

## Implementing HIV Self-Testing in Canada

# **FAQs**

## **FREQUENTLY ASKED QUESTIONS**

For Health Care and Community Providers

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Ver 1.0

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Self-Testing for HIV ("HIVST") is an emerging approach with the potential to increase the uptake of HIV testing as a high impact, low cost, and empowering alternative for those who may not otherwise test, notably in key populations and for people at high risk for HIV infection. This technological innovation in the healthcare industry brings a new testing approach that can be affordable, simple, accessible and convenient.

There is a large body of supporting evidence showing the acceptability and usability of HIVST in various key populations and groups, with both oral fluid and blood-based self-test devices having met key performance and usability indicators for successful implementation. As a result of this, The World Health Organization (WHO) recommends offering HIV self-tests in addition to other more traditional HIV testing approaches (e.g., blood draws, point-of-care testing)

Health Canada is currently reviewing the license application for approval of the first HIV self-test in Canada, the blood-based INSTI HIV Self Test®. The test is made in Richmond BC by a Canadian company: bioLytical Laboratories (<a href="www.bioLytical.com">www.bioLytical.com</a>). The exact date of availability in Canada will depend on Health Canada's decision, when the manufacturer will be able to produce the final approved product, and when implementation and procurement strategies such as e-commerce, and special pilot programs make the test available. It is expected that self-tests will be available to the users very shortly after the license is granted.

A second self-test, the OraQuick HIV Self Test, which is oral-fluid based, is launching studies in Canada in September to bring this test device through Health Canada regulatory approval process and into the Canadian market once approved, likely in late 2021.

Below are a series of Frequently Asked Questions (FAQ) based on available information. As we learn more, we will update this document.

## What is HIV self-testing?

HIV self-testing means that a person can obtain/purchase their own test, do the test themselves and get their results immediately (similar to a home pregnancy test). This means they do not have to go to a facility, clinic or doctor's office. It is important to note that if these initial self-test results are positive, the individual should go to a clinic or health care provider for a blood draw for confirmatory testing. The self-test is different from self-sample collection devices and/or programs that are available for public use, such as mail-order kits which require a person to send a sample of their blood or dried blood spots to a lab for testing.

## How does the self-test work?

The INSTI HIV Self Test is similar to the one "rapid test" approved for use in all provinces/territories in Canada for point-of-care programs (INSTI HIV-1/HIV-2 Antibody Test®) and is produced by the same manufacturer.

It is similar to other home or self-tests such as a pregnancy test: a person does the test on themselves and sees the result within minutes.

To do the test, a person will need to prick their finger to produce a single drop of blood with the materials provided in the test kit, follow the instructions provided in the package insert, and interpret their results. The whole process can take as little as one minute.

The test checks for HIV antibodies (the body's reaction to having HIV) in a small drop of blood taken from the finger. It does not test for the presence of the virus itself.

One drop of blood is processed in the test device. One dot will appear on all completed tests to indicate that the test working. This verifies that enough blood was added, and the test was run properly. If HIV antibodies are present, a second dot appears. Each test kit can only be used once.

The test is performed in 4 simple steps:

