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NOTES

The counselling steps outlined in this document are for use with point of care (POC) HIV test kit(s) that use either a finger stick blood or saliva specimen. These POC HIV test kits have been licensed by Health Canada as class IV medical devices approved for HIV screening at the point of care by health care professionals where appropriate HIV counselling is available.

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.

Please refer to the document titled GUIDELINES FOR THE HEALTH CARE PROFESSIONAL IN THE USE OF POINT OF CARE HIV TEST KITS IN BRITISH COLUMBIA for practical information regarding the implementation of POC screening tests in healthcare settings.

For ease of use, pages 2-3 of these guidelines present an abbreviated version of the steps outlined for client counseling. The remainder of this document (Appendix) provides supplemental information expanding on each of the described steps.

1.0 PRINCIPLES OF POC TESTING

Point of Care (POC) testing is subject to professional guidelines regarding testing procedure, counselling, confidentiality, reporting, and record handling.

1. The use of POC test kits must include client centered pre- and post-test counselling (outlined below in condensed form and in the appendix in an expanded form). Pre- and post-test counselling should be documented in client records.
2. Any person testing for HIV must be offered the option to use initials (non nominal option) or their name (nominal option) as personal identifiers, as per the Communicable Diseases Regulations under the Health Act.
3. The POC test should be implemented only after informed consent has been obtained.
4. This document will use the term “preliminary positive” to describe test results which are not negative, indeterminate or invalid.
5. HIV is a reportable infection in BC. All preliminary positive results obtained using POC test kits **must be reported to the Medical Health Officer** in the Health Service Delivery Area where the test was performed.
6. All preliminary positive results obtained using POC test kits **must be confirmed by submitting a venous sample of blood for standard HIV testing.**



1.1 Pre-Test Counselling – Achieving Informed Consent for POC HIV Testing

Clients opting to test for HIV should be provided the information they need to make an informed decision to test for HIV by a POC testing method. All pre-test counselling sessions should include an invitation to discuss personal risks and risk reduction strategies. It is important to document in the client record that pre test counselling has occurred.

PRE-TEST COUNSELLING

1. Outline the voluntary, confidential POC test procedure, relate 3 month window period to last risk, discuss benefits of testing.
2. Review current information about HIV transmission.
3. Provide opportunity to discuss personal risks and risk reduction strategies.
4. Discuss personal supports and personal preparedness for testing.
5. Outline next steps following negative, preliminary positive, invalid or indeterminate test results.

1.2 Post-Test Counselling – Providing Results from POC HIV Testing

POC testing provides the opportunity to accomplish pre-test counselling and post-test counselling in one visit. Healthcare providers providing POC test results must make every reasonable effort to communicate the result to clients in such a way that the information exchanged is understood. It is important for healthcare providers to document what was discussed in post-test counselling.

WHEN A POC TEST RESULT IS NEGATIVE

1. Interpret the negative POC test result. Relate result to window period and recent risks.
2. Assess that the client has fully understood the result and has good comprehension of the personal implication of the result. Provide opportunity for the client to ask questions.
3. Reinforce HIV prevention information. Discuss risk reduction strategies.
4. Next Steps:
 - a) Plan repeat testing if risk has occurred in the preceding 3 months.
 - b) Provide referrals if necessary.



WHEN A POC TEST RESULT IS PRELIMINARY POSITIVE

1. Interpret a preliminary positive result as a preliminary diagnosis only. False positive results can occur with POC testing.
2. Assess that the client has fully understood the result and has good comprehension of the personal implication of this preliminary result. Provide opportunity for the client to ask questions and deal with issues important to the person.
3. Reinforce mechanisms of HIV transmission. Provide risk reduction counselling. Counsel the client to protect others from sexual secretions, blood and other bodily fluids while waiting for confirmatory test results.
4. Next Steps:
 - a) Submit a venous sample for standard HIV testing.
 - b) Comply with reporting requirements by reporting the preliminary positive result to local MHO for surveillance purposes.

WHEN A POC TEST RESULT IS INVALID OR INDETERMINATE

1. Interpret an invalid or indeterminate result as an unknown result. Repeat the test.
2. Assess that the client has fully understood that an invalid or indeterminate result should not be regarded as a positive result.
3. Reinforce transmission information, placing this prevention effort in the context that their HIV status will be unknown until a confirmatory test result is available.
4. Next steps:
 - a) If second POC test attempt is invalid or indeterminate submit a venous sample for standard testing.
 - b) If repeated tests are invalid, report the occurrence to the manufacturer.



