WHO Prequalification of Diagnostics Programme
PUBLIC ASSESSMENT REPORT

Product: INSTI HIV Self Test
WHO reference number: PQDx 0002-002-01

INSTI HIV Self Test, with product code 90-1071, manufactured by bioLytical Laboratories Inc., Rest-of-World (ROW) regulatory version, was accepted for the WHO list of prequalified diagnostics and was listed on 27 November 2018.

Summary of Prequalification Assessment for the INSTI HIV Self-Test[1]

	Date	Outcome
PQ listing	27 November 2018	listed
Dossier assessment	15 August 2013	MR
Product performance evaluation	13 June 2013	MR

MR: Meets Requirements

Report amendments and/or product changes.

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Public report amendment	Summary of amendment and change request reference, where applicable.	Date of report amendment
2.0	Addition of an intended use specific for HIV self-testing (INSTI HIV Self Test). The new configuration was adapted from their professional use product (INSTI HIV-1/HIV-2 Antibody Test) for which a WHO prequalification assessment has already taken place. Additional data was generated to meet requirements set out in the WHO Technical Specifications Series document	27 November 2018

[1] Dossier assessment and product performance evaluation for the INSTI HIV Self-Test were considered from the previous assessment of professional use product, INSTI HIV-1/HIV-2 Antibody Test, which was prequalified in 2013. Based on the product dossier assessment and product performance evaluation, INSTI HIV Self Test meets WHO prequalification requirements. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for INSTI HIV-1/HIV-2 Antibody Test. https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/

	TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing.[2]	
3.0	Updates in the instructions for use of the product	06 November 2019
4.0	Correction of WHO reference number on the header of the public report from PQDx 0002-002-00 to PQDx 0002-002-01.	30 August 2021
5.0	Changed the white pouch to a grey pouch with no other changes to the pouch material, specifications, or content on the labelling. Both white and grey labels will be used until the inventory with white labels is depleted.	7 January 2025
6.0	A minor administrative labeling change to one of the reagents included in the test kit. Specifically, the text on the reagent label has been revised from "Colour Developer" to "Color Developer." This change was implemented to align with U.S. FDA labeling requirements during the PMA approval process for the INSTI HIV Self Test.	10 March 2026

Intended use:[3]
According to manufacturer's claim, "*INSTI HIV Self Test is a single use in vitro test that is used as a self-test for the detection of antibodies to HIV-1 and HIV-2 in infected individuals using a drop of human fingerstick blood*."

Test kit contents:
The INSTI HIV Self Test is packaged as a single test kit with product code 90-1071. One test kit will contain materials and test components for single use only.

Product code	Item
90-1071	1 x Blotted Membrane Unit (BMU)
	1 x 1.5 mL Sample diluent bottle (Bottle 1)
	1 x 1.5 mL Color developer bottle (Bottle 2)
	1 x 1.5 mL Clarifying solution bottle (Bottle 3)
	1 x Sterile single-use lancet
	1 x Adhesive bandage
	1 x Instructions for Use (IFU)
	1 x Alcohol swab

[2] http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=E2718EC36EFD314EFE87E902244528E1?sequence=1

[3] This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements.

Storage:
The test kit must be stored between 2 and 30 °C.

Shelf-life upon manufacture[4]:
15 months.

Labelling review

The labelling submitted for INSTI HIV Self Test was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer package artwork	Pouch, INSTI HIV, Self Test, NPWS, ROW, EN	C	23/02/2021	51-1266
Pouch / Device label	Webstock, HIV-1_HIV-2 Membrane	A	04/04/2024	51-1622
Reagent bottle labels	Label, Sample Diluent	E	01/10/2016	51-1040
	Label, Colour Developer	F	10/10/2025	51-1041
	Filled and Labeled Clarifying Solution	E	04/10/2016	51-1042
Accessory labeling (e.g., pipettes, buffer caps)	NA	NA	NA	NA
Instructions for Use (IFU)	IFU, INSTI HIV Self Test, NPWS, ROW, EN	C	12/02/2021	51-1267

