CLIA WAIVED

INSTI®

HIV-1/HIV-2 Antibody Test Training Pack

Results in 1 minute

bioLytical® LABORATORIES

insti.com • bioLytical.com

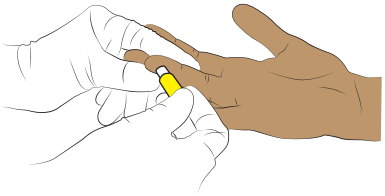
INSTI®

Table of Contents

INSTI® HIV-1/HIV-2 Antibody Test

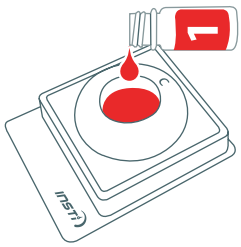
The FDA-approved, Health Canada approved, CE marked, WHO Prequalified, CLIA-waived, INSTI® HIV-1/HIV-2 Antibody Test is an *in vitro* qualitative test for the accurate detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in venous whole blood, fingerstick blood and plasma. Designed as a screening assay, INSTI® contains all the testing components you need in one convenient package. Together with other core strategies, INSTI® is an invaluable tool in the management and prevention of HIV/AIDS.

4 Simple Steps...



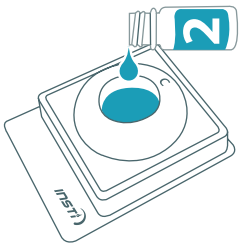
Sample

Collect 50µL of sample and add into Bottle 1.



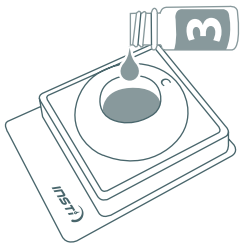
Bottle 1

Pour into Membrane Unit. HIV antibodies, if present, are captured on the test dot by proteins on the membrane.



Bottle 2

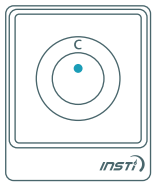
Pour into Membrane Unit to generate a blue control dot and a second dot if HIV antibodies are present.



Bottle 3

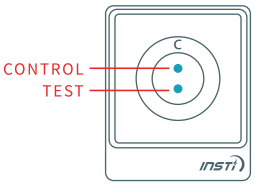
Pour into Membrane Unit to reduce background color and produce more distinct dot(s).

...to one clear answer in 60 seconds.



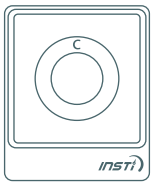
Non-Reactive

One Dot



HIV-Reactive

Two Dots:
Control and Test Dots



Invalid

No Dots

Always read results with INSTI® logo facing you

Advanced Diagnostic Technology

FAST
+ Results in 60 seconds

SIMPLE
+ Easy to understand instructions
+ All reagents in ready-to-use bottles
+ No measuring or drop counting
+ No timing required
+ No additional materials required
+ No refrigeration required

RELIABLE
+ Built-in true human IgG Control assures test validity

CONVENIENT
+ Utilizes venous whole blood, fingerstick blood, or plasma

EXCLUSIVE
+ Uses proprietary HIV-1 and HIV-2 antigens

ACCURATE
+ Excellent correlation with approved laboratory methods for HIV antibody detection
+ Proven early antibody detection

SENSITIVE & SPECIFIC
+ Offers a > 99% combined accuracy

COMMITMENT TO QUALITY

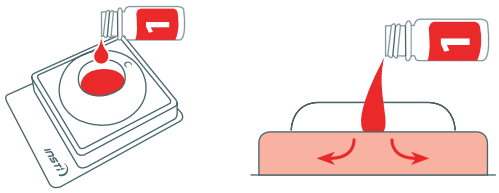
ISO 13485

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

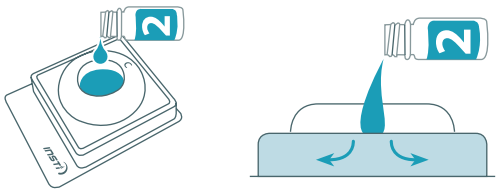
To ensure the integrity and quality of every test, INSTI® is manufactured in a state of the art facility with a fully implemented Certified Quality Management System (ISO 13485:2016 and MDSAP).

All raw materials and processed kit components are thoroughly inspected and tested to ensure they meet strict quality guidelines. Checks at each step of manufacturing ensure continued quality control. Rigorous in-process testing is performed during each production run. All INSTI® solutions are proprietary formulations allowing us to control quality in our own laboratories.

