

# HIV Triline Test Device

Immunochromatographic rapid test for qualitative detection of antibodies against HIV 1/2 in serum/plasma

Catalog #: ID1038C

## INTENDED USE

HIV Card rapid test is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in serum or plasma.

## SUMMARY AND PRINCIPLE OF THE TEST

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the 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 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.

The HIV-Card is a rapid test to qualitatively detect the presence of antibody to HIV-1 and/or -2 in serum or plasma specimen. The test utilizes a combination of recombinant HIV antigen coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in serum or plasma and distinguish them.

The HIV-Card is a qualitative, membrane based immunoassay for the detection of antibody to HIV in serum or plasma. The membrane is 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 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 colored line will appear in the different test line region, showing a positive result of HIV 1 antibody positive or HIV 2 antibody positive or both positive. The absence of the colored 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 colored line will always appear at the control line region if the test has been performed properly.

## REAGENTS

HIV Cassette: 50 pcs

## SHELF LIFE:

When store at temperature, the kits have 24months shelf life. After opened, please use ASAP.

## SPECIMEN COLLECTION AND PREPARATION

The HIV-Card can be performed using either serum or plasma. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. 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. 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. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

## STORAGE OF TEST KIT

Unopened test kits should be stored at 4-30°C

## TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
2. Use the disposal pipette inside the pouch, add 2-3 drops (about 70-100ul) sample into sample well on the cassette.
3. Wait 10-15 minutes and read results. Do not read results after 15 minutes.

## INTERPRETATION OF RESULTS

**Negative:** Only one colored band appears on the control region. No apparent band on the test region.

**Positive:** In addition to a pink colored control band, a distinct pink colored band will also appear in the T1 or T2 test region or both, it show HIV 1 or HIV 2 antibody positive.

**Invalid:** A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.

If only "T" shows positive and "C" negative which can happen with very low titres of HIV 1/2 antibodies after a prolonged time.

## PERFORMANCE OF THE TEST:

Compare with ELISA kits, the rapid test card 100 % relative sensitivity and 99.8% relative specificity.

## LIMITATIONS OF THE ASSAY

1. This HIV-Card is for *in vitro* use only. The test should be used for the detection of antibodies to HIV in serum or plasma specimen.
2. This HIV-Card 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 infection.
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.

## RELATED READING MATERIALS

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2. *New human and simian HIV-related retroviruses possess functional transactivator (tat) gene.* Nature (1987) 328:548-550
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5. Travers, K, Mboup, S, Marlink, R, Gueye-Nidaye, A, Siby, T, Thior, I, Traore, I, Dieng-Sarr, A, Sankale, JL and Mullins, C. *Natural protection against HIV-1 infection provided by HIV-2.* Science (1995) 268:1612-1615

## Manufacturer:

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