

# Distribution of HIV Self-Test Kits by Regional Public Health Teams

## Provincial Population & Public Health Guideline

Clinical Communicable Disease Control, Population and Public Health

**Date approved:** March 7, 2024

**Target Review Date:** March, 2027

## 1. Abbreviations

PHNs	Public Health Nurses
CDTs	Communicable Disease Technicians
STBBI	sexually transmitted and blood-borne infections
POCT	point-of-care testing
PrEP	pre-exposure prophylaxis
PEP	post-exposure prophylaxis

## 2. Purpose

To define guidance for the distribution of HIV self-test kits by regional public health teams who choose to make this service available.

## 3. Scope

These guidelines apply to public health teams in regional health authorities involved in the distribution of HIV self-test kits.

HIV self-test kits can be distributed by any trained direct service staff including Public Health Nurses (PHNs), Communicable Disease Technicians (CDTs), Outreach Workers, or other allied health workers. Staff or volunteers from other organizations

distributing HIV-self tests out of regional public health offices are required to adhere to these guidelines.

## 4. Background

Distribution of HIV self-tests is not required by regional public health teams but highly recommended as part of an STBBI testing strategy. HIV self-tests offer unique benefits and a number of publicly funded projects have made HIV self-test kits accessible for distribution. As procurement opportunities for HIV self-test are evolving, regional public health teams are encouraged to consult the Manitoba Health, Seniors and Long-Term Care, Population and Public Health Communicable Disease Control Unit for information regarding access to HIV self-test kits.

Currently, the INSTI HIV Self-Test is the only approved HIV self-test in Canada, and is referred to in this document as the “HIV self-test”.

- Other rapid point of care HIV tests, such as the INSTI Multiplex or INSTI HIV 1/HIV 2 Antibody test that are performed by health care providers, are **not** currently approved for self-use/distribution and cannot be substituted for HIV self-tests.

The INSTI HIV Self-Test was approved by Health Canada in 2020 and uses the same technology as the point-of-care INSTI HIV 1/HIV 2 Antibody Test. The HIV self-test allows people to test themselves for HIV in their home or other locations, and results can be available within minutes. The HIV self-test can offer unique benefits and enhance equity in access to HIV screening, diagnosis, and engagement in care for priority populations and communities.

- If the self-test result is non-reactive then no further testing is required, as long as the person doing the test is out of the window period defined in the product insert. However, clients who remain at risk for HIV should consider regular ongoing testing and HIV prevention options. See [Manitoba HIV Self-Test Pathway](#)<sup>3</sup>
- A reactive test result requires a confirmatory test and will require the person who uses the self-test to seek out confirmatory testing.

More information on Health Canada approval of this device<sup>1</sup> is available at: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS11033>

## 5. Guidelines

### 5.1. Staff Training and Orientation

Each public health team or site involved in HIV self-test distribution ensures their staff are oriented to the following basic information AND establish a site-specific process for HIV test kit storage, tracking, and inventory. The following orientation elements are recommended:

- Review the video <https://www.youtube.com/watch?v=1G1ia1S7uZo>
- Review this Provincial Population and Public Health Guideline
- Review the HIV self-test product insert<sup>2</sup> available at: <https://www.insti.com/wp-content/uploads/2021/10/51-1220-C-IFU-INSTI-HIV-Self-TestCA-EN.pdf>
- Review the Manitoba HIV Self-Test Pathway<sup>3</sup> available at: <https://www.i-am.health/i-am-media-downloads>
  - Direct link: [Manitoba Care Pathways EN.pdf \(dropbox.com\)](#) Note that this is the document that should be provided to community members along with the HIV self-test kit.
- Complete any regionally specific training or orientation required by your public health team

### 5.2. Inventory Management, HIV Test Kit Storage and Transport Condition

All HIV self-tests kits are stored in a clean supply/medication storage room with ongoing temperature monitoring (e.g., in the same room as the vaccine cooler).

- HIV self-test kits are stored between 2 degrees centigrade (C) and 30 degrees C.
- Inventory is monitored periodically (check inventory / orders against data on number of kits distributed) and stock rotated to ensure oldest stock (earliest expiry date) are used first. Lot numbers of inventory received are recorded.
- HIV self-test kits may be removed from the clean storage room for distribution in office/front desk, but are returned to the secure storage space after business hours.
- HIV self-test kits removed from the building (e.g., for use in outreach) are transferred in a temperature monitored container using a Min/Max thermometer when outdoor temperature is expected to exceed 27 degrees centigrade (C) or go below 5 degrees C. Only clean transport cooler/cooler bags are used to transport HIV self-test kits.