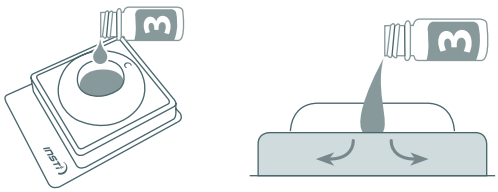
Lateral View of Membrane



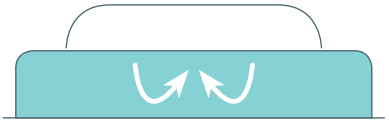
1 Sample Diluent absorbs through membrane into absorbent pad.



2 Color Developer blends with sample in absorbent pad.



3 Clarifying solution washes away other solutions in absorbent pad.



4 Over time, the solutions in the absorbent pad spread uniformly and can stain the membrane from below, occasionally resulting in a faint shadow at the test dot. Always follow the recommended read window.

Quick Reference Guide

- Cover the work space with a new, disposable, absorbent material
- Use new disposable gloves
- Ensure temperature in the testing area is between 2–30°C (35.6–86°F)

Preparation

- Open the membrane unit pouch by tearing the slit located along the side.
- Make sure the membrane unit tab is facing towards you.
- Place Bottle 1 and twist off the red cap; set cap and opened bottle in front of you.

INSTI® HIV-1/HIV-2 Antibody Test

Bottle 1
Sample Diluent

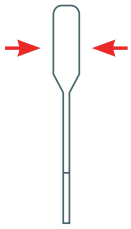
Bottle 2
Color Developer

Bottle 3
Clarifying Solution

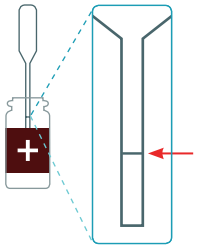
Lancet | Pipette | Alcohol Pad | Membrane Unit

External Quality Control: Sample Collection

Positive and Negative Controls are to be tested individually with INSTI® HIV-1/HIV-2 Antibody Test.



1. Take the pipette and lightly depress the top bulb.



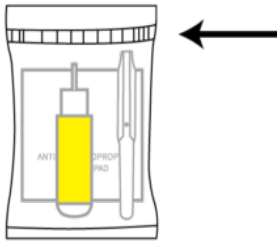
2. Insert pipette tip into the clear liquid in the Control Bottle. Slowly release the top bulb to fill the pipette stem to the black line.

3. Transfer the liquid to Bottle 1 by completely squeezing the bulb.

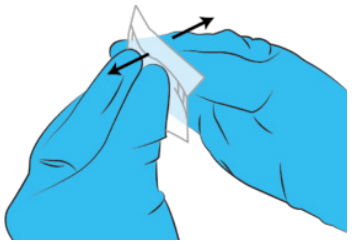
4. Recap and invert a few times.

Note: Use a new pipette for each Control sample collection.

Gather the Fingerstick Support Materials



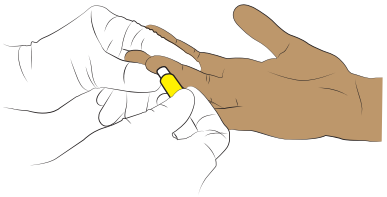
The clear sealed bag contains the lancet, pipette and alcohol pad.



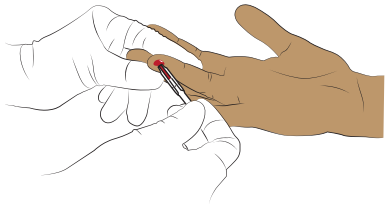
Hold packet up to identify seam that is less visible. Open from this end by pulling it apart.

Guidelines For Obtaining a Fingerstick Sample

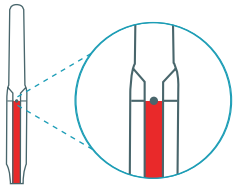
Review package insert and read these instructions completely before starting fingerstick blood collection.



- Clean and dry patient's hands.
- Twist and pull the yellow tip out of the lancet.
- Place the lancet on the fingertip slightly off center, press firmly until you hear a click to puncture the skin.



- SQUEEZE the finger to create a bead of blood.
- Place the pipette tip HORIZONTALLY OR BELOW HORIZONTAL into the blood bead. DO NOT SQUEEZE the pipette bulb; pulse the finger to keep a bead of blood forming.