1.3 Post-Test Counselling – Providing Results from Standard HIV Testing

Healthcare providers must make every reasonable effort to communicate the result to clients in such a way that the information exchanged is understood. It is important for healthcare providers to document what was discussed in post-test counselling.

WHEN A STANDARD HIV TEST RESULT IS NEGATIVE

1. Interpret the negative test result. Relate result to window period and recent risks.
2. Assess that the client has fully understood the result and has good comprehension of the personal implication of the result. Provide opportunity for the client to ask questions.
3. Reinforce HIV prevention information. Discuss risk reduction strategies.
4. Next steps:
 - a) Plan repeat test if risk has occurred in the preceding three months.
 - b) Provide referrals if necessary.

WHEN A STANDARD HIV TEST RESULT IS POSITIVE

1. Interpret the result as a confirmed reactive or positive HIV result. The test has detected antibodies to HIV. The person is infected with HIV.
2. Assess the client's comprehension of the personal implications of this reactive result. Assess personal, community and professional supports. Make referrals as appropriate.
3. Reinforce HIV prevention information. Help client to identify sexual and drug practices which will not infect others.
4. Next Steps:
 - a) Arrange a medical assessment within 30 days
 - b) It is recommended that a confirmatory test be performed following all reactive HIV antibody test results.
 - c) Follow the "RECOMMENDATIONS FOR LABORATORY AND CLINICAL ASSESSMENT OF NEWLY DIAGNOSED HIV POSITIVE PERSONS" found in Chapter 5 of the BCCDC Communicable Disease Manual. Discuss and provide the client handout from the same link.
Link: <http://www.bccdc.org/content.php?item=83>
 - d) Any partner who may have been exposed to HIV through sex or through sharing of drug using equipment should be counselled to have a test. Discuss a plan with the client for the counselling of partners and offer the assistance of the Public Health Nurse.
 - e) Assist the Public Health Nurse with data collection for reporting process.



2.0 APPENDIX

2.1 Pre-Test Counselling – Achieving Informed Consent for POC HIV Testing

Clients testing for HIV should be provided the information they need to make an informed decision to test for HIV by a POC testing method.

All pre-test counselling sessions should include an invitation to discuss personal risks and risk reduction strategies. It is important to document in the client record that the steps recommended for Pre-test Counselling have been covered.

1. Outline the voluntary, confidential POC test procedure, relate 3 month window period to last risk, discuss benefits of testing
 - POC testing is performed on a finger stick specimen of blood, can produce results in 1-5 minutes and is capable of identifying antibodies to HIV when present.
 - Any testing for HIV must be voluntary.
 - A negative result means that either the person is not infected or that they have an acute infection and it is too early to detect antibodies. A window period of three months must be taken into consideration when interpreting negative results.
 - A preliminary positive result obtained by POC testing might be a false positive or might mean the person is infected with HIV. These results must be followed by a confirmatory test.
 - Occasionally, a POC test will not produce a clear negative or positive result. If such an invalid or an indeterminate result occurs, the POC test needs to be repeated. If the second test is invalid a sample of venous blood should be collected and submitted for confirmatory testing.
 - Most persons who have been infected with HIV will produce detectable antibodies within three months of exposure to HIV. This period is known as the window period.
 - It is important to consider the date of the last known risk when assessing the accuracy of any negative antibody test results.
 - A discussion of disadvantages to testing can help clients to make an informed decision. Personal, social and legal consequences to testing continue to exist. Counselling is important to help mitigate any possible negative consequences relating to a positive diagnosis and employment, disclosure, perceptions of future health, impact of diagnosis on self and others, stigma and discrimination.
 - Some advantages to testing:
 - a) Early diagnosis and timely access to treatment
 - b) Prevention of transmission to others if infected
 - c) Relationship planning
 - d) Planning of pregnancy



