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## 1.0 INTRODUCTION

The purpose of this document is to provide guidance regarding the appropriate use of Point of Care (POC) HIV testing in BC. In particular, this guideline suggests clinical scenarios and voluntary HIV counselling and testing settings where POC HIV testing is most indicated. These indications are based on the current epidemiology of HIV transmission in BC, current policy frameworks for HIV testing, and a review of the evidence of impact and use of POC HIV testing.(1)

This guideline will also outline requirements for programs or sites adopting POC HIV testing. This document complements recent guidelines regarding the use of POC HIV test kits, and client counselling guidelines for use with POC HIV test kits.(2;3)

The characteristics and impact of POC HIV testing may be influenced by the characteristics of the specific POC HIV test kit product considered for implementation and the standard HIV testing protocol in use. These guidelines may need revision as new testing products or protocols become available. See Appendix for a description of currently available POC HIV tests in British Columbia.

## 2.0 DEFINITIONS

**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 professionals in clinical or laboratory settings, typically providing results within minutes. Results which are negative are considered final, while a reactive test is considered a preliminary positive result and a venipuncture specimen must be collected for confirmation by standard HIV testing.

**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, ELISA) 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.

**Health care professional:** An individual from a profession in which a person exercises skill or judgment 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.(4)

**High risk:** The following behaviours are associated with increased risk of infection with HIV: having multiple sex partners, unprotected sexual activity, sex with an HIV infected person, sharing of injection drug equipment, and acquisition of other sexually transmitted infections.(5) High risk groups in BC include men who have sex with men (MSM), people who use injection drugs (IDU), Aboriginal persons, incarcerated populations, sex workers and their clients, high risk youth, and persons with sexually transmitted infections.

**Voluntary HIV Counselling and Testing:** A confidential process that enables a person to assess his or her risk of acquiring or transmitting HIV and decide whether to be tested, and if tested provides support when a person receives results.

**Window period:** The time between infection with HIV and the detection of HIV. The window period may vary between different HIV test products or protocols.



### 3.0 EPIDEMIOLOGY OF HIV INFECTION IN BC

The number of HIV tests performed in BC continues to increase slowly, to over 170,000 tests in 2006, of which approximately 25% are performed as a result of prenatal testing. The greatest number of new positive HIV tests are reported in men who have sex with men (MSM), followed by people who use injection drugs (IDU), and heterosexual populations. Aboriginal persons are over-represented among new positive HIV tests, particularly Aboriginal females who accounted for 34% of all new positive HIV tests reported among BC females in 2006.

The Public Health Agency of Canada estimated that in BC in 2005, there were between 340-670 incident HIV infections in BC (of which 45% were MSM, 25% were IDU, and 29% were heterosexual from non-endemic countries).<sup>i</sup> The prevalence of HIV in BC was estimated at 10,420 persons (range 8,600-12,200 persons), of which 46% were MSM, 32% were IDU, and 18% were heterosexual from non-endemic countries. Nationally, an estimated 27% of HIV positive persons are unaware of their infection.(6)

### 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 BC.(7-12)

Expansion and increased availability of HIV testing is one strategy identified at provincial and health authority levels in BC to help achieve these objectives. Expansion of testing is considered one component of comprehensive HIV-related services, generally with emphasis on regional populations at increased risk of HIV infection. Expansion of testing into rural and remote communities has also been identified as a priority.(9;10) Other common themes include the importance of pre- and post-test counselling, 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 are also identified.

National strategies endorse HIV testing accompanied by pre- and post-test counselling as an effective early intervention (by linkage to care) and an effective prevention strategy (by supporting behaviour change).(13) Promoting access to voluntary testing in communities with high rates of HIV infection may be cost-effective. HIV testing must be accompanied by three key elements: testing must be confidential, accompanied by pre- and post-test counselling, and conducted with informed consent.(5) These are also key elements of BC's current HIV counselling guidelines for use with POC HIV tests.(2)

### 5.0 COMPARISON OF POC AND STANDARD HIV TESTING

- POC HIV tests licensed for use in Canada will have similar sensitivity and specificity compared to standard HIV screening tests (Sn, Sp > 99%). While a negative result is considered final, 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, positive screening tests are immediately followed by confirmatory testing, and the result returned to the patient is final. A positive POC HIV test is conveyed to

<sup>i</sup> Surveillance and Risk Assessment Division, CIDPC, Public Health Agency of Canada (personal communication)



the client as a preliminary result, and collection of a blood specimen for confirmatory testing is required in order to provide the client with the final result.

