



**GUIDELINES FOR USE OF THE POINT OF CARE HIV TEST KIT**  
**Information for the Health Care Professional in British Columbia**

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**NOTES:**

*The point of care (POC) HIV test kit is only used to perform the initial screening for HIV antibodies. If a client’s POC HIV test result is reactive, it is considered a “preliminary positive”. A venous blood sample must then be collected for confirmatory testing by routine laboratory HIV testing.*

***All preliminary positive test results from POC HIV test kits must be reported to the local Medical Health Officer.***

*The health care professional needs to be aware that POC HIV test kits may be designed to detect HIV-1 antibodies only, HIV-2 antibodies only or both HIV-1 and HIV-2 antibodies. Any claims made by the manufacturer are verified by Health Canada through the licensing process.*

*The guidelines outlined below are for use with the following point of care (POC) HIV test kit(s) that use either finger stick blood or saliva specimens. These POC HIV test kits have been licensed by Health Canada as class IV medical devices.*

<b>Manufacturer</b>	<b>Name of Point of Care HIV Test</b>	<b>License Issue Date</b>	<b>External Quality Control*</b>
bioLytical Laboratories Inc  1208–13351 Commerce Parkway Richmond BC Canada V6V 2X7 Toll Free: 1-866-674-6784 Phone: 604-204-6784 Fax: 604-244-8399	INSTI™ HIV-1 Rapid Antibody Test Kit  specimen - finger stick blood	October 25, 2005	In place. Aug 2007

*The BCCDC highly recommends that an external quality control measure (i.e. an organization independent of the manufacturer is carrying out quality control on its POC HIV test kits) is in place for the POC HIV test kits before the test kits are used extensively. Please note that an external quality control process does not eliminate requirements for on-site quality assurance activities to ensure appropriate use and interpretation of POC test kits.*

*The BCCDC does not assume any liability associated with the use of any POC HIV test kits.*

*The information outlined in this document is intended as guidelines for the health care professional. The POC HIV test kits must be used by a licensed health care professional.*

\* Quality control can be defined as the activities undertaken to verify the accuracy of a test result.



## 1.0 BACKGROUND

The purpose of this document is to assist health care professionals in British Columbia who decide to implement point of care (POC) HIV testing in their clinical practice.

POC HIV test kits that have been licensed by Health Canada are to be used by licensed health care professionals. POC HIV test kits are not licensed for direct sales to the consumer.

In British Columbia, POC HIV test kits are not reimbursed by the Medical Services Plan. These test kits are not funded by the Ministry of Health nor are they distributed by the BCCDC. To purchase POC HIV test kits, health care professionals need to contact the manufacturer.

## 2.0. ROUTINE LABORATORY HIV TESTING

Routine laboratory HIV testing involves a health care professional collecting a venous blood sample from the client then shipping the sample to a designated HIV testing laboratory.

Routine laboratory testing for HIV consists of the following steps:

1. Blood sample is screened with an enzyme immunosorbent assay (EIA). If the initial EIA test is negative then no further testing is necessary. If the initial EIA test is reactive then the sample is screened again with another EIA.
2. The EIA-reactive blood sample is then tested by Western blot for confirmation.
3. If the Western blot test is positive then the client is confirmed positive for HIV antibodies. If the Western blot is negative or indeterminate then the client may be in a period of HIV seroconversion (i.e. window period) or the initial EIA screen test was falsely reactive. Further testing is required to resolve the client's HIV status.

**Note:**

*EIA screening for HIV may be done in various designated HIV laboratories in this province. However, ALL confirmatory testing of EIA reactive blood samples is done at the BCCDC Laboratory Services.*

### 2.1 Window Period

There are two profiles of clients who may be in the HIV window period. A client with a reactive EIA screen test and a negative or indeterminate Western blot test result may be in the HIV window period because the client's immune response has not yet produced a sufficient level of HIV antibodies to confirm the presence of HIV infection. Similarly, a client who has engaged in high risk activity in the previous 3 months and who tests negative with the EIA screen may also be in the HIV window period.



According to the *Canadian Guidelines on Sexually Transmitted Infections, 2006 Edition*, clients who may be in the HIV window period should be counselled on the need to:

- repeat HIV testing over the next 3 months, and
- protect their partners when engaging in high risk activity.