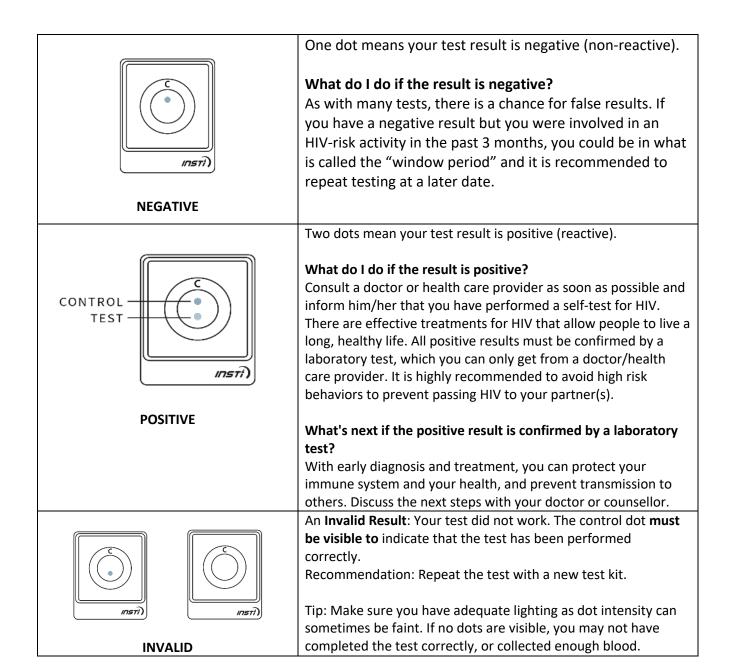
- 1. Use the lancet to prick the finger and form the blood drop;
- 2. Allow the blood drop to fall into Bottle 1 (red cap), mix by inverting a few times, then pour entirely into the test device;
- 3. After Bottle 1 contents have fully absorbed into the test device, mix and pour the contents of Bottle 2 (blue cap);
- 4. After Bottle 2 contents have fully absorbed into the test device, mix and pour the contents of Bottle 3 (clear cap), and read results immediately after the contents are absorbed into the device. There is no wait time.

For more information, watch the video to see how the test works: insti.com/hiv-self-test/

#### What do the results look like?

The test has a built-in control dot to let people know whether they've performed the test correctly and if they have added a sufficient amount of blood. If there is no control dot visible after completing the test procedure, the test did not work. This means that any result is invalid and must not be interpreted/used. The control dot must appear for the test to be interpreted/used.

If two blue dots appear, the test is reactive and confirmatory testing will need to be done. Confirmatory testing can be obtained through a sexual health clinic and/or physician/health care provider who will request the confirmatory test. See below for results descriptions and related questions that self-testers may ask:



### *Is the test accurate?*

Yes, clinical studies have shown that the test is accurate. When the test is done correctly, it will detect HIV antibodies more than 99% of the time once the body's immune response has produced sufficient antibodies. However, a positive self-test result does not necessarily mean the individual has HIV, as it still needs to be confirmed by a follow-up blood test by a Public Health Laboratory. Individuals using the kit are advised in the package insert that they need to see a health care provider (e.g., sexual health clinic, physician) to obtain a confirmatory test.

The INSTI HIV antibody test is very sensitive and specific. Sensitivity was shown in clinical trials to be 99.6% (i.e., the percentage of results that will be reactive when HIV is present). This means that up to 4 false negative results could be expected out of every 1,000 self-tests in individuals who have HIV. A reactive result can appear within 21-22 days after exposure. This is an important reminder for people to test frequently when in the window period, which is 3 months from the time when HIV might have been acquired. Specificity of the INSTI self-test was shown to be 99.5% (i.e., the percentage of results that will be negative when HIV is not present) when performed by untrained users in a Canadian study. This means that up to 5 false positive results could be expected out of every 1,000 self-tests in individuals who do not have HIV. This is an important reminder for people to obtain confirmatory testing of all self-test reactive results.

To ensure the maximum accuracy of the self-test, it is extremely important for those who self-test to carefully read and follow all labeled instructions. Even when used according to the labeled instructions, there will be a small number of false negative and false positive results.

## How soon after a chance of getting HIV should a person take the test (the "window period")?

If a person is HIV positive, the person may have developed a detectable immune response as early as three weeks after exposure. Following exposure, antibodies can take time to reach detectable levels so using the self test earlier than three weeks could produce false negative results even if the exposure had led to infection. However, for some people antibodies are not detectable until three months after exposure. This three-month period following exposure is known as the *window period*.

So, while a person may have a reactive test at three weeks after potential exposure to HIV, if their result is negative, an HIV infection cannot be ruled out until three months after exposure. Individuals may choose to test within the window period of three months, but until a negative result is received after this period, HIV infection cannot be fully ruled-out.

