RAPID HBSAG/HIV I&II/HCV/SYPHILIS PANEL TEST

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

Catalog Number: 1N19C2, 1N25C2

For In Vitro Diagnostic Use Only

INTENDED USE

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

SUMMARY AND EXPLANATION

HBsAg Test: Hepatitis B virus (HBV) is an enveloped; double- stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces acute or chronic liver diseases and in some cases that can lead to cirrhosis and carcinoma of the liver. Hepatitis B surface antigen or HBsAg, which was previously described as Australia antigen is the most important protein of the envelope of Hepatitis B Virus. The surface antigen contains the determinant “a”, common to all known viral subtypes, immunologically distinguished in two distinct subgroups (ay and ad). HBV has 10 major serotypes and four HBsAg subtypes have been recognized (adw, ady, ayw, and ayr). HBsAg can be detected 2 to 4 weeks before the ALT levels become abnormal and 3 to 5 weeks before symptoms develop.

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 Antibody 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.

Syphilis Antibody Test: Syphilis is a disease caused by Spirochete bacterium called Treponema pallidum (TP). If untreated, the organisms move throughout the body and can cause damage to many organs, making syphilis a life-threatening disease if not treated early enough. People who have been infected with syphilis experience different symptoms during the 3 stages of the disease. Early, which is defined by the presence of the chancre at the site of inoculation syphilis may be further divided into primary, secondary, and early latent syphilis; late syphilis includes late latent and the various forms of tertiary syphilis. The serological response to syphilis involves production of antibodies to a wide range of antigens, including non-specific antibodies and specific anti-TP antibodies. The first detectable response to infection is the production of specific antitreponemal IgM, which can be detected within 4 to7 days after the chancre appears and until the end of the second week of infection; antitreponemal IgG appears at about four weeks later. By the time that symptoms develop, most patients have detectable IgG and IgM.

PRINCIPLE

HBsAg Test is a double antibody sandwich immunoassay. Colloidal gold conjugated anti-HBsAg antibody complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip re-hydrating the gold conjugate complexes. If present, HBsAg will react with the gold conjugate complexes forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-HBsAg antibodies immobilized there and a visible red line appears. If there is no HBsAg in sample, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until they are captured in the Control Zone (C) by immobilized goat anti-mouse IgG antibody aggregating a red line, which indicates the validity of the test.

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 Antibody 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.

Syphilis Antibody Test employs chromatographic lateral flow test device in a cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to TP antigens (P47, P45, P17, P15) are dry-immobilized at the end of nitrocellulose membrane strip. TP antigens are bond at the Test Zone (T) and rabbit anti-TP antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, TP antibodies (anti-TP) will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by TP antigens generating a visible red line. If there are no anti-TP 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-TP aggregating in a red line, which indicates the validity of the test.

MATERIAL PROVIDED

1. Rapid HBsAg/HIV I&II/HCV/Syphilis Panel Test Card.
2. Sample Buffer
3. Instruction for use.

MATERIAL 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 ^{o}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.
4. Do not modify the test procedure.

5. Avoid moisture.

6. A test giving an invalid result should be repeated.

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^{o}C instead 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.

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 4 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 4 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

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.

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.

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.

LIMITATION

1. Negative results do not exclude the possibility of HBV/HIV/HCV/Syphilis exposure or infection. Infection through recent exposure (seroconversion) may not be detectable.

2. The positive result obtained with Rapid HBsAg/HIV I&II/HCV/Syphilis Panel Test Card alone

cannot be the final diagnosis of HBV/HIV/HCV/Syphilis 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

For HBsAg Test:

Clinical Sensitivity

The results of the HBsAg Test in total of 1048 samples (345 ELISA confirmed positive specimens and 703 ELISA confirmed negative specimens) showed the sensitivity was 100%.

Clinical Specificity

The results of the HBsAg Test in total of 1048 samples (345 ELISA confirmed positive specimens and 703 ELISA confirmed negative specimens) showed the specificity was 99.1%.

Cross Reactivity

No cross reactivity was observed with specimens from patients infected with HAV, HCV, HEV and RF.

Interference

No interference was found with bilirubin (240 μmol/L), hemoglobin (9 g/L) or triglycerides (25 mmol/L) on the sensitivity and specificity of the test.

For HIV I&II Test:

Accuracy

In a clinical evaluation of the performance of Rapid 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%**	

Cross Reactivity

No cross reactivity was observed with specimens from patients infected with HAV, HBV, HCV, HEV, Syphilis and RF.

For HCV Antibody Test:

Clinical Specificity

The results of the Rapid HCV Antibody Test in total of 1054 samples (324 confirmed positive specimens and 721 confirmed negative specimens) showed the specificity was 99.2%.

Clinical Sensitivity

The results of the Rapid HCV Antibody Test in total of 1054 samples (324 confirmed positive specimens and 721 confirmed negative specimens) showed the sensitivity was 99.1%.

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

Interference

No interference was found with bilirubin (250 µmol/L), hemoglobin (9 g/L) or triglycerides (25 mmol/L) on the sensitivity and specificity of the test.

For Syphilis Antibody Test:

Accuracy
In clinical evaluations of the performance of Rapid Syphilis Antibody Test, 716 confirmed negative and 354 positive samples were tested. A sensitivity of 98.6% (349/354) and a specificity of 99.0% (709/716) were obtained.Overall, agreement with the reference test is 98.9%.

	Reference Test		
Rapid Syphilis Antibody Test		Positive	Negative
	Positive	349	7
	Negative	5	709
	Agreement	98.6%	99.0%

Cross Reactivity
No cross reactivity was observed with specimens from patients infected with HAV, HBV, HCV, HEV and RF.

Interference
No interference was found with bilirubin (10 mg/dL), hemoglobin (20 mg/dL) or triglycerides (600 mg/dL) on the sensitivity and specificity of the test.

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