[4] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

Labels

Description	Box Artwork	Size	Colours
Pouch, INSTI HIV, Self Test, ROW, EN	51-1266C	8” x 6”	PMS7710 C, PMS 2225 C, PMS 2587 C, Flood white x2

3 side seal pouch 8”w X 6” h

tear notch 1” away from side of pouch

.375” Seal

.375” Seal

LOT # SPACE 1.80 in

BACK PANEL

INSTI®

HIV Self Test

Instant Result
No timers, no wait time

Simple
Just 1 drop of blood

Early Detection
Proven to detect the earliest HIV antibody (IgM)

Single use HIV screening test

CONTENTS: 1 TEST DEVICE, INSTRUCTIONS, 3 BOTTLES, BANDAGE, LANCET, ALCOHOL WIPE

bioLytical®

Manufactured by bioLytical Laboratories Inc.
406-13251 Delf Place, Richmond, BC V6V 2A2 Canada
www.INSTI.com

IVD 2°C 30°C

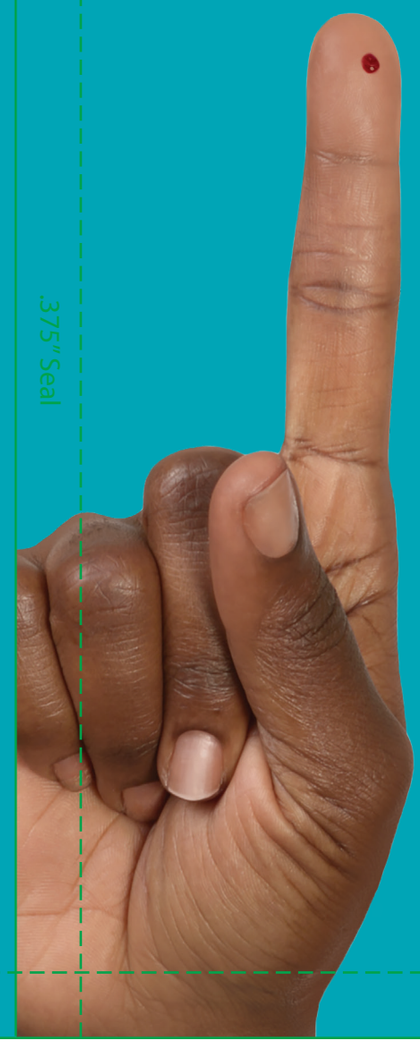
Do not use if you are on Anti-Retroviral Treatment (ART)