### When should a person take the test?

If there is no reason that a person could have been exposed to HIV, then there is no need to be tested for HIV. Deciding on when and how to take the test is a personal decision. Some people will choose to test frequently and others may test occasionally. Some people may choose not to do an HIV self-test. For those who decide to complete an HIV self-test, some people may choose to do so alone in a private setting of their choice. Others may want some support prior to, after or during the self-test procedure. People should give careful consideration about whether they want someone else to see their results at the same time as they do. They should feel comfortable and safe with whomever and wherever they take the test and know who to contact at any time if they need help or information in dealing with their results.

## Where can a person get help with doing the test?

There are several support mechanisms available to individuals who need help with doing a self-test:

 The test kit will contain complete, easy to follow instructions on how to complete the test along with frequently asked questions and contact information about sexual health info-lines;

- The manufacturer's video on how to complete the test is available on the bioLytical Laboratories website (<u>www.biolytical.com</u>). The package insert also contains a scannable QR code that will link the individual to the self test video; and
- A national telehealth platform to support access of HIV self-testing and linkages to care with support of a network of peer navigators will be available in the early fall as part of an implementation science program being developed by the CIHR Centre for REACH 3.0 / The MAP Centre for Urban Health Solutions at St. Michael's Hospital in Toronto along with community organizations such as CBRC and WHIWH.

# What should an organization consider if they plan to acquire and distribute HIV self-tests for the community?

There are several considerations related to the handling, storage, and inventory management of supplies of self-test kits. As a licensed medical device, optimal kit quality and performance must be maintained. It is advisable to work with local public health authorities to ensure optimum condition of the kits is maintained at all times. For example, kits will need to be stored according to the manufacturer's specifications, and kit expiry dates will need to be tracked to ensure no expired tests are distributed.

#### Other considerations include:

- Ensuring adequate resources to manage programming;
- Equipping your space you will require a temperature monitored storage space for kits, a
  private space for testing if self-testers will test on site, and biohazard/sharps waste disposal;
- Training staff on how the test works, how to assist with self-testing and how to review results minimizing liability risks, and providing ongoing training on test counselling and support; and
- Maintaining an updated referral network, especially clinical referrals.

## What supports can community agencies provide people seeking self-testing?

In addition to the REACH-led national HIV self-test and linkage to care program with peer navigators, some people may want to learn more about the test from a staff member at a local community agency (e.g., AIDS Service Organization), or they may want to take the test at an agency and have a staff person present to guide them through completion of the test or interpretation of their results.

It is important for agencies to be aware that self-tests are specifically licensed for people to do the test on themselves. This means people who use a self-test are taking on the responsibility of doing the test correctly. If staff are asked to help with completing the test, they should assist only by guiding the self-tester through the labelled instructions and not be put in a situation where they are determining the result of the test or whether someone is HIV-positive.

If agencies choose to provide what has been referred to as "supervised" self-testing (ie, be present or on virtual link to guide the individual through the self-testing process), it is advisable that the agency staff/volunteers:

- DO NOT complete the test on behalf of the client, especially DO NOT conduct the finger puncture of the client's skin, as this is a procedure limited to certain regulated health professionals;
- DO NOT indicate to the client that they have HIV; instead, the agency staff/volunteer may choose to confirm the number of spots that appear on the test, refer the client to the package insert for details on result interpretation, and remind the client that the self-test is an initial test requiring confirmatory testing if positive.

After a person has completed testing, there is a very important role an agency can play in providing referrals to testing clinics for confirmatory testing, Pre-Exposure Prophylaxis (PrEP) or Post Exposure Prophylaxis (nPEP) services, and/or other services as appropriate. For more information on PrEP and to determine who would be a good candidate for PrEP, consult local PrEP program services.

It is important to offer support to people choosing to take the test and remind them that if their result is reactive, **people** living **with HIV who receive care and treatment continue to live long healthy lives.** 

# What are potential roles for Community-Based Organizations in supporting new testing technologies such as self-testing?