**Note:**

*Nucleic acid amplification testing (NAAT) does not test for HIV antibodies but rather for nucleic acids. NAAT testing may detect an HIV infection in a client who is in the window period (usually within 1 to 2 weeks after infection) prior to the development of antibodies. Presently, NAAT for HIV is not routinely available for diagnostic purposes in BC.*

### **3.0 POINT OF CARE HIV TEST KIT**

Each POC HIV test kit contains testing reagents, materials and an instructional insert. A lot number and expiry date is stamped on the outside of each sealed POC HIV test kit.

The POC HIV test kit is designed for a single use to screen one specimen for HIV antibodies. The package insert for the test kit will indicate the appropriate type of specimen (i.e. finger stick blood or saliva) to collect. Any licensed POC HIV test kit approved by Health Canada will have the same sensitivity and specificity ( $\geq 99.0\%$ ) for HIV screening as the HIV screening methods used in approved HIV testing laboratories.

POC HIV test kits may be designed to detect HIV-1 antibodies only, HIV-2 antibodies only or both HIV-1 and HIV-2 antibodies. Any claims made by the manufacturer are verified by Health Canada through the licensing process.

The POC HIV test only performs initial screening on the client's specimen sample (i.e. finger stick blood or saliva). If a client's POC HIV test result is reactive, it is considered to be a "preliminary positive". A venous blood sample must then be collected for confirmatory testing by routine laboratory HIV testing.

### **4.0 BEFORE USING THE POINT OF CARE HIV TEST KIT**

Listed below are issues for consideration before introducing the POC HIV test kits into clinical practice.

- With POC HIV testing, the health care professional assumes responsibility for both the collection of a specimen (i.e. finger stick blood or saliva) and the testing.
- If the health care professional is not asking the client to pay for the POC HIV test kit then the cost of purchasing the POC HIV test kits needs to be included in the operational budget. The test kits will not be reimbursed by Medical Services Plan nor funded by the Ministry of Health.



- Similar to standard HIV testing, obtaining informed consent and protecting client confidentiality applies to POC HIV testing.
- HIV pre- and post-test counselling guidelines must be relevant and appropriate for POC HIV testing.
- A preliminary positive POC HIV test result will require a venous blood sample to be drawn from the client for confirmatory testing by routine laboratory HIV testing.
- Procedures for the safe disposal of all specimens, reagents and materials used in POC HIV testing should be established. Specimens and materials should be disposed of as medical waste rather than in the regular garbage.
- Staff should be trained in the correct use of the POC HIV test kits.
- Quality assurance and control procedures should be established in the clinical practice. Appropriate procedures are further elaborated in Section 10.0 of these guidelines.
- Verify that no POC HIV test kits have exceeded their expiry dates. Do not use expired POC HIV test kits.

## **5.0 HIV PRE- AND POST-TEST COUNSELLING GUIDELINES**

HIV pre- and post-test counselling guidelines incorporating POC HIV testing have been prepared by the BCCDC and are available in the Communicable Disease Control Manual, Chapter 5: Sexually Transmitted Infections. The manual can be accessed on the BCCDC website at:

<http://www.bccdc.org/content.php?item=83>

## **6.0 USING THE POINT OF CARE HIV TEST KIT**

POC HIV testing consists of a series of time-sensitive steps and procedures that must be correctly carried out in order to obtain accurate test results. Users of POC HIV test kits must strictly follow the manufacturer's instructions on the package insert. Any questions regarding the instructions should be referred directly to the manufacturer.



## 7.0 INTERPRETING POINT OF CARE HIV TEST RESULT

### 7.1 Test Result – Next Steps

A plan of care will need to be implemented based on the POC HIV test result. The health care professional will also provide the client with post-test counselling based on this test result.

The table below outlines how to proceed with each possible POC HIV test result.