6 86597 01071 6

REF 90-1071

51-1266C

Result in **1 Minute**



INSTI®

HIV Self Test

Over 99% accurate

1 Drop. 1 Minute.

Negative

Positive

.375” Seal

.375” Seal

.375” Seal

.375” Seal

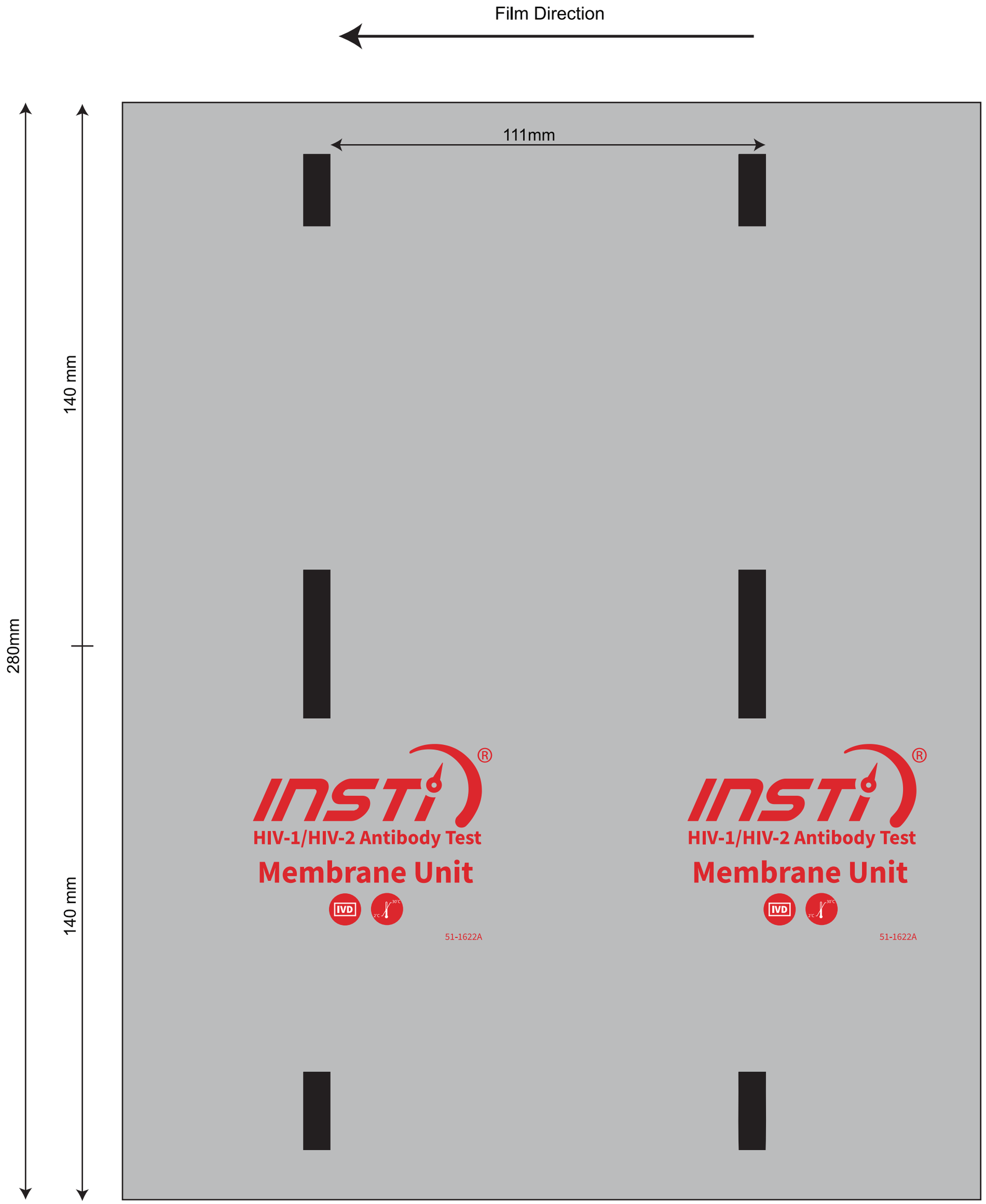
8”

6”

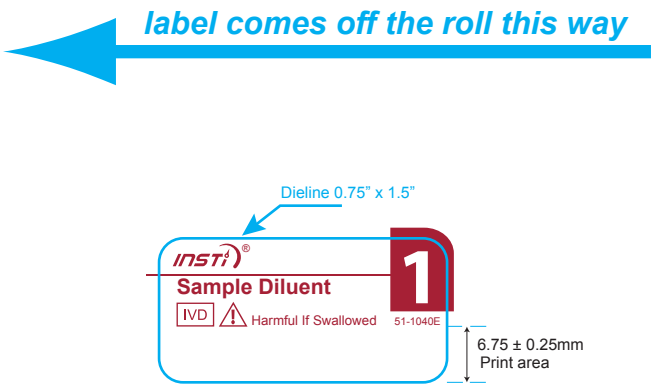
6”

12”