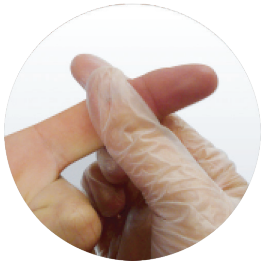
- **To fill the pipette,** capillary action will automatically draw the blood to the black fill line.
- Be sure to not cover the air hole between the black line with your fingers.

Detailed Procedure: Collecting a Fingerstick Blood Sample

Refer to training video for further assistance.
www.insti.com/hiv-test/

1 Patient to wash hands thoroughly in warm soapy water or use alcohol pad to clean fingertip. Allow their hands to dry.

2 With gloves on, milk fingers towards the tip while observing which finger is optimal—look for the one that has the deepest color for the ultimate blood flow.

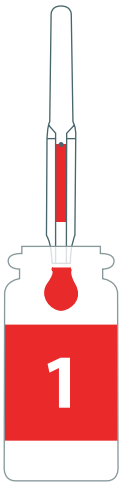


3 Hold the finger correctly as you use the lancet.

4 Angle the capillary tube downwards when collecting the blood sample so capillary action will be assisted by gravity.

Tips
- Continue to milk the finger.
- Obtain a good bead of blood before inserting the pipette.
- Hover pipette in the bead of blood. Avoid direct contact with the skin.

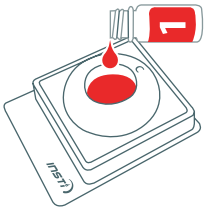
Test Procedure (continued)



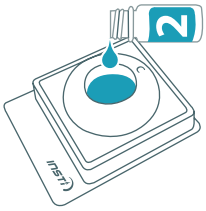
1. When the pipette is filled, TRANSFER THE SPECIMEN (BLOOD) INTO BOTTLE 1 by squeezing the pipette bulb.

+ If it does not release, cover the air hole on the black line with your fingers and squeeze again.

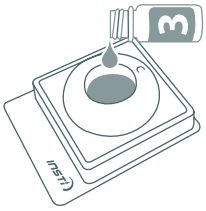
2. Recap **Bottle 1**, and invert a few times.



3. Pour Bottle 1 with specimen into the center of the membrane unit. Allow to absorb completely, then immediately proceed to the next step.



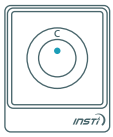
4. Invert Bottle 2 a few times before pouring into the membrane unit. Allow to absorb completely, then immediately proceed to next step.



5. Pour Bottle 3 into the membrane unit. Allow to absorb completely then interpret the result.

Interpretation of Result

Results must be interpreted within five minutes.



NON-REACTIVE

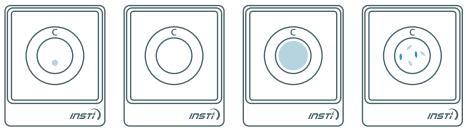
Only one blue control dot appears on the top.

A NON-REACTIVE test result means that HIV antibodies were not detected in the specimen. The test result is interpreted as negative for HIV antibodies. However, this does not exclude possible infection with HIV.

REACTIVE

Two blue dots appear: one control and one test dot. (Note: One dot may be darker than the other.)

A REACTIVE test result means that HIV antibodies have been detected in the specimen. The test result is interpreted as Preliminary POSITIVE for HIV antibodies.



INVALID

No control dot is an invalid result.

An INVALID test result means that the test was run incorrectly or insufficient specimen was added. Repeat the test once with a new sample collection and INSTI® test.

Frequently Asked Questions

What is the accuracy of the INSTI® kit?

Proven accuracy of over 99%.

What kind of storage conditions are needed?

INSTI® should be stored at 2-30°C (35.6–86°F).

Does INSTI® differentiate HIV-1 from HIV-2 Antibodies?

No. INSTI® contains antigens from HIV-1 and HIV-2 in the membrane unit and can detect antibodies to HIV-1 and/or HIV-2 in patients' specimens, but it will not differentiate the two.

Is a reactive INSTI® test conclusive of HIV diagnosis?

No. As in all assays for HIV antibody, false positives can occur infrequently with INSTI®. INSTI® is considered as a first-line test only, and all patients with reactive INSTI® results should be re-tested with an HIV confirmatory assay before final HIV antibody status can be determined.

Does INSTI® only react with whole blood samples?

No, you can use the INSTI® kits with whole blood, fingerstick blood, or plasma samples.