Test Result	Next Steps
Negative	<ol style="list-style-type: none"> <li>1. Final test result. No confirmatory testing required.</li> <li>2. If the client engaged in high risk activity in the previous 3 months then repeat HIV testing should be recommended in accordance with the <i>Canadian Guidelines on Sexually Transmitted Infections, 2006 Edition</i>.</li> </ol>
Preliminary Positive	<ol style="list-style-type: none"> <li>1. MUST be confirmed.</li> <li>2. Collect a venous blood sample from the client with the preliminary positive test result for confirmatory testing by routine laboratory HIV testing. Write the name of the POC HIV test kit and the lot number on the test requisition.</li> <li>3. Report the preliminary positive test result to the local Medical Health Officer.</li> </ol>
Indeterminate (result appears positive but not certain)	<ol style="list-style-type: none"> <li>1. Test again with a new POC HIV test kit.</li> <li>2. If the second test result on this client is indeterminate then collect a venous blood sample from the client for routine laboratory HIV testing. Write the name of the POC HIV test kit and the lot number on the test requisition.</li> </ol>
Invalid (cannot determine test result)	<ol style="list-style-type: none"> <li>1. Test again with a new POC HIV test kit.</li> <li>2. If the second test result on this client is invalid then collect a venous blood sample from the client for routine laboratory HIV testing. Write the name of the POC HIV test kit, the lot number, and "invalid POC test result" on the test requisition.</li> <li>3. After the client has left the exam room, run the positive and negative controls on several new POC HIV test kits.</li> <li>4. If the test results for the controls are invalid or incorrect then there may be a "device failure" with this batch of test kits.</li> <li>5. Report the device failure to the manufacturer.</li> <li>6. It is recommended that the health care professional complete and submit a voluntary Problem Report Form to Health Canada about the device failure. Refer to Section 8.0 of these guidelines for the procedure.</li> <li>7. Immediately discontinue the use of the POC HIV test kits. Collect and submit venous blood samples from clients for routine laboratory HIV testing until notified by the manufacturer or Health Canada that the problem with the POC HIV test kits has been rectified.</li> </ol>



## 7.2 False Preliminary Positive POC HIV Test Result

As with routine laboratory HIV screening tests, it is important to note that false positive test results will also occur with POC HIV testing, especially in testing populations that have a low rate of HIV infection. It is imperative that a venous blood sample is collected from the client with a preliminary positive POC HIV test result for confirmatory testing by routine laboratory HIV testing.

## 7.3 Negative POC HIV Test Result

A client who has engaged in recent high risk activity and who has a negative POC HIV test result may not have a sufficient level of antibodies to confirm the presence of HIV infection and thus may be in the window period. This client should be counselled to protect his/her partners when engaging in any high risk activity until an HIV test can be repeated 3 months after the last potential risk exposure. According to the *Canadian Guidelines on Sexually Transmitted Infections, 2006 Edition*, to rule out HIV infection with confidence, further retesting is recommended at 6 months following the last high risk exposure for those presenting with late clinical signs and symptoms of HIV infection or those with an impaired immune response.

## 8.0 DEVICE FAILURE

In the event that the POC HIV test results with the positive and negative controls are invalid or incorrect, or the POC HIV test kits produce repeated invalid test results, the health care professional must report this to the manufacturer who is legally required to report this to Health Canada.

It is highly recommended that the health care professional also report this device failure to Health Canada through the submission of a voluntary Problem Report Form that can be obtained from the following Health Canada website:

[www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep\\_md\\_prob-rap\\_inc\\_im\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm_e.html)

Once completed, the Problem Report Form can be faxed or mailed to:

Health Canada  
Health Products and Food Inspectorate  
Western Operational Centre  
Attention: Supervisor, Inspections and Investigations  
#400 – 4595 Canada Way  
Burnaby, BC V5G 1J9

Fax: 604-666-3149  
Phone: 604-666-3350



## 9.0 REPORTING RESPONSIBILITIES

### 9.1 Preliminary Positive POC HIV Test Result

Under Schedule A of the BC Health Act Communicable Disease Regulation, HIV is a reportable communicable disease. In accordance with the *BC Health Act*, all health care professionals who use the POC HIV test kits are required to comply with the provincial HIV reporting requirements. All preliminary positive test results from POC HIV test kits must be reported to the local Medical Health Officer.

### 9.2 Negative POC HIV Test Result

Standard HIV testing involves the collection of a venous blood sample from the client which is forwarded to an approved laboratory for HIV testing. Most of the blood samples in this province are forwarded to the BCCDC Laboratory Services for HIV testing. This permits the BCCDC to monitor the HIV testing volume in this province. However, an individual with a negative test result from a POC HIV test will no longer need to submit a venous blood sample to the BCCDC for routine laboratory HIV testing. Accordingly, the BCCDC will have no record of this individual accessing HIV testing.

In order for us to assess how much POC HIV testing is occurring in this province, please forward to HIV Surveillance (BCCDC) either by telephone (604-660-2090) or fax (604-775-0808), on a quarterly basis, the number of negative test results obtained from using the POC HIV test kits. No accompanying demographic information is required, simply the number of negative POC HIV test results.

