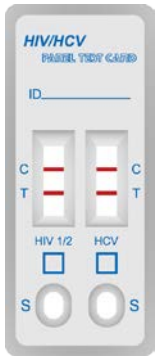
Rapid HIV I&II/HCV Panel Test Card

FOR THE QUALITATIVE ASSESSMENT OF HIV I&II ANTIBODIES AND HCV ANTIBODY IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

Catalog Number: 1N32C2



For In Vitro Diagnostic Use Only

INTENDED USE

Rapid HIV I&II/HCV Panel Test Card, is an immunochromatography assay for the qualitative detection of antibodies to Human Immunodeficiency Viruses(HIV I&II) and antibodies against hepatitis C virus (HCV Ab) in human serum, plasma or whole blood.

SUMMARY AND EXPLANATION

HIV I&II Test: 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.

HCV Test: Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA (9.5 kb) virus belonging to the family of Flaviviridae. Six major genotypes and series of subtypes of HCV have been identified. Isolated in 1989, HCV is now recognized as the major cause for transfusion associated non-A, non-B hepatitis. The disease is characterized with acute and chronic form. More than 50% of the infected individuals develop severe, life threatening chronic hepatitis with liver cirrhosis and hepatocellular carcinomas. Since the introduction in 1990 of anti-HCV screening of blood donations, the incidence of this infection in transfusion recipients has been significantly reduced. Clinical studies show that significant amount of HCV infected individuals develop antibodies to NS5 non-structural protein of the virus. For this, the third generation tests include antigens from the NS5 region of the viral genome in addition to NS3 (c200), NS4 (c200) and the Core (c22). Third generation tests have improved sensitivity and shorten the time between infection with HCV and the appearance of detectable antibodies (window period) to 60 days.

PRINCIPLE OF THE ASSAY

HIV I&II Test 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.

HCV Ab Test employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated goat anti-human IgM and mouse anti-human IgG are dried and immobilized on the fiberglass strip. HCV antigens are immobilized at the Test Zone (T) and goat anti mouse IgG antibodies are immobilized at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, HCV antibodies will bind the gold conjugated anti-human IgG and/or IgM forming complexes. These complexes will continue to migrate along the strip until the Test Zone (T) zone where they are captured by the HCV antigens to form a visible red line. The un-bound gold conjugate will continue to move and bind with goat anti-mouse IgG at the Control Zone (C) forming a visible red line. If no HCV antibodies in sample, only a red line is appeared at the Control Zone (C), which indicates the validity of the test.

MATERIAL PROVIDE

1. Rapid HIV I&II/HCV Panel Test Card
2. Sample Buffer
3. 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. This kit is for in vitro diagnostic use only.
2. This kit is for PROFESSIONAL use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose of specimens after autoclaving them at 121° C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and do not no smoke, eat or drink while performing assays.
9. Wear gloves during the whole procedure.

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

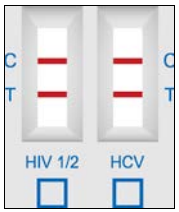
1. The control zone is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not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

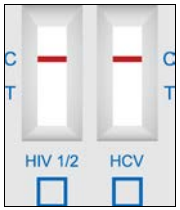
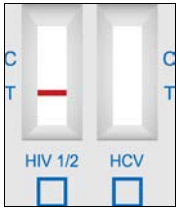
PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch, label the test card with specimen identity, place the test card on a flat horizontal surface.
3. Using the transfer pipet to draw up the sample. Dispense one drop (40-50μL) specimen to the 2 sample wells marked as “S” respectively and wait a few seconds until the samples are completely absorbed by sample pads.
4. Add one drop (40-50μL) sample buffer into the 2 sample wells marked as “S” respectively.
5. Read the result at 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:Results read after 30 minutes may not be accurate.

INTERPRETATION OF RESULTS

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.

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		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/HCV exposure or infection. Infection through recent exposure (seroconversion) may not be detectable.
2. The positive result obtained with Rapid HIV I&II/HCV Panel Test alone cannot be the final diagnosis of HIV/HCV infection. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing with other analytical system (e.g. ELISA) is required to confirm any positive results..
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

***HIV I&II Test*:** In a clinical evaluation of the performance of HIV I&II Test 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 HIV I&II Test.

Serum Type	Number of samples tested	HIV I&II Test	
		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

HCV Test:
In clinical evaluation of the Rapid HCV Antibody Test, 727 confirmed negative and 327 positive samples were tested. A sensitivity of 99.1% (324/327) and a specificity of 99.2% (721/727) were obtained. Overall, agreement with the Predicate Test is 99.1%.

	Predicate Test		
Rapid HCV Antibody Test		Positive	Negative
	Positive	324	6
	Negative	3	721
	Agreement	99.1%	99.2%

No cross reactivity was observed with specimens from patients infected with HAV, HBV, HIV, HTLV, CMV, and TP.

REFERENCES

1. U.S. Department of Health and Human Services. Biosafety in microbilogical and biomedical laboratories. HHS Publication(NIH) 88-8395. Washington:U.S. Government Printing Office, May 1988.
2. Essex, M. (1999) Human immunodeficiency viruses in the developing world. Adv Virus Res 53: 71-88.
3. Kanki, P.J., Hopper, J.R. and Essex, M. (1987) The origins of HIV-1 and HTLV-4/HIV/2. Ann N Y Acad Sci 511: 370-375.
4. Gallo, R.C., Saluahuddin, S.Z., Popovic, M., et al. (1984) Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. Science 224: 500-503.
5. 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.
6. Post transfusion hepatitis. In: Moore SB, ed. Transfusion-Transmitted Viral Diseases. Alington, VA. Am. Assoc. Blood Banks, pp. 53-38.
7. Alter HJ., Purcell RH, Holland PV, et al. (1978) Transmissible agent in non-A, non-B hepatitis. Lancet I: 459-463.
8. Choo Q-L,Weiner AJ, Overby LR, Kuo G, Houghton M. (1990) Hepatitis C Virus: the major causative agent of viral non-A, non-B hepatitis. Br Med Bull 46: 423-441.
9. Engvall E, Perlmann P. (1971) Enzyme linked immunosorbent assay (ELISA): qualitative assay of IgG. Immunochemistry 8:871-874.

IVD

4°C 30°C

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