Some potential activities for community-based organizations could include:

- Conducting point-of-care tests;
- Promoting awareness of HIV self-testing and encouraging frequent and regular use by those who may be infected with HIV;
- Distributing HIV self-tests;
- Being a HIV testing information source for people in your community (including to people who have not accessed your services previously). For example, this might include supporting a client who received a self-test from somewhere else; explaining the need for a confirmatory HIV tests for diagnosis if a self-test is reactive; demonstrating how tests are used for those who need help; providing pre- and post-test counselling; and potentially supervising self-tests;
- Assisting those who are interested to navigate the appropriate resources and follow-up;
- Supporting people who have a negative test in their service delivery region to link up with prevention (i.e., harm reduction, PrEP, etc) and ongoing testing supports;
- Supporting people who have a positive test in their service delivery region to link with care and/or access community-based services – e.g., Peer Navigator for the newly diagnosed for people living with HIV and/or people living with hepatitis C; health care providers; and
- Supporting quality control of self-test kits.

## Are the results of a self-test confidential?

Results of the test are private to the person taking the test, unless they choose to seek supervised self-testing. There is no requirement for the person to disclose the results of their test to others. As the results are not reported, public health does not become involved with individuals who test reactive on a self-test, however individuals who present to health care providers with a reactive self-test result should be informed that the result may be reportable to Public Health according to regulations. Individuals who

present to health care providers with a reactive self-test result should also be informed of options for obtaining a confirmatory test and obtaining treatment and care, as required. Completed self-test devices, if used in a home environment, should be placed back into the test kit pouch along with all test kit materials, for more discreet disposal in regular household trash.

### What should a person do if they get a reactive self-test result?

The HIV self-test is an initial test and while a reactive result should be considered a presumptive positive result, confirmatory testing is required to determine if the person has HIV. All reactive results will need to be confirmed by laboratory testing through a Healthcare Provider to confirm or to rule out HIV infection.

However, if a person gets a non-reactive (negative) self-test result and believes they were infected very recently (i.e., up to 3-days or 72 hours), they should go immediately to their nearest emergency department to determine whether they are a candidate for Post Exposure Prophylaxis (PEP). The timing of PEP is very important: it must be started within 72 hours of exposure to HIV.

At any time throughout the self-testing process, individuals may benefit from the following resources:

- Provincial Sexual Health or HIV/AIDS Infoline: can help people find follow-up testing near them to confirm their result;
- Primary healthcare provider: can do follow-up HIV testing and work with people who test positive to begin treatment and care;
- Sexual health clinic: can provide HIV testing and counselling services;
- bioLytical Laboratories: the company that makes the test and has provided some self-testing resources. (www.biolytical.com);
- CATIE: a national resource centre for information about HIV and hepatitis C. CATIE educators are available by phone or email from Monday to Thursday from 10 a.m. to 6 p.m. (Eastern Time). Call 1-800-263-1638 (or 416-203-7122 in Toronto), email info@catie.ca or visit https://www.catie.ca
- Community-based HIV/AIDS services: These local agencies support many people living with HIV. They can help with questions and concerns. They can provide emotional support, and practical supports, including help to find a doctor, and programs to help pay for treatments;
- HIV411: online tool providing information on local HIV and Hepatitis C programs. https://hiv411.ca/

## Will the test be available for free, or will there be a cost?

At present, the manufacturer is planning on an e-commerce program where self-test kits can be purchased online. In time, self-test kits may also be purchased from a local retailer (i.e. pharmacy) at a cost determined by the retailer. Details will be announced by the manufacturer once the self-test is licensed.

Shortly after the INSTI HIV Self Test® is approved by Health Canada, the CIHR Centre for REACH 3.0 / MAP Centre for Urban Health Solutions at St. Michael's Hospital in Toronto will be launching a large self-test implementation and linkage to care project in partnership with community-based organizations and

8

telehealth platforms to provide self-tests and peer navigation services free of charge to participants. Details of this program will be announced prior to the launch.

There is no known government program planned at this time to provide free or discounted test kits to people in Canada wanting to self-test for HIV.