2. Review current information about HIV transmission

- People risk transmitting or contracting HIV in these circumstances:
- during pregnancy, childbirth or via breast milk if mother is HIV positive.
- when they have unprotected sexual contact: penile-anal and penile-vaginal intercourse without a condom (high risk) performing oral sex without a barrier (low risk); receiving oral sex (negligible risk)
- when they have direct blood-to-blood contact;
- when they share needles or syringes (including injection drug use, tattooing, piercing with shared/unclean equipment)
- having concurrent partners places an individual at greater risk for acquiring HIV and other STIs and for transmitting these infections to others. Concurrent relationships involve having more than one sexual partner (or drug equipment sharing partner) in a given period of time and going back and forth between them – while maintaining sexual relationships (or drug sharing practices) with all of them.
- if a person received blood or blood products in Canada before November 1985 (for other countries risk of transmission varies depending on testing of donated blood).
- During the first one to two months of an HIV infection a person is very infectious to others.
- An HIV positive person is also highly infectious to others when he or she has a sexually transmitted infection.
- Persons who are HIV negative are more susceptible to HIV when they have a sexually transmissible infection.
- HSV-2 (Herpes Simplex Virus 2) infection with or without lesions increases the risk of acquiring or transmitting an HIV infection.

3. Provide opportunity to discuss personal risks and risk reduction strategies

- Invite the client to discuss their lifestyle risks and to participate in a discussion of strategies to reduce risk.
- Consistent use of latex or polyurethane condoms reduces risk.
- Consistent use of personal, clean drug use equipment can prevent the risks which occur when equipment is shared with others.
- Sometimes personal triggers can be identified which contribute towards risk taking, e.g. excessive drinking or drug use, visiting certain locations, vacations.
- Improved negotiation skills and coaching may help people to avoid some high risk activities, e.g. casual/anonymous/unprotected sex and risks associated with sharing needles, syringes or other injection drug use equipment.
- Frequent HIV testing for individuals with high risk lifestyles can provide helpful information to confirm HIV status.



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- Antiretroviral therapy is available to decrease the risk of mother-to-child transmission if a woman is HIV positive and pregnant (decreased by $\geq 80\%$).
4. Discuss personal supports and personal preparedness for HIV testing
 - Discuss the person's personal coping mechanisms, in particular whether they feel prepared to hear the result of the POC test when complete.
 - To assess a person's readiness to test you could ask two questions: "What result are you expecting? / How do you think you will respond if the result is a preliminary positive result?"
 - Review the person's access to support (personal, community, medical). To assess personal support systems you could ask: "Who could you discuss the result of today's test with?"
 5. Outline next steps following negative, preliminary positive, invalid or indeterminate test results.
 - Negative POC results: test should be repeated if risk has occurred in the past three months.
 - All preliminary positive results must be reported to the MHO in the HSDA where the test is being performed.
 - To confirm that preliminary positive results are accurate and to rule out false positive results, a tube of venous blood must be submitted for confirmatory testing. Personal identifiers used for this confirmatory test should match the identifiers reported to the Medical Health Officer from the preliminary positive POC result.
 - An invalid or an indeterminate result cannot be interpreted. These results do not indicate either negative or preliminary positive status. When invalid results occur, repeat the test with a new POC test kit. If an invalid or indeterminate result persists a second time submit a sample for laboratory testing and report the malfunction to the manufacturer.
 6. Document the content of the pre-test counselling session
 - It is important to record that pre-test counselling occurred and to document what was covered.



2.2 Post-Test Counselling – Providing Results from POC HIV

POC testing provides an opportunity to provide results and to counsel clients about the implication of the results in the same session as the pre-test counselling.

Healthcare providers providing POC test results must make every reasonable effort to communicate the result to clients in such a way that the information exchanged is understood. It is important for healthcare providers to document that post-test counselling has occurred.

2.2.1 When a POC Test Result is Negative

1. Interpret the negative POC test result. Relate result to window period and recent risks.
 - A negative result indicates either no infection or the person is in the “window period” (3 months) of infection, with no detectable antibodies.
 - A client who has engaged in recent high risk activity and who has a negative POC HIV test result may be infected but may not have detectable antibodies at the time of the test. This client should be counselled to protect his/her sexual or drug equipment sharing partners when engaging in any high risk activity until the HIV test can be repeated three months after the last potential exposure.
2. Assess the client has fully understood the result and has a good comprehension of the personal implication of the result. Provide opportunities for the client to ask questions.
3. Reinforce HIV prevention information, discuss risk reduction strategies.
 - If no risk in the past three months discuss a risk reduction plan with the client to help them focus on how they could remain HIV negative.
4. Next Steps:
 - a) Plan repeat testing if risk has occurred in the preceding 3 months.
 - If the person has a history of seroconversion illness, a venous sample should be submitted to the provincial HIV laboratory for HIV screening and the person should be counselled to protect all sexual partners and contacts with whom they share drug equipment until the results of confirmatory testing have been received.
 - b) Provide referrals as necessary
 - c) Document what was discussed in post-test counselling.