Do's & Don'ts

DO'S

+ Read the entire package insert and become familiar with its contents prior to beginning the test.
+ Ensure all test components and any stored specimens are stored at 2–30 °C (35.6–86 °F). If refrigerated, bring it to room temperature 15–30 °C (59–86 °F) before performing the test.
+ Use INSTI Controls to ensure proper kit performance.
+ Warm the fingertip before using the lancet, to ease blood flow.
+ Allow the alcohol from the swabbed fingertip to dry completely before applying the lancet.
+ After addition of blood sample to Bottle 1, invert a few times and immediately pour into the membrane unit.
+ Invert Bottle 2 a few times.
+ Use local universal precaution guidelines for infectious materials in handling and disposing of specimens and used test materials.

DON'TS

× Do not add specimen directly to the INSTI® membrane unit
× Do not mix reagents from different lots.
× Do not use reagents or kits beyond the stated expiration date on the outer packaging.
× Do not use the test kit if there is any sign of damage to or previous opening of the sealed membrane pouch, or leakage in any of the reagent bottles.
× Do not conduct repeated sampling of fingerstick blood with the capillary pipette. 50µl should be collected in one continuous flow.
× Do not dilute the specimens prior to adding to Bottle 1 of the INSTI® test.
× Do not add the test sample/sample diluents' contents to the membrane unit without mixing.
× Do not introduce delays between any of the INSTI® procedural steps.

How long does it take to perform a single test?

INSTI® preparation is minimal and results show up in 60 seconds. Results are interpreted immediately after pouring the Clarifying Solution (Bottle 3) into the membrane unit.

Are INSTI® results as accurate as laboratory-based HIV testing procedures?

Yes. INSTI® is a registered and approved medical device and has undergone extensive clinical trials that have demonstrated its accuracy in direct comparison to laboratory-based methods. Much of this data is published in the package insert.

Does INSTI® detect HIV antibodies early in the course of infection?

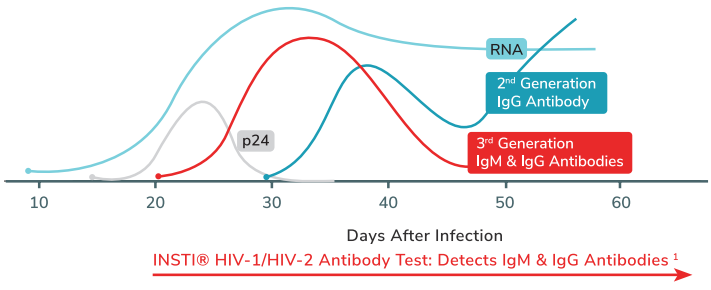
Yes. In commercial HIV seroconversion panels and 'real life' documented seroconversion cases, INSTI® is equivalent to the most sensitive laboratory-based assays in early antibody detection. However, patients who are in the pre-antibody "window period" of HIV infection may not be reactive in the INSTI® test.

What is a window period?

The window period is the time from the HIV infection to when a test can correctly give a positive result. If a patient may have been exposed to HIV within the last 12 weeks, and the results are negative, they would need to test again after at least 12 weeks have passed since their exposure.

How soon post-infection can INSTI® detect HIV antibodies?

Depending on the person and how quickly their immune system generates HIV antibodies after infection, the INSTI® HIV Test can become positive in as little as 21–22 days after infection[1], or it could take up to three months to generate a positive result.



[1] Moshgabadi, N., et al. Sensitivity of a rapid point of care assay for early antibody detection is enhanced by its ability to detect HIV gp41 antibodies, *Journal of Clinical Virology* (2015) 71:67–72. http://dx.doi.org/10.1016/j.jcv.2015.08.005

Do INSTI® kits have a built-in sample addition control?

Yes, the procedural control for the INSTI® kit consists of a protein capable of capturing the IgG normally present in human blood components. IgG is present in blood components in both normal and HIV positive human specimens. Captured IgG reacts with a chromatic agent to produce a visual sign (dot) on the membrane.

What is the stability of the test results in the test membrane?

The test results will remain visible in the INSTI® test unit for an indefinite period after performing the test. We recommend reading the results immediately after the test for optimal dot intensity.

Where can I learn more about bioLytical and INSTI®?

For inquiries or to learn more, please visit our websites at: www.insti.com and www.bioLytical.com

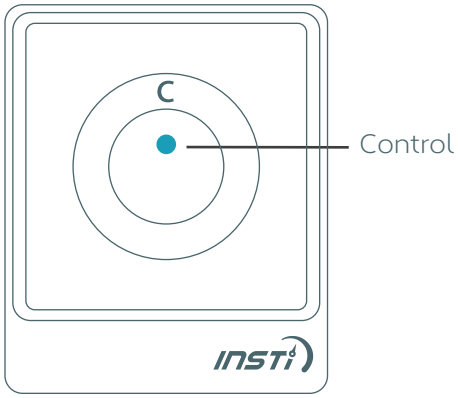
Quality Control

Built-in Sample Addition Control

The INSTI® HIV Antibody Test has a built-in sample addition control capture that demonstrates assay validity and adequate sample addition. A blue color in the control dot indicates that the proper specimen was added and that the assay procedure was performed correctly. The control dot will be visible on all valid INSTI® tests.