### The following are questions that may be asked by self-test users:

How early can this test detect HIV? Based on bioLytical's studies, INSTI demonstrates third generation performance and detects HIV antibodies of the IgM and IgG class. IgM antibodies are the earliest antibodies that the body produces after an HIV infection and can be detectable within 21-22 days<sup>1,2</sup>. Depending on how quickly a person's immune system generates HIV antibodies after infection, it could still take up to 3 months to get a positive result (although this is rare). If you think you have been exposed to HIV within the last 3 months, and your results are negative, you will need to test again after at least 3 months have passed since your possible exposure. The time from HIV infection to when a test can correctly give a positive result is referred to as the 'window period'.

**How do I dispose of this test?** You can place all items of the self-test back into the bag and discard with normal household garbage.

Where can I store the test? The test should be stored between 2°C and 30°C, unopened and away from direct sunlight.

#### **Test Procedure Questions**

1. How do I make sure I get enough blood?

Before starting the test, relax and drink a glass of water. Warm your hands. Place your hand below waist level to promote blood flow. Before using the lancet, look for a spot on the side of your finger-tip that is smooth, not calloused and away from your fingernail.

2. What happens if I spill some of the Bottle contents outside the test device?

Continue with the test procedure. The test result is valid as long as the control dot is visible (even if it is faint) after pouring Bottle 3 into the test device.

3. How will I know if my test was done correctly?

The INSTI HIV Self Test® has a built-in control dot to show that the test has been performed correctly and that you have added the proper sample type and amount of blood sample. If the control dot does not appear (invalid test result), your test has not worked. It is not possible to draw conclusions from this result and you will need to perform another test. In the event of repeated invalid results, consult a doctor.

4. When can I read the result?

You can read the result instantly or within 1 hour of completing the test procedure. This means that you can read the test device right after pouring Bottle 3. Make sure the control dot is visible before reading your result.

#### **Common Errors**

Points we need to clarify to self-testers:

Often people do not read the Instructions for Use It is important to carefully follow the instructions for use to perform the test properly People forget to rub their finger until warm before using the lancet, thus blood flow is not as good When blood flow is optimal, it is much easier to get the freeflowing drop of blood required to drop into Bottle 1 Rub finger and hand UNTIL WARM. People are afraid to lancet or ask if it is painful PRESS HARD The lancet is not painful, it is just mild finger prick. A helpful tip is to firmly press the lancet on the middle or ring finger, away from the finger-nail or finger pad. Place lancet on the side of finger tip. Scraping the blood drop from the fingerstick onto the rim of Bottle 1. Dropping the blood directly into Bottle 1 is an important step that should not be missed. The blood should drop from the finger into the bottle; do not scrape it on the rim of the bottle. If the drop is not falling, then just wait and be patient. Once enough blood has gathered it will eventually Let 1 drop **FALL** into Bottle 1. form a droplet. You may need to massage the finger to Twist on cap of Bottle 1. promote blood drop formation.

10

In addition to the FAQ above, the INSTI HIV Self Test® package insert contains questions and answers for the benefit of the self-test user: (subject to revision pending Health Canada approval of final test kit labelling). It is recommended to have a self-test package insert on hand for reference at all times.

#### Intended Use

The INSTI HIV Self Test is a single use in vitro self-test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood. The test is intended for use as a self-test by users 18 years or older.

Disposal
Discard with normal household waste or in accordance with local regulations.

#### **Warnings and Precautions**

- ATest components are harmful if swallowed due to the presence
- if swallowed due to the presence of Sodium Azide
   All blood samples should be handled as if capable of transmitting infectious diseases.
   Clean up spills.
   Keep out of the reach of children.