See attachment for a template that can be used to fax the number of negative POC HIV test results by month.

## 10.0 ACTIVITIES TO PERFORM IN THE CLINIC TO ASSURE THE ACCURACY AND RELIABILITY OF THE POINT OF CARE HIV TEST KIT

### **Note:**

*As noted, the BCCDC highly recommends that an external quality control measure (i.e. an organization independent of the manufacturer is carrying out quality control on its POC HIV test kits) is in place for the POC HIV test kits before the test kits are used extensively.*

*Listed below are activities that the health care professional should carry out in the clinical setting to assure the accuracy and reliability of the POC HIV test kits.*

The single use POC HIV test kit presents unique challenges: testing is often performed by the health care professional who does not have formal laboratory training; there may be no residual specimen that can be re-tested; and conventional quality control methods cannot be used. The following activities will help to assure the accuracy and reliability of the POC HIV test kits that are used in clinical practice.



## 10.1 Quality Assurance

Quality assurance can be defined as activities undertaken to ensure that a test meets its stated performance standards. For POC HIV test kits, quality assurance can be achieved through the following activities:

- Identification of one health care professional in the organization who will assume the ultimate responsibility for all aspects of POC HIV testing (i.e. training of staff, updating counselling guidelines, documentation, communications, etc.).
- Strict adherence to the manufacturer's instructions on the package insert when using POC HIV test kits.
- Training staff in how to use the POC HIV test kits, including refresher training at regular intervals.
- Completion of several practice runs before using POC HIV test kits with clients.
- Monitoring of staff performance on a regular basis.
- Monitoring the performance of the POC HIV test kits by testing with positive and negative controls on a regular basis.
- Monitoring storage and room temperatures since POC HIV test kits must be stored in an environment that is within the temperature range as specified by the manufacturer.
- Maintenance of a test result log.

## 10.2 Documentation of Test Result

A POC HIV test result log will provide an account of each test kit used. The test result log should include the following: date of test; test kit lot number; unique client identifier; gender; age or date of birth; test result; date the confirmatory test was ordered (if required); signature of the health care professional who performed the test; and a comment section.

The test result log should account for all POC HIV test kits used, including the positive and negative controls. The control results should be recorded in the same manner as the client results. The destruction of expired POC HIV test kits should also be recorded. The test result log should be retained on file consistent with the document retention policies of the health care professional's place of employment/program.

It is important to document each test kit that has been used in case a look-back is required. Example: A device failure with a POC HIV test kit of a certain lot number – all test results from this batch of test kits with the specified lot number will need to be identified for possible client re-testing. The test result log will easily identify all the test kits with this specific lot number and the corresponding clients who will need to be notified (unless a confirmatory test has been done).

See attachment for an example of a POC test result log.

An alternative to maintaining a test result log is to simply record the manufacturer and lot number of the test kit used in the client's chart along with his/her test result. A log will, however, need to be maintained to keep track of the test kits that are used for running controls and the destruction of expired test kits.



### 10.3 Quality Control

Quality control can be defined as the activities undertaken to verify the accuracy of a test result. A manufacturer will often sell or provide quality control materials separately from the POC HIV test kits. These control materials contain vials of known HIV antibody positive and negative specimens. They are used to evaluate the performance of the test kits and to also check whether the health care professional is using the test kits correctly.

Quality control kits should be used under the following circumstances:

- By the newly trained health care professional prior to actually using the POC HIV test kit on clients.
- By the health care professional 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. In general, sites testing large numbers of clients (e.g. 25 or more clients per week) may run controls less often than facilities that conduct fewer tests.

A control is often built into each POC HIV test kit. This built-in control, often a visual signal such as a control spot, is not a substitute for the positive and negative controls described above. The built-in control provides information on whether an adequate sample of the client's specimen has been added to the test. If a visual signal does appear then the sample is adequate. If a visual signal does not appear then the test is invalid and the test should be repeated with a new test kit and a new specimen sample from the client. If the built-in control fails again then the problem should be reported to the manufacturer as described in Section 8.0 of these guidelines. Also, it is important to discontinue the use of the POC HIV test kit and instead collect a venous blood sample from the client for routine laboratory HIV testing as described in Section 7.0 of these guidelines.



