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Purpose of the BC HIV Point of Care Test (POCT) Site Operations Manual

The purpose of this manual is to provide guidance regarding the clinical use and operational considerations of HIV POC testing in BC for approved test locations. The manual is presented as separate topics to enable readers to quickly access information.

Included in these manual documents are recommendations and procedures for the appropriate use of HIV POC test kits; and quality assurance/operational components required to use HIV POC test kits, such as training, documentation, purchasing and inventory control.

This manual does not address pre- and post-test discussions surrounding HIV POC testing; these are separate guidelines located in <u>Chapter 5</u> of the BCCDC Communicable Disease Control Manual.

<u>HIV Testing Guidelines for the Province of BC</u> (released by the Office of the Provincial Health Officer) is also available for reference. Testing by Point of Care Test (POCT) is referenced in the document.

Recommendations in the Site Operations Manual are broadly applicable to any test location in BC offering HIV POC testing. Some sections, such as purchasing and inventory control, and reports and documentation, are specific to test locations receiving HIV POC test kits through the provincial program.

A separate <u>guidance</u> document is available for additional considerations when locations wish to expand test providers beyond nurses/LPNs, nurse-practitioners, and physicians.

Please note that information in the Site Operations Manual section documents apply to ALL TEST PROVIDERS.

Overview and Indications for HIV Point of Care (POC) Testing

Background

HIV Point of Care (POC) tests (also known as "rapid" HIV tests) are screening tests for HIV antibodies. These tests are performed while a client waits, and provide results within minutes. A reactive result is considered preliminary and needs to be confirmed with standard HIV serology. In Canada, the INSTI™ HIV-1/HIV-2 Rapid Antibody Test from bioLytical Laboratories (INSTI™ HIV Test) is the only HIV POC test product currently licensed for use in community health care settings.

Since 2011, the BC Centre for Disease Control (BCCDC) and BCCDC Public Health Laboratory (PHL) support a centralized, province-wide HIV POC testing, distribution, and quality assurance program for HIV community test locations under the Hope to Health Program.

In September 2015, each Health Authority identified partners responsible for clinical and operational oversight of their plan for expansion of HIV testing. Each Health Authority now includes HIV testing by POC as part of their overall HIV test strategy. Each Health Authority has a plan for approval of new HIV POC test locations and review/oversight of existing test locations.

The BC HIV POC Test Program (provincial program) supports many, but not all, of the test locations in BC. Test kits may be purchased directly from bioLytical by test locations not supported by the BC Program.

HIV POC testing is one component of an overall strategy to provide and expand access to HIV testing services. The BC Program provides POC tests and supplies them free-of-charge to health care settings that meet the BC Program standards and have approval from their regional Health Authority.

Indications for HIV POC Testing

Priorities for use of HIV POC test kits within the BC Program are for community/outreach health settings with one or more of the following characteristics:

- The prevalence of undiagnosed HIV is expected to be high.
- Not returning for test results is common among those being tested.
- Individuals are reluctant to test because of perceived or real community HIV bias.
- Provision of this test result is expected to improve public health follow-up or connection to HIV clinical care.

If a client requests a HIV test, then one is done, but the POC option may not be the best choice.

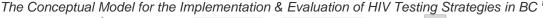
Providers use clinical judgment based on discussions with clients to assess HIV risk exposure and test window period as well as client agreement to determine the most appropriate HIV test.

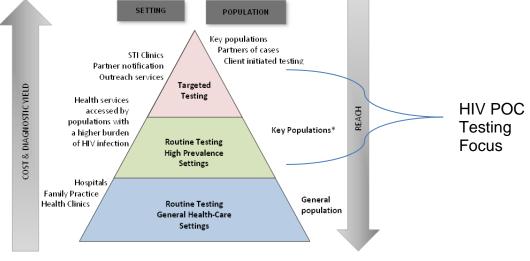
A phlebotomy/serology test is generally the preferred method for routine HIV screening of a general low-HIV-risk population. The current screening HIV laboratory test in BC detects both HIV antigen and antibodies and can detect HIV 10 to 15 days before the POC test.

When both HIV serologic and POC tests are available, and providers are trained and competent to use the POC test, the best (but rare) clinical decision for a specific client situation may be to conduct both a POC and a phlebotomy test. Usually one or the other test modality is chosen.

The focus of the BC HIV POCT Program is support of testing in community. Testing done within a research framework is funded by the research application process. Testing done within a hospital facility is funded and supported by hospital processes.

BC has adopted a model to guide the development of HIV testing services based on the expected prevalence of HIV in specific settings or populations. The Conceptual Model for the Implementation and Evaluation of HIV Testing Strategies in BC shows where HIV testing by POC is suggested as an additional HIV test tool:





¹ Adapted from the Conceptual Framework for the Vancouver Coastal Health HIV Testing Program developed by R. Gustafson, M. Thumath, K. MacPherson, C Buchner (2013): Vancouver Coastal Health.

Benefits of HIV Testing by POC

Providing a HIV test through POC has many potential benefits:

- Increased acceptance of HIV testing among some individuals.
- Individuals undergoing HIV POC testing are more likely to receive their test result.
- The rapid turnaround time associated with HIV POC testing can guide urgent decision-making to prevent HIV infection or to improve patient care.

All of these may result in a more timely detection of HIV, resulting in improved clinical outcomes; as well as to potentially reduce possible secondary infections.

Challenges with HIV Testing by POC

HIV testing through POC also has challenges:

- Confirmatory testing of HIV POC results is not immediately available at the time of testing.
- The likelihood of false positive results is higher in populations at low risk of HIV infection.
- HIV POC testing may lead to decreased uptake of testing for other infections which may also be indicated (e.g. HCV, syphilis).
- HIV POC testing does not capture early HIV infections (i.e. acute HIV).
- Cost, especially for sites doing few client tests per month.