#### Storage

**Questions and Answers** 

- 2°C Store in the original
- packaging in a cool, dry location between 2 to 30°C. DO NOT FREEZE. Do not store in direct sunlight. Do not open the test device pouch until you are ready to take the test.
- © Consult Instructions for Use © For single use only. Do not reuse.
- Use by ■ In vitro diagnostic medical device
- ENGE Sterilization using irradiation ■ Catalogue Number
- Manufacturer

#### General

- 1. What is HIV and AIDS? HIV What is HIV and AIDS? HIV (Human Immunodeficiency Virus) is the virus that causes AIDS (Acquired Immunodeficiency Syndrome) if left untreated. When a person becomes infected with HIV, the virus begins to attack his or her immune stream which his HIV, the virus begins to attack his or her immune system, which is the body's defense against illness. As a result, that person becomes more susceptible to disease and infection. When his or her body loses the ability to fight diseases, that person is diagnosed with AIDS. There is no cure for HIV infection. However, treatment for HIV is highly effective.
- 2. How does someone acquire HIV? HIV spreads through contact with blood, semen, pre-seminal fluid, rectal fluid, vaginal fluids, or breast milk of an infected person. Transmission can occur from unsafe sex. It can also result from exposure to blood through the sharing of syringes or needles. Women living with HIV can pass the virus to their babies during pregnancy, childbirth, and breastfeeding. HIV is not transmitted by casual contact (sharing food, dishes, clothing, etc.), saliva, casual kissing, food preparation or insect bites.
- 3. What is an antibody? Antibodies are produced by your body's immune system in response to harmful organisms like viruses and bacteria. Their purpose is to defend against infection.

#### About the Test

About the Test

4. How does the INSTI HIV Self
Test work? INSTI HIV Self Test
is a blood test for detecting HIV
antibodies. The test produces
result in the form of either one
dot (control dot) or two dots
(control and test dots). Control
dot is the built-in control
mechanism and is visible if the
test is performed correctly. A test
dot will only be visible if sample
contains antibodies to HIV. The
test is performed by adding a
drop of blood to Bottle 1. This
diluted sample is then poured
into the test device followed
by solutions in Bottle 2 and
Bottle 3, sequentially after each
solution has absorbed through
the test device. Test procedure

must be completed in the proper sequence without delays between steps.

5. How accurate is the test?
Extensive research studies have shown that this test is extremely accurate when performed correctly.

Sensitivity of a test is defined as the percentage of test results that will be positive when HIV is actually present. This is based on clinical evaluations on the test. This test has a proven clinical sensitivity of X%, which means that on average XX in every 1,000 positive results will be correct. Specificity of a test is defined as the percentage of test results that will be negative when HIV is not present. This test has a proven clinical specificity of Y%, which means that on average Y in every 1,000 negative results will be correct.

- 6. What is a false positive result? A false positive result is when a test result is positive, but the true HIV status of the person is negative (not infected with HIV).
- 7. What is a false negative result?
  A false negative result is when a test result is negative, but the true HIV status of the person is positive (infected with HIV).
- B. How early can this test detect HIV? Based on biolytical's studies, INSTI demonstrates third generation performance and detects HIV antibodies of the IgM and IgG class. IgM antibodies are the earliest antibodies that the body produces after an HIV infection and can be detectable within 21-22 days<sup>14</sup>. Depending on how quickly a person's immune system generates HIV antibodies after infection, it could still take up to 3 months to get a positive result. If you think you have been exposed to HIV within the last 3 months, and your results are negative, you will need to test again after at least 3 months have passed since your exposure. The time from HIV infection to when a test can correctly give a positive result is referred to as the 'window'. 8. How early can this test detect correctly give a positive result is referred to as the 'window period'.

<sup>1</sup>Moshgabadi N, et al. "Sensitivity of a rapid point of care assay for early HIV antibody

detection is enhanced by its ability to detect HIV gp41 IgM antibodies," J Clin Virol (2015)

Cohen M, et al. " The detection of acute HIV infection" J.Infect. Dis. 202 (2010) 270-277.

#### Test Procedure

- 9. How do I make sure I get enough blood? Before starting the test, relax and drink a glass of water. Warm your hands, Place your hand below waist level to promote blood flow. Before using the lancet, look for a spot on the side of your finger tip that is smooth and not calloused and away from your fingernail.
- away from your Ingernal.

