## BC HIV Point of Care Test Site Operations Manual 2019-01-28 Page 1 of 2

## **PHSA Laboratories**

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| Definitions                              |  |
|--|--|
| Acute HIV infection                      | The first 4-6 weeks after HIV infection is a period when a person often has a high viral load.<br>There is a greater likelihood of transmitting HIV to others, compared with individuals in later<br>stages of HIV infection. Individuals with acute HIV infection may test falsely negative on HIV<br>antibody tests if they are tested within the window period.   |
| Community Health<br>Representative (CHR) | Health care providers or "care providers" (PHAC, 2013) working in Indigenous communities but employed by an external agency or the health authority.   |
| Confirmatory Test                        | Venous blood sample sent to the laboratory to confirm a reactive HIV POC test result.  |
| False Negative Result                    | A false negative result is reported when the POC test fails to detect a HIV infection. Since the BC Program does not include parallel blood testing with POC, such findings are discovered only when standard HIV laboratory tests are run and reported back to the test location. The most common reason for not detecting HIV is because the client is in early acute phase, and has not produced antibodies at sufficient levels that they can react with the test material, and be detected by the test provider. Underlying medical conditions that affect antibody production, long-term antiretroviral therapy and HIV-1 group N subtype infections may also result in a false negative result. |
| False Positive Result                    | A false positive result is reported when the result for confirmatory testing is "not indicative of HIV infection", but the POC result was reactive. Such results occur more commonly if there is a low prevalence of HIV infection in the population being testing (i.e. general population). The most common cause of a false positive result is cross-reacting antibodies of other origins.  |
| IgG Control                              | Each INSTI test kit membrane contains an internal/IgG control that should create a blue dot for each test. This indicates that enough sample and reagents were added so that if HIV antibodies are present in the sample, they should turn the "test dot" blue.  |
| INSTI™ kit                               | The INSTI™ kit is currently the only HIV POC test device approved by Health Canada for<br>community use. This product is manufactured by bioLytical Laboratories.  |
| 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.  |
| Master Lot number                        | The master lot number is the number which appears on the outer foil packet of each INSTI™ kit, or each set of INSTI™ controls. The master lot number covers the contents of each packet and is the number that is referenced if there is a problem or a recall occurs.   |
| Non-Regulated Care Providers<br>(NRCPs)  | Care providers who are not regulated by a regulatory body / College falling under the Health Professions Act (BC Laws 1996).   |
|  | This may include community outreach workers, community health workers, peers, care aides and non-regulated counselors, etc.  |
| Point of Care (POC) HIV test<br>KIT      | The supplies provided by the manufacturer to do one HIV test by Point of Care. One INSTI™ test kit packet includes fingerpoke supplies, 1 test membrane, 1 each of solutions 1, 2, and 3.  |
| Point of Care (POC) HIV test             | HIV POC tests (or rapid HIV tests) are screening tests for antibodies to HIV. These tests are licensed by Health Canada for use by health care providers in clinical or laboratory settings, typically providing results within minutes.   |
| Point of Care HIV Test location          | Location supported by and meeting the expectations of the BC HIV Point of Care Test Program<br>and the geographic Health Authority within which the test location is found. Such test locations<br>are provided with publically-funded resources and support to provide HIV tests by Point of Care<br>to clients in their communities.   |

## BC HIV Point of Care Test Site Operations Manual 2019-01-28 Page 2 of 2

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| Point of Care Test location<br>Lead        | The individual at a HIV POCT location with the overall responsibility for ensuring that: the quality and technical aspects of HIV POC testing are conducted correctly; the ordering of test kits and supplies is completed; and the monthly reporting and ongoing training and competencies of staff are maintained.   |
|--|--|
| Proficiency Test (PT)                      | A high-level Quality Assurance activity that involves a group of test locations performing the same test on the same unknown samples(s). Results are analyzed for all results and the resultant report compares the test location performance to the group.  |
| 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 Control (QC)                       | The activities undertaken to verify the accuracy of a test result or the operational techniques<br>and activities used to fulfill requirements for quality. Quality control materials are tested to<br>ensure each lot of HIV POC test kits is reacting and performing as expected, and to assess that a<br>test provider can see the colour reaction of a weak positive, under the test environment lighting<br>levels. |
| QC Test                                    | The set of vials needed to complete one QC test. The set consists of 1 HIV-negative and 1 anti-<br>HIV-1 positive sample. Both samples must be tested at the same time to assess performance of the test kit, test provider and testing environment.   |
| Regulated allied health care professionals | Professionals for whom HIV testing does not traditionally lie within their scope of professional practice (e.g., non-physician, non-registered nurse).   |
|  | This may include dentists, pharmacists, chiropractors, physiotherapists, massage therapists, occupational therapists, dietitians, social workers, etc.   |
| Test provider                              | Individual who does HIV POC tests. This person is aligned with a HIV POC test location, and meets test location, Health Authority and Provincial Program training and competence requirements.   |
| True Positive                              | A true positive result is reported to the BC Program based on confirmation of a POC reactive result by standard HIV laboratory test results.   |
|  | Note that a true positive POCT result will automatically enter the provincial formal HIV Positive reporting system.  |
| Voluntary HIV testing                      | A confidential process that allows a person to discuss HIV acquisition and transmission with the 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.  |

The current window period for detection of HIV by the INSTI<sup>™</sup> test is 3 months.

| BC  | British Columbia                 | PHL    | Public Health Laboratory |
|---|----------------------------------|--------|--------------------------|
| BCCDC British Columbia Centre for Disease |                                  | POC(T) | Point of Care (Test)     |
|   | Control                          |        |                          |
| CHR                                       | Community Health Representative  | PT     | Proficiency Test         |
| HA  | Health Authority                 | QA     | Quality Assurance        |
| MHO                                       | Medical Health Officer           | QC     | Quality Control          |
| NRACP                                     | Non-Regulated Allied Health Care |        |                          |
|   | Provider                         |        |                          |
|   |                                  |        |                          |