With INSTI®, if the control dot appears, this indicates the following:

- The test has been performed correctly.
- The flow-through mechanism of INSTI® has worked properly.
- The correct amount and type of specimen has been added to the membrane unit.
- In the absence of a visible test dot, this is a valid non-reactive result.
- Any test dot that is readily visible is a valid reactive result.



External Quality Controls

The INSTI® Controls are used to ensure that the test functions correctly. It is advisable that external control material, consisting of one HIV negative, one HIV-1 positive, and one HIV-2 positive, be tested with INSTI®:

- At regular intervals or with each batch of INSTI® test run,
- For new INSTI® use verification,
- When switching to a new lot number of INSTI® test kits
- Or as part of your laboratory's standard quality control procedures

It is the responsibility of each user of the INSTI® HIV Antibody Test to establish an adequate quality assurance program to ensure proper performance under their specific locations and conditions of use.

INSTI® Controls

Positive and Negative Controls are to be tested individually with INSTI® HIV-1/HIV-2 Antibody Test.

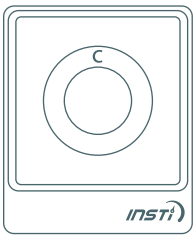
HIV-1 POSITIVE CONTROL

HIV-2 POSITIVE CONTROL

HIV NEGATIVE CONTROL

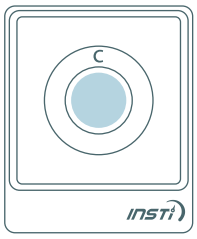
Troubleshooting

Invalid Results



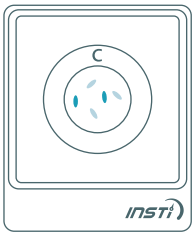
NO DOTS

Usually an indication that substantially less than 50µl of specimen was used. Could also be an indication that the INSTI® solutions were added in the wrong sequence. Testing should be repeated.



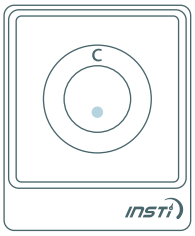
SOLID COLOR

A uniform blue tint across the entire membrane which obscures the control and test dots is an indication that the reagents were not used in the correct sequence. Testing should be repeated.



SPECKS ON THE MEMBRANE

This could be caused by slight aggregation of the contents of Bottle 2. If the control dot is clearly visible, test results are valid even with specks on the membrane. Specks can also appear on the membrane if the kit was used past the expiry date, in which case the results are not considered valid.



TEST DOT ONLY

This might occur very rarely and may be an indication that the test procedure has not been followed properly or there was a manufacturing problem. Testing should be repeated, and these occurrences should be reported to bioLytical Laboratories immediately.

Additional factors which may cause invalid results:

- The membrane unit has not been used immediately after opening.
- Reagents from different kit lots are combined to perform the INSTI® test.
- Using reagents in the wrong order.
- Some reagents are spilled while pouring into the membrane unit.
- The INSTI® kits were stored at temperatures outside the approved storage temperature range.
- The membrane has been contaminated causing blockage of flow.

Product Information

Information Type	Product Details
Method	Flow-through
Time to results	As little as 60 seconds
Storage conditions	35.6–86 °F (2–30 °C)
Test shelf life	15 months
Sample type	Fingerstick, venous whole blood, or plasma
CLIA complexity	Waived for fingerstick blood, moderate complexity for venous whole blood and plasma

If the second test result is also invalid, contact technical assistance with the affected lot numbers at: 1 604 204 6784 or customercare@biolytical.com

bioLytical® LABORATORIES

Improving the quality of people's lives by providing innovative solutions for infectious disease diagnosis.

Head Office
1108-13351 Commerce Parkway
Richmond, British Columbia
Canada V6V 2X7

US Office
1465 Slater Road PO Box 5007
Ferndale, Washington
United States 98248

Main 1 604 204 6784
Toll-Free 1 866 674 6784
Fax 1 604 244 8399

insti.com | bioLytical.com

65-3001(C) 01/2019