  10. The contents of Bottle 1, 2 or 3 do not absorb into the test device. It is very rare for this to happen, but if it does, you will not be able to complete the test procedure and read the results. You will need to perform another test. In some instances, samples may exhibit longer than normal flow times through the test device. This is due to variable factors, such as cellular components within the whole blood sample. Failure to follow the instructions may also result in leakage and/or overflow of liquids from the test device.
- 11. What happens if I spill some of the contents of Bottle 1, Bottle 2 or Bottle 3 outside the test device? Continue with the test procedure. The test result is valid as long as the control dot shows a visible dot after pouring Bottle 3 into the test device.
- Bottle 3 into the test device.

  12. How will I know if my test was done correctly? The INSTI HIV Self Test has a built-in control dot to show that the test has been performed correctly and that you have added the proper sample type and amount of blood sample. If the control dot does not appear (invalid test result), your test has not worked. It is not possible to draw conclusions from this result and you will need to perform another test. In the event of repeated invalid results, consult a doctor.

#### **Test Results**

If you are unsure of your result you should go to a doctor to perform more testing.

- 13. When can I read the result?
  You can read the result instantly
  or within 1 hour of completing
  the test procedure. Make sure
  the control dot is present before
  reading your result.
- 14. I have used the test but no dots appeared. What should I do? Make sure you have adequate lighting. If no dots are visible, you may not have completed the test correctly, or collected enough blood. You will need to per
- . What do I do if the result is positive? A Positive Result: Consult a doctor as soon as possible and inform him/her that you have performed a self test for HIV. All positive results must be confirmed by a laboratory test. HIV is preventable and you can help to stop the spread of HIV. It is highly recommended to avoid high risk sexual behaviors to prevent passing HIV to your partner. 15. What do I do if the result is
- 16. What's Next After A Positive Result? Having HIV does not mean you have AIDS. With early diagnosis and treatment, it is unlikely that you will develop AIDS. Discuss the next steps with your doctor or counsellor.
- 17. What do I do if the result is negative? A Negative Result: As with many tests, there is a chance for false results. If you have a negative result but you were involved in an HIV-risk activity in the past 3 months, you could be in what is called the "window period" and it is recommended to repeat testing at a later date.

18. Can any medication or medical conditions affect the result?

• Always read the manufacturers' instructions for any medication you are taking before conducting the test.

• A false negative result can occur for the following reasons:

» Have been on long term antiretroviral treatment

» Have a severe blood disorder, such as multiple myeloma

» Have higher than normal haemoglobin

For Questions Or Further Support Call your provincial and territorial HIV/AIDS hotlines:

AB: 1-800-772-2437 NT: 1-800-661-0844 BC: 1-800-661-4337 NU: 1-800-661-0795 MB: 1-800-782-2437 NS: 1-800-566-2437 NL: 1-800-563-1575 ON: 1-800-668-2437 (EN), NB: 1-800-561-4009 1-800-267-7432 (FR)

PE: 1-800-314-2437 YT: 1-800-661-0408 ext. OC Info-Santé: 811 Portail VIH/sida du QC: 1-877-Portail (767-8245) sk: 1-800-667-6876

EASTERN ARCTIC:

1-800-661-0795

Manufactured by: bioLytical Laboratories, Inc. 13351 Commerce Parkway, Suite 1108 Richmond, BC, Canada V6V 2X7 Phone: +1 604-204-6784 www.biolytical.com 90-1044, 90-1053 INSTI HIV Self Test 51-1220(Cdraft) XX-Mar-2020 © Copyright 2020. All rights reserved. English

## References

<sup>1</sup> Moshgabadi N, et al. "Sensitivity of a rapid point of care assay for early HIV antibody detection is enhanced by its ability to detect HIV gp41 IgM antibodies." J Clin Virol (2015) Oct; 71:67-72.

Ver 1.0

<sup>&</sup>lt;sup>2</sup> Cohen M, et al. " The detection of acute HIV infection" J.Infect. Dis. 202 (2010) 270–277.