RAPID HIV I&II TEST CARD - Serum

FOR THE QUALITATIVE ASSESSMENT OF HIV I&II ANTIBODIES
IN HUMAN SERUM OR PLASMA

Catalog Number: 1N01C1

For In Vitro Diagnostic Use Only

INTENDED USE
Rapid HIV I&II Test Card is a single use, rapid test device, double antigen sandwich immunoassay for qualitative detection of antibodies to Human Immunodeficiency Viruses or HIV I&II in serum or plasma. It is intended for medical institution as the aid for the diagnosis of possible HIV infection. The product may be used for the quick screening of blood donors and blood products.

SUMMARY AND EXPLANATION
The Human Immunodeficiency Viruses type 1 and type 2 are etiological agents of the acquired immunodeficiency syndrome (AIDS). HIV has been isolated from patients with AIDS, AIDS related complex (ARC) and from healthy individuals at high risk for AIDS. Infection with HIV is followed by an acute flu-like illness. This phase may remain unnoticed and the relationship to HIV infection may not be clear in many cases. The acute phase is typically followed by an asymptomatic carrier state, which progresses to clinical AIDS in about 50% of infected individuals within 10 years after seroconversion.

Serological evidence of HIV infection may be obtained by testing for HIV antigens or antibodies in blood of individuals suspected of HIV infection. Antigen can generally be detected during the acute phase and during the symptomatic phase of AIDS only. Antibodies to HIV-1 and/or HIV-2 may be detected throughout virtually the total infection period, starting at or shortly after the acute phase and lasting until the end stage of AIDS. Therefore, the use of highly sensitive antibody assays is the primary approach in serodiagnosis of HIV infection.

PRINCIPLE OF THE ASSAY
Rapid HIV I&II Test Card employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HIV-1 gp120, gp41 and HIV-2 gp-36 are dry-immobilized at the end of nitrocellulose membrane strip. HIV 1+2 antigens are bond at the Test Zone (T) and rabbit anti-HIV 1+2 antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If there are HIV1 or HIV 2 antibodies in sample, they will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) zone where they are captured by the HIV 1+2 antigens generating a visible red line. If there are no HIV 1 or HIV 2 antibodies in sample, no red line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the rabbit anti-HIV 1+2 antibodies aggregating in a red line, which indicates the validity of the test.

MATERIAL PROVIDE
1. Rapid HIV I&II Test Card:
   Test Zone: contains recombinant HIV1+2 antigens
   Control Zone: contains rabbit anti-HIV 1+2 antibodies
   Conjugate Pad: contains colloid gold conjugated with recombinant HIV1+2 antigens
2. Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED
Materials required but not provided: Disposable Gloves, Disinfectant, Safety Lancet, Alcohol Prep-Pad, Clock or Timer, Specimen Collection Container, Centrifuge, Biohazard Waste Container.

STORAGE AND STABILITY
Store the test device at 4 to 30°C. Do Not Freeze. The test device will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS
1. For *in vitro* diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

SPECIMEN COLLECTION AND PREPARATION
1. The human serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. Patient samples are performed best when tested immediately after collection. Specimen may be stored, if the sample cannot be tested within 24 hours. The red blood cells should be removed to avoid hemolysis. Serum or plasma should be frozen until the test can be performed. Whole blood samples should be refrigerated at 2–8°C in stead of being frozen. Allow sample to reach room temperature before proceeding.
4. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

QUALITY CONTROL
1. The control zone is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

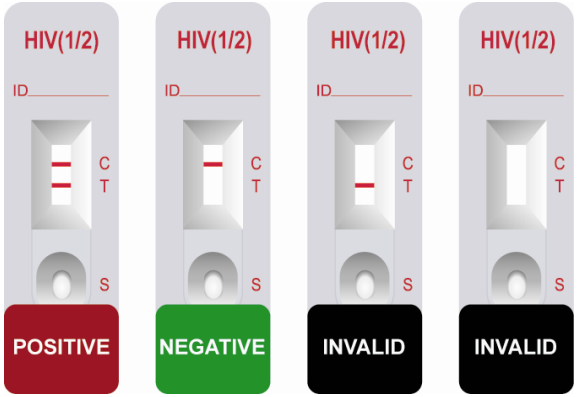
PROCEDURE
1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Label the test card with specimen identity.
4. Place the test card on a flat horizontal surface.
5. Dispense 2 drops (80-100μL) of sample into the specimen well "S" using the sample dropper provided.
6. Read the result within 20 minutes. Reactive samples can be read as soon as distinct colored bands appear on both test zone and control zone. To confirm a negative result, please read the result at 20 minute after adding sample.

Note: 1. Results read after 30 minutes may not be accurate.

INTERPRETATION OF RESULTS
Reactive: Positive
If two colored bands are visible within 20 minutes, the test result is reactive or positive and valid. The test result can be read as soon as a distinct colored band appears in the test area.

Non-reactive: Negative
If test area has no color band and the control area displays a colored band, the result is non-reactive or negative and valid.

Invalid result:
The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.



LIMITATIONS OF THE PROCEDURE

1. Negative results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure (seroconversion) to HIV may not be detectable. For positive or reactive results, line intensity cannot be used to evaluate the anti-HIV antibody levels. A test giving an invalid result should be repeated. Rapid HIV I&II Test Card is not intended use for differentiation between recognition of HIV-1 antibodies and HIV-2 antibodies.
2. If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many highly sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity.
3. This kit is intended ONLY for testing of individual sample. Do not use it for testing of cadaver sample, saliva, urine or other body fluid, or pooled (mixed) blood.
4. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

PERFORMANCE CHARACTERISTICS

In a clinical evaluation of the performance of Rapid HIV I&II Test Card using 2567 confirmed negative and 510 positive samples, sensitivity was 99.6% (508/510) and specificity was 99.7% (2560/2567). The overall agreement with the reference ELISA tests is 99.7%.

Sites	HIV positive sera		HIV negative sera	
	Total	Positive	Total	Negative
One	101	99	149	142
Two	7	7	1784	1784
Three	300	300	436	436
Four	102	102	198	198
Total	**510**	**508**	**2567**	**2560**
Agreement	**99.6%**		**99.7%**	

The precision of three lots tested with Chinese FDA QC panel showed 100% agreement. In order to check possible interferences with potentially cross-reactive sera, an independent evaluation was performed with one hundred samples. The variety of sera samples containing possibly interfering substances were tested and found no interfering with Rapid HIV I&II Test Card.

Serum Type	Number of samples tested	Rapid HIV I&II Test Card	
		Negative	Positive
RF Positive	15	15	0
Acute Hepatitis A	10	10	0
Syphilis Positive	5	5	0
Hepatitis A Recovery Phase	10	10	0
Hepatitis C	16	16	0
Infectious disease with non hepatitis B	20	20	0
HBsAg, HBeAg and HBcAb Positive	20	20	0
Fetal Serum	4	4	0
Total	100	100	0

REFERENCES

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4. Kenealy, W., Reed, D., Cybulsky, R., et.al. (1987) Analysis of human serum antibodies to human immunodeficiency virus (HIV) using recombinant ENV and GAG antigens. *AIDS Res Human Retrovir* 3: 95-105.

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