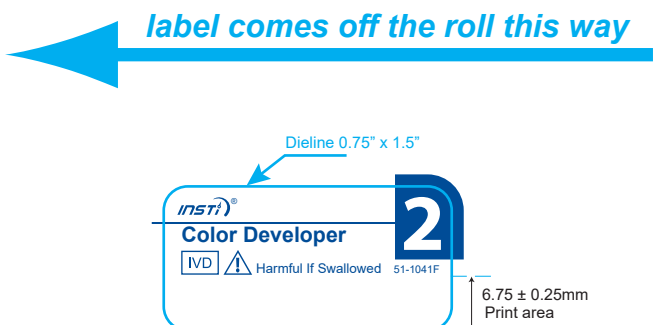
Description	Box Artwork	Size	Colours	
Webstock, HIV-1HIV-2 Membrane (MAM)	51-1622A	See proof	PMS1795 C	Flood White X 2
			Black	Cool Gray 4C



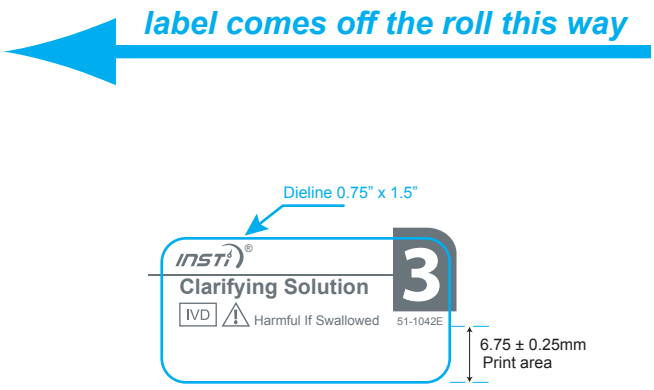
Description	Artwork	Finishing	Size	Colour
AW, Label, Sample Diluent	51-1040E	None	0.75” x 1.5”	Red PMS 201



Description	Box Artwork	Size	Finishing	Colours
Label, Color Developer	51-1041F	0.75” x 1.5”	None	PMS 2945 C



Description	Artwork	Finishing	Size	Colour
AW, Label, Clarifying Solution	51-1042E	None	0.75” x 1.5”	Grey PMS 431



2. Instructions for use[5]

[5] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

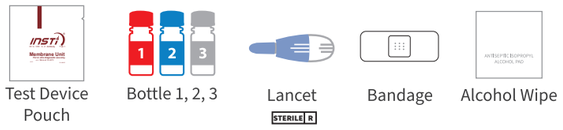
ENGLISH

INSTI® HIV Self Test

insti.com

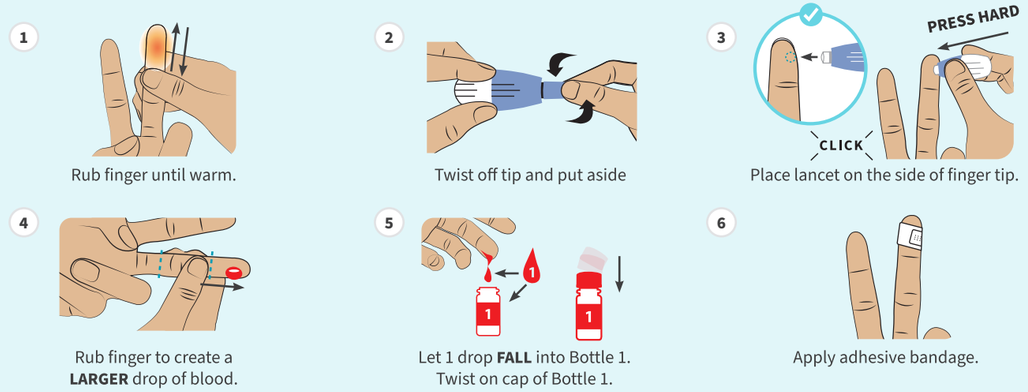
Do not use if you have a bleeding disorder or are on ART
Do not use if the test device pouch is broken
Do not use if past expiration date on outer packaging

Contents

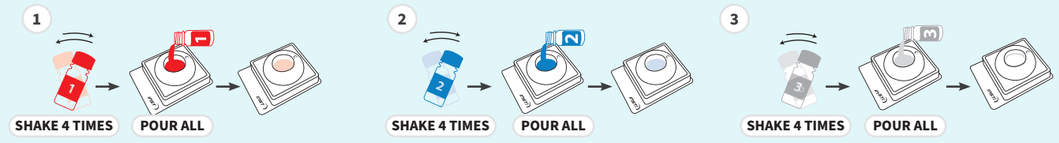


Preparation

Step 1: Collect Blood



Step 2: Test



Step 3: Read Result

Read your result right away

Intended Use

The INSTI HIV Self Test is a single use *in vitro* test that is used as a self-test for the detection of antibodies to HIV-1 and HIV-2 in infected individuals using a drop of human fingerstick blood.