2.2.2 When POC Test Result is Preliminary Positive

1. Interpret a preliminary positive result as a preliminary diagnosis only. False positive results can occur with POC testing.
 - A preliminary positive result most often indicates a true HIV infection, but false positive results are possible, particularly in low HIV prevalence population.
2. Assess that the client has fully understood the result and has good comprehension of the personal implication of this preliminary result. Provide opportunity for the client to ask questions and deal with issues important to the person.
3. Reinforce mechanisms of HIV transmission. Provide risk reduction counseling. Counsel the client to protect others from sexual secretions, blood and other bodily fluids while waiting for confirmatory test results.
 - latex or polyurethane condoms used correctly may reduce risks to partners
 - sharing of drug using equipment during this period is highly discouraged;
 - protect others from sexual secretions, blood and other bodily fluids;
 - discuss the risks to others if they donate blood, organs, tissue, sperm or breast milk
 - Assist client to make a plan for risk reduction to others.
 - Disclosure of this preliminary result to partners will enable partners to make decisions to protect themselves.
4. Next Steps:
 - a) Submit a venous sample for standard HIV testing.
 - To rule out the possibility of a false positive result, all preliminary positive POC test results need confirmatory testing by standard laboratory testing methods.
 - Counsel client regarding how the results of confirmatory testing will be reported, how to collect results and next steps if confirmatory test is negative (non reactive) or positive (reactive).
 - b) Comply with reporting requirements by reporting the preliminary positive result to local MHO for surveillance purposes.
 - c) Document what was discussed in the post-test counselling session.



2.2.3 When POC Test Result is Invalid or Intermediate

1. Interpret both invalid and indeterminate results as an unknown result. Repeat the test.
 - An invalid or indeterminate result can be caused by improper use of test kit or test kit malfunction. Repeat the test with another POC test kit.
2. Assess that the client has fully understood that an invalid or indeterminate result should not be regarded as a positive result.
 - To determine that a client remembers what was discussed during the pre-test session about invalid and indeterminate results, ask the client what they remember.
3. Reinforce transmission information, placing this prevention effort in the context that their HIV status will be unknown until a confirmatory test is available.
 - Reinforce that until the test is repeated with another POC test kit or confirmed by a standard laboratory test method, the client should not make any assumptions about what their HIV status might be.
 - Counsel regarding risk reduction.
4. Next steps:
 - a) If the result of the second test is also invalid or indeterminate submit a venous sample for standard testing.
 - b) If repeated tests are invalid, report the occurrence to the manufacturer.
 - See GUIDELINES FOR USE OF THE POINT OF CARE HIV TEST KIT for details of the indication for and method for reporting to the manufacturer.
 - c) Document the process in the client record.



2.3 Post-Test Counselling – Providing Results from Standard HIV Testing

Healthcare providers must make every reasonable effort to communicate the result to clients in such a way that the information exchanged is understood. It is important for healthcare providers document what was discussed in the post-test counselling session.

2.3.1 When a Standard HIV Test Result is Negative

1. Interpret the negative test result. Relate result to window period and recent risks.
 - The three month window period must still be taken into consideration.
2. Assess that the client has fully understood the result and has good comprehension of the personal implication of the result. Provide opportunity for the client to ask questions.
 - Do not make personal assumptions about whether a person is pleased or distressed by a negative test result.
 - Encourage the client to verbalize what the result means to them.
3. Reinforce HIV prevention information. Discuss risk reduction strategies.
4. Next steps:
 - a) Plan repeat test if risk has occurred in the preceding three months.
 - Repeat the test if there is a recent history of seroconversion illness and counsel the client to protect all partners.
 - b) Provide referrals if necessary.
 - c) Document what was discussed in post-test counselling.

