HIV 1/2

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC13

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for subtyping of antibody to HIV 1 and/or 2 in human serum and plasma samples.

CLINICAL SIGNIFICANCE

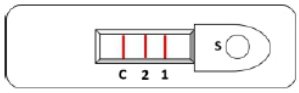
HIV is the etiologic agent of Acquired immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with a high potential of risk for developing AIDS. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and -2 elicit an immune response.

Detection of HIV antibodies in serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.

Despite the differences in their biological characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

PRINCIPLE

The HIV ½, a 3-line Test Device (serum/plasma) is a qualitative, membrane based immunoassay for the detection of antibody HIV in serum or plasma. The membrane coated with recombinant HIV antigens on the test line region of the device.



When a serum or plasma specimen is applied at one end of the membrane, it reacts with recombinant HIV antigen coated particle that has already been applied to the specimen pad at the same end. The mixture then migrates chromatographically towards the other end of the membrane and reacts with the recombinant HIV antigens on the membrane in the test line region. If the serum or plasma contains antibodies to HIV-1 or HIV-2, a coloured line will appear in the test line regions for either HIV-1 and/or HIV-2, showing a positive result. The absence of the coloured line indicates that the serum or plasma does not contain the anti-HIV antibodies, showing a negative result. To serve as a procedural control, a coloured line will always appear at the control line region if the test has been performed properly.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Instructions for use.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The HIV 1/2 3-line Test Device (serum/plasma) can be performed using either serum, plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. 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. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

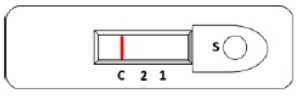
TEST PROCEDURE

Allow test cassette, specimen, 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 flat surface. Hold the dropper vertically and suck 10 µl of serum/plasma up to notch level and then press dropper to dispense sample in to the sample well (S) of the test device.
3. Then add 2 drops (70 µl) of buffer from the dropper bottle to the sample well (S) of the device and start the timer. Avoid trapping air bubbles in the sample well (S).
4. Wait for the red line(s) to appear. The test line should be read at 15 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:



One red line appears in the control region (C). No apparent red or pink line appears in the test regions (1 or 2).

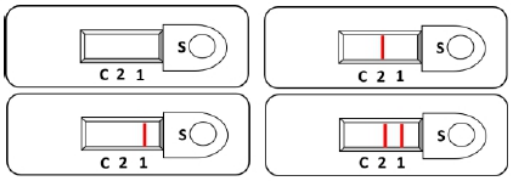
POSITIVE RESULT:

HIV-1 Positive:
The presence of a band at 'C' and at '1' within the Result Window, indicates a positive result for HIV-1.

HIV-2 Positive:
The presence of a band at 'C' and at '2' within the Result Window, indicates a positive result for HIV-2.

HIV 1 & 2 Positive:
The presence of a band at 'C' and bands at '1' and/or '2' within the Result Window, no matter which band appear first, indicates a positive result for HIV-1 or/and HIV-2 respectively.

INVALID TEST:
No visible band at the control region. Repeat with a new test device.



NOTE: The intensity of the red colour in the test line region (T) will vary depending on the concentration of anti-HIV 1/2 antibodies present in the specimen. However, neither the quantitative value nor the rate of increase in anti-HIV 1/2 antibodies can be determined by this qualitative test.

QUALITY CONTROL

Although the testing device contains an internal quality control (red coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

LIMITATIONS

1. The test is for in vitro use only. The test should be used for the detection of antibodies to HIV in serum or plasma.
2. The test will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 and/or -2 infections.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or western blot analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of HIV-1 and/or -2 infection.

BIBLIOGRAPHY

1. Chang, SY, Bowman, BH, Weiss, JB, Garcia, RE and white, TJ. The origin of HIV-1 isolates HTLV-IIIB, Nature.
2. Arya, SK, Beaver, B, Jagodzinski, L, ensoli B, kanki, PJ, Albert, J, Fenyo, EM, Biberfeld, G, Zagury. JF and Laure, F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987).

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
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