For Questions Or Further Support

+1 604 204 6784
customercare@biolytical.com
www.insti.com

Questions and Answers

General

1 What is HIV and AIDS? The 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 system. 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. Though there is no cure for HIV infection, treatment for HIV is highly effective.

INSTI® HIV Self Test is designed to detect HIV antibodies in a human blood sample. These antibodies are produced by your body's immune system in response to harmful organisms like viruses and bacteria in order to defend against infection.

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.

About the Test

3 How does the INSTI HIV Self Test work? INSTI® HIV Self Test is a qualitative immunoassay that uses blood to detect HIV-1 and HIV-2 antibodies. The test produces a result in the form of either one dot (control dot) or two dots (control and test dots). The control dot is our built-in control feature that appears if you have performed the test correctly. A test dot will only be visible if the sample contains antibodies to HIV.

4 How early can this test detect HIV? Antibodies that can be detected by this test can appear 4-12 weeks after exposure or in some cases as early as 3 weeks after exposure[1]. However a small percentage of people will take up to 3 months to develop detectable levels of HIV antibodies. This amount of time after exposure before your body has developed antibodies is referred to as a "window period".

If your body has not yet produced these HIV antibodies, you may falsely test negative. If you have been exposed to HIV within the last 3 months, and your results are negative, it is important to test again after 3 months.

[1]Cohen M, et al. (2010). The Detection of Acute HIV Infection. The Journal of Infectious Diseases, 202(S2):270-277. doi:10.1086/655651

Test Procedure

5 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.

6 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 fingertip that is smooth and not calloused and away from your fingernail.

7 Was my test done correctly? The INSTI® HIV Self Test has a built-in control dot that will appear if you have performed the test correctly, including adding the proper sample type and the amount of blood sample. If the control dot does not appear, your test is invalid and did not work. You will need to repeat with a new test. If repeated invalid results occur, go to clinic for confirmatory testing.

Test Results

Read your result within 5 minutes. If you are unsure of your result, go to clinic for confirmatory testing.

8 What happens if my test 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 the test in 3 months.

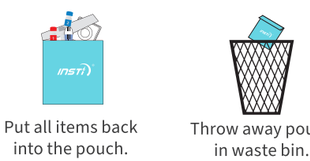
9 What happens if my test result is positive? A **Positive Result**: Go to a clinic as soon as possible and inform him/her that you have performed a self test for HIV. All positive results must be confirmed by a laboratory test.

HIV is preventable and you can help stop the spread of HIV. It is highly recommended to avoid high risk sexual behaviors to prevent passing HIV to your partner. 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.

10 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 (ART)
  - > Have a severe blood disorder, such as multiple myeloma
  - > Have higher than normal haemoglobin
- A positive result can occur if you participated in an HIV vaccine study, but it may not mean that you are infected with HIV.

Disposal



Blood can transmit infectious diseases. Clean up spills. Dispose in accordance to local regulations.

2°C 30°C Store at 2 - 30°C
Caution. Contains sodium azide. Harmful if swallowed.
Consult Instructions for Use
Do not reuse
Use by date
IVD For in vitro diagnostic use
STERILE R Sterilization using irradiation
REF Catalogue Number
LOT Lot number
Manufactured by

Manufactured by
bioLytical LABORATORIES
bioLytical Laboratories, Inc.
406 - 13251 Delf Place
Richmond, BC, Canada V6V 2A2
+1 604-204-6784
www.biolytical.com

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