- The window period may differ slightly between POC HIV test products and standard HIV screening tests, which may lead to infrequent discrepant results
- Typically health care professionals find POC HIV tests to be easy to use. Unlike automated protocols in place for interpretation of 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
- 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
- Unlike standard HIV testing, the health care professional 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. POC HIV tests rely on provider directly reporting preliminary positive results to Medical Health Officers.

## **6.0 EVIDENCE OF IMPACT OF POC HIV TESTING**

### **6.1 Knowledge gaps**

It is important to note the limitations of the available evidence regarding the potential impacts of POC HIV testing:

- The use of POC HIV testing in rural or remote communities has not been well evaluated, as most reports are based on programs in large urban centres. There may be unique features of HIV testing in rural or remote communities; for example, lower volume of HIV testing, increased concerns regarding confidentiality, and availability of community resources or supports which are required for individuals who test positive
- The typical reported use of POC HIV testing is in clinics or settings with high volume of HIV testing. The incorporation of POC HIV testing into routine primary care settings (e.g. family physician offices) or other low volume HIV test settings has not been well described.
- The psychological impact of receipt of a preliminary positive POC HIV test, or a false positive HIV POC test has not been well evaluated

### **6.2 Potential benefits**

The potential positive impacts of POC HIV testing include:

- POC HIV testing is highly acceptable to and preferred by clients presenting for testing and to health care professionals 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 independently for receipt of confirmatory test results
- The rapid turnaround time associated with POC HIV testing can guide urgent decision-making to prevent HIV infection or to improve patient care



### 6.3 Potential harms

The potential negative impacts of POC HIV testing include:

- 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 sexually transmitted infections has been associated with the use of POC HIV testing, possibly due to disinhibition on receipt of a negative test result or compression of counselling into a single visit
- POC HIV testing may lead to decreased uptake of testing for other infections (e.g., hepatitis C, syphilis)
- While not well evaluated, it is possible that there may be a negative psychological impact for some individuals who receive a preliminary positive or false positive POC HIV test result
- With POC HIV testing there may be missed opportunities for partner notification (and prevention of further HIV transmission) due to non-reporting of preliminary positive results to public health, particularly if confirmatory testing is not performed

## 7.0 APPROPRIATE USE OF POC HIV TESTING

### 7.1 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 and test window period in acting on the result of POC HIV tests.

#### 7.1.1 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 reduced if antiretroviral medications are administered to the mother during pregnancy or labour, or to the infant after birth.(14) 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>ii</sup>

#### 7.1.2 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.(15) 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.

#### 7.1.3 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).

<sup>ii</sup> Refer to Oak Tree Clinic, BC 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))



## 7.2 Voluntary HIV Counselling and Testing Settings

There are three characteristics of settings where the use of POC HIV testing is most indicated.

### 7.2.1 Settings with client populations with high HIV prevalence

POC HIV testing may lead to increased uptake and volume of HIV testing, and use in settings where the patient population is known or suspected to have a high prevalence of HIV may contribute to reducing the proportion of HIV positive individuals who are unaware of their HIV status. Examples include primary care clinics or outreach programs accessed by high risk populations.

### 7.2.2 Settings where not returning for test results is common among high risk clients

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 high risk clients tested do not return for receipt of 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.

### 7.2.3 Settings accessed by high risk clients 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 high risk individuals in testing. However, as the testing health care professional is likely not the patient's primary 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.