2.3.2 When a Standard HIV Test Result is Positive

1. Interpret the result as a confirmed reactive or positive HIV result. The test has detected antibodies to HIV. The person is infected with HIV.
2. Assess the client's comprehension of the personal implications of this reactive result. Assess personal, community and professional supports. Make referrals as appropriate.



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- Ask the client to describe the impact of this result to avoid making incorrect assumptions.
 - Persons who have recalled sessions when they were given reactive HIV results consistently reported they remembered little of what was discussed except the manner in which the result was handled by the healthcare provider.
 - Assess community supports by asking who do they plan to tell about their diagnosis, and where can they receive assistance and support in the next 24 hours. (This becomes of critical importance when results are provided preceding holidays or weekends when access to services could be limited)
3. Reinforce HIV prevention information. Help client to identify sexual and drug practices which will not infect others.
- Of particular importance is a discussion about current sexual and drug equipment sharing partners and their risks for acquiring HIV.
 - Review the following information on HIV transmission:
 - A newly diagnosed person may be in the acute phase of their infection and therefore highly infectious. Prompt viral load and CD4 testing following HIV diagnosis is necessary to determine degree of infectivity. If a person is in the acute phase of an HIV infection it is recommended that the person does not have sex or share drug using equipment.
 - Viral load testing can be ordered by physicians and is performed through the Centre for Excellence in HIV/AIDS at St. Paul's Hospital.
 - HIV positive individuals who have a subsequent sexually transmitted infection will experience a rise in their HIV viral load. During this episode, they are more infectious to others.
 - HSV-2 (with or without lesions) in persons with HIV can make them more infectious to others.
 - HIV positive people who have concurrent partners will be more likely to spread HIV to others. Concurrent relationships involve having more than one sexual partner (or drug equipment sharing partner) in a given period of time and going back and forth between them – while maintaining sexual relationships (or drug sharing practices) with all of them.
 - After the acute infection subsides, an HIV positive person can reduce the risk of infecting others by using latex or polyurethane condoms correctly, by not sharing drug use equipment, and by not donating blood, organs, tissue, semen or breast milk.
 - HIV positive women who are pregnant should consult a physician regularly. Incidence of infant transmission can be greatly reduced through use of antiretroviral medications and feeding the child formula rather than breast milk.



4. Next Steps:
 - a) Arrange a medical assessment within 30 days.
 - A medical assessment should be arranged with a physician who has experience with HIV.
 - b) Offer to repeat the test by standard testing methods if the client is questioning accuracy of the result.
 - It is recommended that all subsequent tests be submitted using the same identifying information in order to compare test results.
 - d) Follow the “RECOMMENDATIONS FOR LABORATORY AND CLINICALASSESSMENT OF NEWLY DIAGNOSED HIV POSITIVE PERSONS” found in Chapter 5 of the Communicable Disease Manual. Discuss and provide the client handout from the same link.
(Link: <http://www.bccdc.org/content.php?item=83>)
 - These recommendations were compiled by the BC Center for Excellence in HIV/AIDS.
 - Provide client with the handout:” INFORMATION FOR PERSONS NEWLY DIAGNOSED WITH HIV” (also found in the Communicable Disease Manual)
 - Refer clients to the website **www.stdresource.com** for links to community support agencies
 - d) Any partner who may have been exposed to HIV through sex or through sharing of drug equipment should be counselled to have a test. Discuss a plan with the client for the counselling of partners and offer the assistance of the Public Health Nurse.
 - e) Assist the Public Health Nurse with data collection for reporting process.
 - f) Document what was discussed in the post-test counselling session.



3.0 SUGGESTED LINKS

A. Information for healthcare providers regarding clinical management:

STD Resource.com
<http://www.stdresource.com>

BC Centre for Excellence in HIV/AIDS
<http://www.cfenet.ubc.ca>

BCCDC Communicable Disease Manual
<http://bccdc.org/content.php?item=83>

Canadian guidelines on Sexually Transmitted Infections – 2006 edition
<http://www.phac-aspc.gc.ca/std-mts/index.html>

B. Resource for persons newly diagnosed with HIV:

STD Resource.com
<http://www.stdresource.com>

British Columbia Persons with AIDS Society
<http://www.bcpwa.org>

BC Centre for Excellence in HIV/AIDS
<http://www.cfenet.ubc.ca>

BCCDC Communicable Disease Manual
<http://bccdc.org/content.php?item=83>