_\_\_\_\_  
 Supervisor's signature: \_\_\_\_\_ Expiry Date: \_\_\_\_\_

Date of Test	Tester Initials	Client Identifier 1* (i.e., Name, Chart Number, DOB)	Client Identifier 2*	POC Test Result	HIV Serology Collected or Requested (Yes, No)	HIV Serology Result	Reactive POC Test Final Result	Notes / Comments
Oct 3	MG	John Doe	08/31/72	Reactive	Yes	Non-reactive	FP	
Oct 3	JS	Jane Doe	04/16/89	Non-reactive	No			
Oct 3	JS	Jim Doe	12/23/68	Non-reactive	Yes	Reactive		Acute infection
Oct 4	PR	James Doe	07/17/91	Invalid (#1)				
"	"	"	"	Invalid (#2)	Yes	Non-reactive		
Oct 4	PR	June Doe	11/04/84	Reactive	Yes	Reactive	TP	
Oct 4	PR	Positive Control	Lot: B3346	Reactive				Expected Quality Control Result
Oct 5	PR	Negative Control	Lot: B3347	Non-reactive				Expected Quality Control Result
Oct 5	MG	Jennifer Doe	03/21/92	Reactive	No	Not Done	PP	Lost to Follow-up

\* A minimum of two client identifiers is recommended for accuracy of client identification.  
 ^ 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 V - Monthly Summary Report**

Testing Site: \_\_\_\_\_ Report period: \_\_\_\_\_ to \_\_\_\_\_

<b>A. INVENTORY TRACKING:</b>	
Number of POC HIV test kits in inventory at start of period	<input type="text"/>
Number of POC HIV test kits in inventory at end of period	<input type="text"/>
Number of POC HIV test kits removed from inventory during period and transferred to another testing site <i>Name of other testing site:</i>	<input type="text"/>
<b>B. USE OF POC HIV TESTS FOR DIAGNOSTIC TESTING:</b>	
Number of clients with:	
1. Non-reactive POC HIV test results	<input type="text"/>
2. Reactive POC HIV test results	
a. Preliminary positive ( <i>serology not performed</i> )	<input type="text"/>
b. True positive ( <i>serology performed &amp; reactive</i> )	<input type="text"/>
c. False positive ( <i>serology performed &amp; non-reactive</i> )	<input type="text"/>
	<i>Total:</i> <input type="text"/>
3. Invalid POC HIV test results	<input type="text"/>
4. Indeterminate POC HIV test results	<input type="text"/>
<b>C. USE OF POC HIV TESTS FOR OTHER REASONS:</b>	
Number of test kits used for quality control testing	<input type="text"/>
Number of test kits used for training and/or proficiency testing	<input type="text"/>
<b>D. DISPOSAL OF POC HIV TEST KITS:</b>	
Number of test kits wasted <i>Please explain:</i>	<input type="text"/>
Number of test kits expired and discarded	<input type="text"/>

Report completed by: \_\_\_\_\_

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



**APPENDIX VII – Quality Control Log**

Testing site: \_\_\_\_\_

Date	Tester Initials	POC Test Lot Number	Quality Control Material (Negative, Positive)	Quality Control Lot Number	POC Test Result <i>Reactive</i> <i>Non-reactive</i> <i>Invalid</i> <i>Indeterminate</i>	POC Test performs as expected? (Yes, No)	Notes / Comments	Supervisor Initial
Oct 4	PR	B1A245	Positive	B3346	Reactive	Yes		
Oct 4	PR	B1A245	Negative	B3562	Non-Reactive	Yes		
Oct 6	PR	B1A245	Positive	B3346	Non-Reactive	No	Notified Somagen.	

See Section III (3.0) for recommended use of Quality Controls.



**APPENDIX VII – Quality Control Log**

Testing site: \_\_\_\_\_

Date	Tester Initials	POC Test Lot Number	Quality Control Material (Negative, Positive)	Quality Control Lot Number	POC Test Result <i>Reactive Non-reactive Invalid Indeterminate</i>	POC Test performs as expected? (Yes, No)	Notes / Comments	Supervisor Initial
Oct 4	PR	B1A245	Positive	B3346	Reactive	Yes		
Oct 4	PR	B1A245	Negative	B3562	Non-Reactive	Yes		
Oct 6	PR	B1A245	Positive	B3346	Non-Reactive	No	Notified Somagen.	

See Section III (3.0) for recommended use of Quality Controls.



## APPENDIX VIII — Summary of Test Properties

<b>INSTI™ HIV-1 / HIV-2 Antibody Test Kit</b> Supplier: bioLytical Laboratories Inc. License Issue Date (Class IV Medical Device): October 25, 2005																
<b>COMPONENTS:</b> 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																
<b>SPECIMEN TYPE:</b> Fingertstick blood, EDTA-treated whole blood or plasma, serum.																
<b>VALIDATION FOR USE:</b> Validated for HIV-1, HIV-2 antibodies. Not validated for detection of antibodies to HIV-1 Group O or N subtypes.																
<b>TEST PERFORMANCE:</b>																
Sensitivity	Fingertstick whole blood ♥ :															
Specificity	Sensitivity 99.6% [95% CI 98.9-99.9%], Specificity 99.7% [95% CI 99.4-99.8%]															
Positive Predictive Value (PPV)	Fingertstick whole blood: PPV varies according to HIV prevalence. <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2">HIV Prevalence</th> <th>PPV</th> </tr> </thead> <tbody> <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> </tbody> </table>	HIV Prevalence		PPV	0.1%	(1 in 1000)	12.5%	0.2%	(1 in 500)	22.2%	1.0%	(1 in 100)	58.9%	10.0%	(1 in 10)	94.0%
HIV Prevalence		PPV														
0.1%	(1 in 1000)	12.5%														
0.2%	(1 in 500)	22.2%														
1.0%	(1 in 100)	58.9%														
10.0%	(1 in 10)	94.0%														
Low Antibody Titer	Performance equivalent to standard HIV testing protocols using commercial low titer performance panels.															
Window period	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%].															
<b>PRECAUTIONS:</b> 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.																
<b>STORAGE:</b> Storage temperature 15-30 °C, shelf-life 12 months.																
<b>EXTERNAL QUALITY CONTROL:</b> In place (August 2007)																

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



**APPENDIX IX - Testing Supply Verification Record**

Site: \_\_\_\_\_

Receipt Date (dd/mm/yy)	Lot#	Expiration Date (dd/mm/yy)	Insert #	Received	Damage or other comments	Initials
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		
				___ 24 tests ___ Ind Kits ___ QC Other, specify:		