- Regional public health teams have a system or site lead for reporting and investigating excursions to storage/transport conditions for HIV self-test kits and determining what to do with the kits that were exposed to unrecommended conditions (e.g., call product manufacturer for advice regarding excursion, destroyed tests may be used for training).
  - In the event of an HIV self-test lot number recall from a lot that has already been distributed to the public, consult regional Medical Officer of Health and Provincial Communicable Disease Control Unit for strategy and support to communicate to the public.

### 5.3. Client Eligibility

Regional public health teams will determine their HIV self-test distribution strategy based on availability and stock of HIV self-tests, local epidemiology of HIV, and opportunities in service delivery. For individuals receiving safer injection harm reduction supplies, sexually transmitted and blood-borne infections (STBBI) testing should be recommended, facilitated, or offered as feasible, and HIV self-tests actively offered as available.

Clients receiving an HIV self-test must self-report a minimum age of 16 years.

For clients below age of 18 years, regional public health teams offer options for point-of-care testing (POCT) or traditional STBBI testing first. HIV self-tests are not recommended for individuals aged under 18 years<sup>1</sup>, but if the client declines other testing options, distribution of an HIV self-test is acceptable for those aged 16 or 17 years.

### 5.4. Provision of HIV Self-Test Kit and Client Information

A maximum of 2 kits may be provided to each eligible client

Staff check the expiry date on the kit to ensure it has not expired. Do not distribute tests that are within 2 weeks of expiry.

Provide the client with the printed Manitoba HIV Self-Test Pathway<sup>3</sup> [Manitoba Care Pathways\\_EN.pdf \(dropbox.com\)](#)

The following messages are provided to the HIV self-test recipient:

- *This is a test you can do yourself at a later time wherever you feel safe and prepared.*

- *The test should be kept between 2 and 30 degrees Celsius, do not freeze it. If you have the test for a while before you use it, make sure you check the expiry date before you use it.*
- *When you do the test, it should be at room temperature, 15 to 30 degrees.*
- *There are instructions in the kit with pictures. I can walk through them with you if you like?*
- *You'll need to use the lancet in the kit to poke your finger, you'll need one or two drops of blood. Are you comfortable with that? People with bleeding disorders may want to consult their health care provider.*
- *Self-tests are only available for HIV. We recommend that people should be routinely tested for all STBBIs. Would you like help to find options for you to be tested for all STBBIs?*
- *Do you have any questions? Have you thought about what you would do if the test is positive?*
- *Finally, HIV self-tests are not recommended for people who are taking HIV medications (including post-exposure prophylaxis [PEP] or pre-exposure prophylaxis [PrEP]), or for people participating in an HIV vaccine study.*

## 5.5. Documentation and Tracking

HIV Self-Test Kits can be tracked along with other harm reduction supplies for the purpose of inventory reconciliation. Lot number of kits distributed to individuals do not need to be recorded, however the program inventory keeps track of all lot numbers received.

For clients who are not receiving services that would be documented in a health record (e.g., harm reduction supplies only), HIV self-test kit distribution does not need to be recorded in a health record. No individual identifiers need to be collected or recorded for HIV self-test distribution.

If a client is already receiving a service for which documentation in the health record is occurring, distribution of the HIV self-test to that individual should also be documented in the health record AND tracked according to the regional or site-specific process.

## 6. Validation and References

1. Health Canada (2000). Regulatory Decision Summary: INSTI HIV Self-Test. Available at: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS11033>
2. Biolytical (2018). INSTI HIV Self-Test Instructions for Use. Available at: <https://www.insti.com/wp-content/uploads/2021/10/51-1220-C-IFU-INSTI-HIV-Self-TestCA-EN.pdf>

3. I Am Health (n.d.). Care Pathways – Manitoba. Available at: <https://www.i-am.health/i-am-media-downloads>

Manitoba HIV Self-Test Pathway Direct Link:  
[https://www.dropbox.com/scl/fi/ram3qewqe3rx0ld2hsmiv/Manitoba\\_Care-Pathways\\_EN.pdf?rlkey=rnyxa5v86zk828vll3h8baps9&e=1&dl=0](https://www.dropbox.com/scl/fi/ram3qewqe3rx0ld2hsmiv/Manitoba_Care-Pathways_EN.pdf?rlkey=rnyxa5v86zk828vll3h8baps9&e=1&dl=0)