PATHKITS

SIMPLE HIV 1 & 2

Product Code: **PKRK014**
Kit Contents (**25 Kits**)
Shelf Life: 24 Months

Kit Components	Quantity (Units)
Test Strip	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

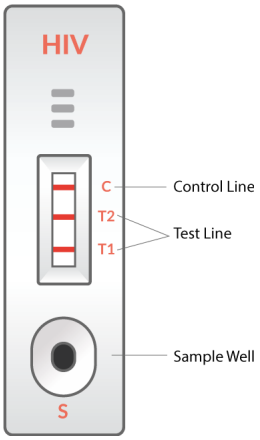
Acquired immunodeficiency syndrome (AIDS) is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus (HIV) (1,2). HIV virus belongs to the family Retroviridae Genus Lentivirus which is a single stranded RNA virus but after the infection of target cell, the viral RNA genome is converted (reverse transcribed) into double-stranded DNA by a virally encoded enzyme, reverse transcriptase (3). Human immunodeficiency Virus (HIV) is transmitted by both sexually transmitted infection (transfer of blood, pre-ejaculate, semen, and vaginal fluids) and non-sexually (infected mother to her infant during pregnancy, during childbirth by exposure to her blood or vaginal fluid, and through breast milk). According to the World Health Organization (WHO) Acquired Immune Deficiency Syndrome (AIDS) and AIDS related complex is a major global public health issue, having claimed 36.3 million lives so far. There is no cure for HIV infection. However, with increasing access to effective HIV prevention, diagnosis, treatment and care, including for opportunistic infections, HIV infection has become a manageable chronic health condition, enabling people living with HIV to lead long and healthy lives (4). An accurate diagnosis of Acquired Immune Deficiency Syndrome (AIDS) and AIDS related complex (ARC) caused by the HIV Virus by The Simple HIV 1&2 allows for the rapid, qualitative detection of a HIV 1&2 antigens directly from fingerstick whole blood, venipuncture whole blood and plasma specimens.

Intended Use

Simple HIV 1&2, Rapid Human Immunodeficiency Virus Test (Serum/Plasma) is a rapid immunoassay for the qualitative detection of Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in serum or plasma. It is for professional *in vitro* diagnostic use only.

Principle

Simple HIV 1&2 Rapid Human Immunodeficiency Virus Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HIV 1 and HIV 2 recombinant antigens in the test line region T1 and T2 of the device. When a specimen is applied at one end of the membrane, it reacts with HIV recombinant antigen coated gold conjugate in the test. The mixture then migrates chromatographically by capillary action and reacts with the recombinant HIV recombinant antigens on the membrane in the test line region.



If the specimen contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line region T1 & T2, showing a positive result. The absence of the colored test line T1 & T2 indicates that the serum or plasma does not contain the anti-HIV antibodies, showing a negative result. A colored line will always appear at the control line region to serve as a procedural control. This indicates if the proper volume of specimen has been added and that membrane wicking has occurred.

Warnings and Precautions

1. Read these instructions for use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.

Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198
Email: info@pathkits.com

8. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens.
11. The test results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15–20-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e., an electric fan or strong air-conditioning.
13. Specimen with extremely high concentrations of red blood cells, fibrin should be re-centrifuged before use

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Specimen Collection and Handling

Specimens to be tested should be obtained and handled by standard methods for their collections.

1. **Serum:** Allow the blood to clot, then centrifuge to separate the serum.
2. **Plasma:** Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
4. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials Required but not provided

1. Timer or Stopwatch.
2. PPE and other consumables for collection and disposal of samples.

Limitations

1. Although a positive result may indicate infection with HIV- 1 or HIV- 2 virus, a diagnosis of HIV infection can only be made on clinical grounds, if an individual meets the case definition for HIV infection established by the Centers for Disease Control. For samples repeatedly testing positive, more specific supplemental tests must be performed. Immunochromatographic testing alone cannot be used to diagnose HIV infection even if the antibodies against HIV- 1/HIV-2 are present in-patient specimens. A Negative result at any time does not preclude the possibility of HIV-1/HIV- 2 infection.
2. The HIV-1&2 rapid test is only used for the HIV antibodies screening test; the final diagnosis of HIV infection should be definite by the confirmation test.
3. A “Hook Effect “may be seen with very strong positive samples to weaken the color intensity of test bands. Dilute the sample 5 to 10 times can help improve this sample specific effect.

Test Procedure

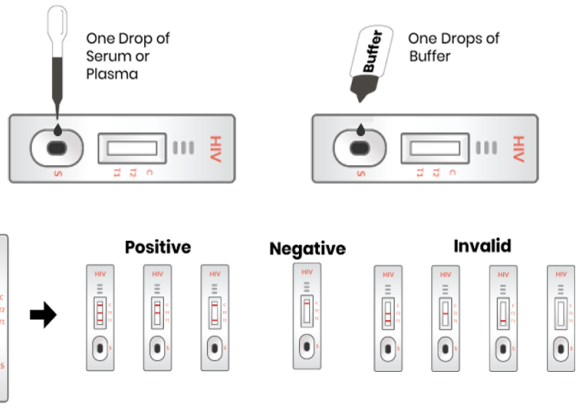
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
3. **For Serum or Plasma Specimens**: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
4. Wait for the red line(s) to appear. The result should be read in 15 minutes.
7. Do not interpret the result after 15 minutes
8. Discard the test card immediately after reading the results at 20 minutes.

Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198
Email: info@pathkits.com

PATHKITS

SIMPLE HIV 1 & 2



Interpretation of results

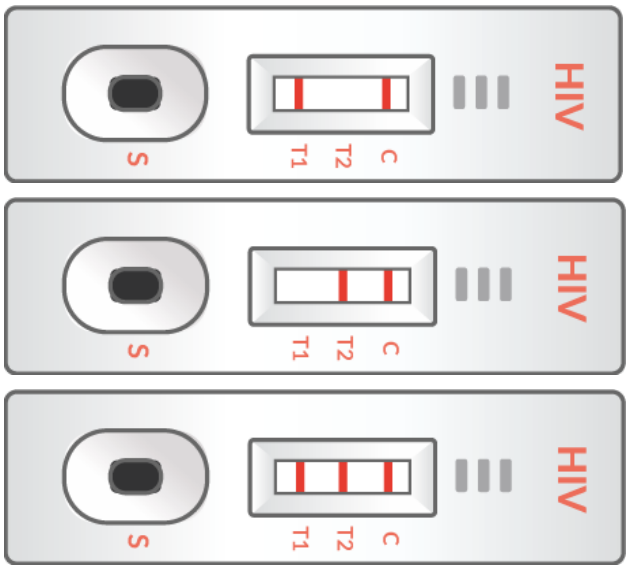
Positive Results

(Please refer to the illustration below)

HIV - 1 POSITIVE: In addition to the presence of the C line, if only the T1 line develops, the test indicates the presence of HIV-1 antibodies in the specimen. The result is HIV-1 positive.

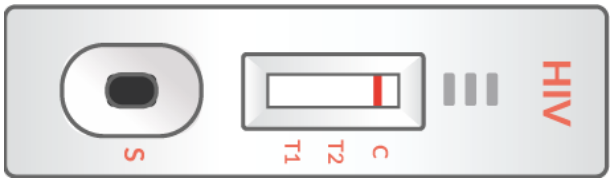
HIV - 2 POSITIVE: In addition to the presence of the C line, if only the T2 line develops, the test indicates the presence of HIV-2 antibodies in the specimen. The result is HIV-2 positive.

HIV - 1 and HIV - 2 POSITIVE: In addition to the presence of the C line, both the T1 and the T2 lines develop, the test indicates the presence of HIV-1 and HIV-2 antibodies in the specimen. The result isHIV-1 and HIV-2 positive.



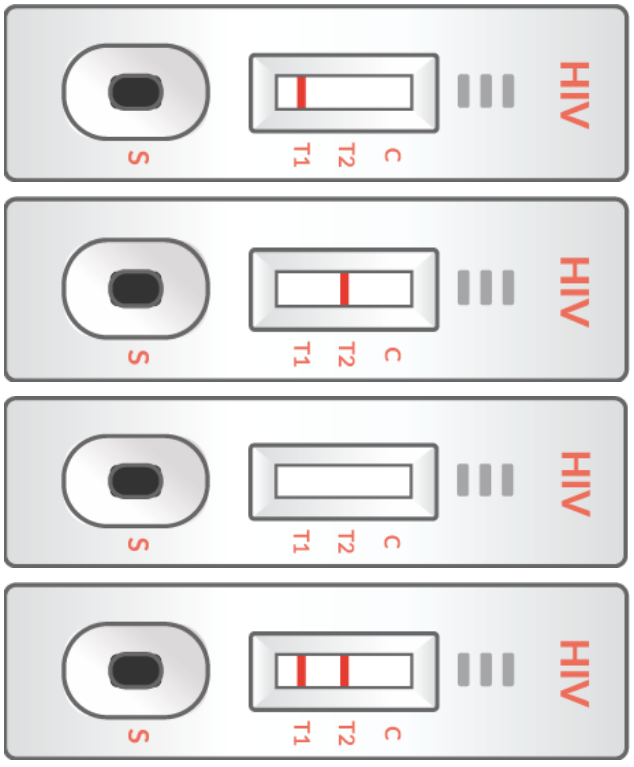
NOTE: Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

Negative Result: Appearance of only one coloured line at Control (C) region and absence of any color in both test bands (T1 and T2) means that no HIV antibodies were found in the sample.



Invalid Results

Control line does not appear in the Control (C) region. If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198
Email: info@pathkits.com

Quality Control

Internal procedural controls are included in the test. A Colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume.

References

1. Gallo, R. C., Salahuddin, S. Z., Popovic, M., Shearer, G. M., Kaplan, M., Haynes, B. F., ... & Markham, P. D. (1984). Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. *science*, *224*(4648), 500-503.
2. Curran, J. W., Morgan, W. M., Hardy, A. M., Jaffe, H. W., Darrow, W. W., & Dowdle, W. R. (1985). The epidemiology of AIDS: current status and future prospects. *Science*, *229*(4720), 1352-1357.
3. Smith, J. A., & Daniel, R. (2006). Following the path of the virus: the exploitation of host DNA repair mechanisms by retroviruses. *ACS chemical biology*, *1*(4), 217-226.
4. https://www.who.int/news-room/fact-sheets/detail/hiv-aids

Technical Assistance

For customer support, please contact our Technical Support:
PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P),
Gurgaon -122001, India Customer care No.: +91-7303429198
Email: info@pathkits.com