## 8 REQUIREMENTS FOR SETTINGS ADOPTING POC HIV TESTING

The following requirements are recommended for settings adopting POC HIV testing:

- POC HIV testing is confidential, accompanied by pre- and post-test counselling, and conducted with informed consent
- Testing is conducted by physicians, or nurses or other health care professionals practicing under delegated authority from a physician, who are trained in HIV test counselling and result delivery
- Capacity exists to provide additional support to individuals testing preliminary positive and to facilitate confirmatory standard 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
- Plans for program evaluation should accompany implementation of POC HIV testing, particularly in a setting where evidence is limited regarding use or potential impacts



## 9. REFERENCES

- (1) Gilbert M. Impact and use of point of care HIV testing: a public health evidence paper. BC Centre for Disease Control; 2007. (available at [www.bccdc.org](http://www.bccdc.org) under "Statistics and Reports")
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- (6) Boulos D, Yan P, Schanzer D, Remis RS, Archibald CP. Estimates of HIV prevalence and incidence in Canada, 2005. Canada Communicable Disease Report, 2006; 32(15):165-74.
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- (12) Vancouver Community HIV/AIDS Strategic Plan 2007-2012. Vancouver Coastal Health; 2007.
- (13) Leading together: Canada takes action on HIV/AIDS (2005-2010). Canadian Public Health Association; 2005.
- (14) Burdge DR, Money DM, Forbes JC, Walmsley SL, Smail FM, Boucher M, et al. Canadian consensus guidelines for the management of pregnant HIV-positive women and their offspring. Canadian Medical Association Journal (online) , 1-14. 24-6-2003.
- (15) BC Centre for Disease Control. Blood and Body Fluid Exposure Management. 2005 May.



**10. APPENDIX: AVAILABLE POC HIV TEST PRODUCTS**

| <b>INSTI™ HIV-1 Antibody Test Kit</b><br>Supplier: bioLytical Laboratories Inc.<br>License Issue Date (Class IV Medical Device): October 25, 2005  |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
|--|---|-----------------------|--|------------|------|-------------|-------|------|------------|-------|------|------------|-------|-------|-----------|-------|
| <b>COMPONENTS:</b><br>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><br>Fingertstick blood, EDTA-treated whole blood or plasma, serum.  |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| <b>VALIDATION FOR USE:</b><br>Validated for the detection of HIV-1 antibodies only.  |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| <b>TEST PERFORMANCE:</b>   |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| Sensitivity<br>Specificity   | Fingertstick whole blood ♥ :<br>Sensitivity 99.5% [95% CI 98.8-99.8%], Specificity 99.3% [95% CI 98.9-99.5%]  |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| 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" style="text-align: center;"><u>HIV Prevalence</u></th> <th style="text-align: center;"><u>PPV</u></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0.1%</td> <td style="text-align: center;">(1 in 1000)</td> <td style="text-align: center;">12.5%</td> </tr> <tr> <td style="text-align: center;">0.2%</td> <td style="text-align: center;">(1 in 500)</td> <td style="text-align: center;">22.2%</td> </tr> <tr> <td style="text-align: center;">1.0%</td> <td style="text-align: center;">(1 in 100)</td> <td style="text-align: center;">58.9%</td> </tr> <tr> <td style="text-align: center;">10.0%</td> <td style="text-align: center;">(1 in 10)</td> <td style="text-align: center;">94.0%</td> </tr> </tbody> </table> | <u>HIV Prevalence</u> |  | <u>PPV</u> | 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% |
| <u>HIV Prevalence</u>  |   | <u>PPV</u>            |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| 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 (Abbott AxSym) on 25 established commercial seroconversion panels the INSTI™ HIV-1 Antibody 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-1 Antibody Test was not reactive by the last bleed in the seroconversion panel.  |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| <b>PRECAUTIONS:</b><br>False negative or invalid test results may be obtained in patients with severe hypogammaglobulinemia conditions (e.g., multiple myeloma).   |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| <b>STORAGE:</b><br>Storage temperature 15-30 °C, shelf-life 12 months.   |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |
| <b>EXTERNAL QUALITY CONTROL:</b><br>In place (August 2007)   |   |                       |  |            |      |             |       |      |            |       |      |            |       |       |           |       |

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