## **11.0 WHEN TO USE THE POINT OF CARE HIV TEST KIT**

Provided that quality assurance and control procedures are established in the clinical practice and an independent, external quality control measure is in place, POC HIV testing could be the most efficient and perhaps the only feasible way to provide information to a client about his/her HIV status. It is left to the discretion of the health care professional as to when and where to use the POC HIV test.

The POC HIV test would be appropriate to use (1) when a client's HIV status needs to be known immediately or (2) when a client cannot or will not access standard HIV testing.

As mentioned, with POC HIV testing, all preliminary positive test results must be confirmed and reported to the local Medical Health Officer.

## **12.0 QUESTIONS ABOUT POINT OF CARE HIV TESTING**

Any questions about POC HIV testing, please contact HIV Education (BCCDC):

Telephone: 604-660-1979

Fax: 604-775-0808



### 13.0 ONLINE INFORMATION SOURCES

The titles below are online sources of further information.

**Title:** Point-of-Care HIV Testing Using Simple/Rapid HIV Test Kits: Guidance for all Health-Care Professionals --- (this document is currently under revision)

**Author:** Public Health Agency of Canada (April 2000)

**Website:** [www.phac-aspc.gc.ca/publicat/ccdr-rmtc/00vol26/dr2607ea.html](http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/00vol26/dr2607ea.html)

**Title:** Canadian Guidelines on Sexually Transmitted Infections, 2006 Edition

**Author:** Public Health Agency of Canada

**Website:** [http://www.phac-aspc.gc.ca/std-mts/sti\\_2006/sti\\_intro2006\\_e.html](http://www.phac-aspc.gc.ca/std-mts/sti_2006/sti_intro2006_e.html)

**Title:** Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach

**Author:** World Health Organization and Centers for Disease Control and Prevention (2005)

**Website:** [www.who.int/entity/diagnostics\\_laboratory/publications/HIVRapidsGuide.pdf](http://www.who.int/entity/diagnostics_laboratory/publications/HIVRapidsGuide.pdf)

**Title:** Rapid HIV Testing

**Author:** Centers for Disease Control and Prevention

**Website:** [www.cdc.gov/hiv/topics/testing/rapid/index.htm](http://www.cdc.gov/hiv/topics/testing/rapid/index.htm)

**Title:** Rapid HIV Screening at the Point of Care: Legal and Ethical Questions

**Author:** Canadian HIV/AIDS Legal Network (2000)

**Website:** [www.aidslaw.ca/publications/publicationsdocEN.php?ref=284](http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=284)

**Title:** Rapid HIV Testing Workbook and Implementation Guidelines for Limited Testing Facilities in New York State

**Author:** New York State – Department of Health (revised February 2006)

**Website:** [www.health.state.ny.us/diseases/aids/testing/rapid/workbook.htm](http://www.health.state.ny.us/diseases/aids/testing/rapid/workbook.htm)

**Title:** New Jersey Rapid Testing HIV Website

**Author:** University of Medicine & Dentistry of New Jersey

**Website:** [www.njhiv.org](http://www.njhiv.org)

**Title:** Rapid HIV Testing

**Author:** Erica Weir, Canadian Medical Association Journal (May 30, 2000)

**Website:** [www.cmaj.ca/cgi/content/full/162/11/1605](http://www.cmaj.ca/cgi/content/full/162/11/1605)

**Title:** Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests

**Author:** Morbidity and Mortality Weekly Report (March 19, 2004)

**Website:** [www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm)



### NUMBER POINT OF CARE HIV TEST KITS USED

**FAX TO:** HIV Surveillance  
BC Centre for Disease Control

**FAX NO:** 604-775-0808

Name of POC Test Site: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Phone: \_\_\_\_\_

E-mail: \_\_\_\_\_

Month	Number of NEGATIVE Test Results	Number of INDETERMINATE or INVALID Test Results	Number of Test Kits Used for QUALITY CONTROL	Number of Test Kits SPOILED*
January				
February				
March				
April				
May				
June				
July				
August				
September				
October				
November				
December				

\* Number of test kits SPOILED includes test kits that have exceeded their expiry dates and instances where the health care professional has incorrectly used the test kits.

*Note:*

*Forwarding to HIV Surveillance (BCCDC) the number of NEGATIVE test results will assist with assessing how much POC HIV testing is occurring in this province. Forwarding the number of INDETERMINATE or INVALID test results, the number of kits used for QUALITY CONTROL and the number of kits SPOILED will assist with estimating the percentage of kits wasted.*

