HBsAg /HCV /HIV Combo Rapid Test Cassette (Serum/Plasma) Package Insert

REF IBCH-335	English

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C Virus and antibodies to HIV type 1, type 2 in serum or plasma. For professional in vitro diagnostic use only.

【INTENDED USE】

The HBsAg/HCV/HIV Combo Rapid Test Cassette (Serum /Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen(HBsAg),antibodies to Hepatitis C Virus and antibodies to HIV type 1, type 2 in serum or plasma..

【SUMMARY】

The HBsAg Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen.[1]The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HCV Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens.[2,3] Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.[4,5]

The HIV 1.2 Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in serum or plasma.

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 high potential risk for developing AIDS.[6] HIV 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[7] Both HIV 1 and HIV 2 elicit immune response.[8] Detection of HIV antibodies in serum, 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.[9] Despite the differences in their biological characteristics, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity.[10,11]Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.

【PRINCIPLE】

The HBsAg Rapid Test (Serum/Plasma) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. This test is for in vitro diagnostic use only, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The HCV Rapid Test (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the cassette. During testing, the serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The HIV 1.2 Rapid Test (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1.2 in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains anti-HBsAg conjugated particles, anti-HBsAg coated on the membrane; recombinant HCV antigen conjugated particles, HCV antigen coated on the membrane and HIV1.2 recombinant antigens conjugated particles, HIV1.2 recombinant antigens coated on the membrane.

【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 the procedure 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 assayed.
5. Humidity and temperature can adversely affect results.

【STORAGE AND 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】

- The HBsAg /HCV /HIV Combo Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- 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.

【MATERIALS 】

Materials Provided

- Test Cassettes
- Buffer
- Sample Droppers
- Package Insert

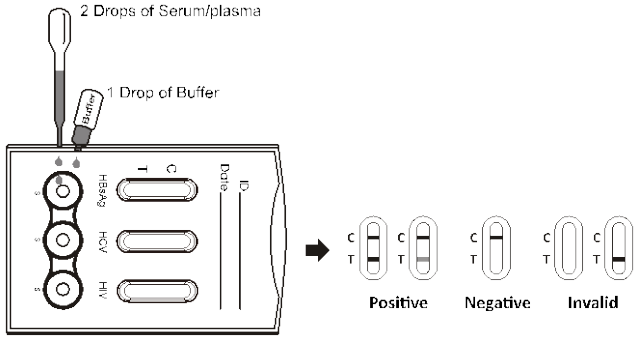
Materials Required But Not Provided

- Specimen Collection Containers
- Centrifuge
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer **2 drops of serum or plasma (approximately 50µL)** to the each sample well, then add **1drop of buffer (approximately 40µL)**to each sample well and start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. Do not interpret the result after **20 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: * Two distinct colored lines appear. One color line should be in the control region (C) and another color line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg antigen, HCV antibody and HIV antibody present in the specimen. Therefore, any shade of red in the test region should be considered positive.

NEGATIVE: One color line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test individually for all the three sections. Three colored lines appearing in control line regions (C) for all the three sections is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. This test is for in vitro diagnostic use only.
2. This test has been developed for testing serum or plasma specimens only. The performance of the test using other specimens has not been substantiated.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HBsAg, HCV antibody or HIV 1.2 antibody
4. The HBsAg Rapid Test cannot detect less than 1 PEI ng/ml of HBsAg in specimens.
5. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
6. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of HBsAg and/or Hepatitis C Virus and/or HIV1.2 infection.

【EXPECTED VALUES】

The HBsAg/HCV/HIV Combo Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial EIA test , respectively. The correlation between these two systems is over 99%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

1. HBsAg

The HBsAg Rapid Test (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/ml. All 10 HBsAg subtypes produced positive results on The HBsAg Rapid Test (Serum/Plasma). The test can detect 1 PEI ng/ml of HBsAg in serum/plasma.

Antibodies used for the HBsAg Rapid Test (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

The results show that the relative sensitivity of the HBsAg Rapid Test (Serum /Plasma) is >99.9% and the relative specificity is 99.7%.

Method		EIA		Total Results
HBsAg Rapid Test Cassette (Serum /Plasma)	Results	Positive	Negative	
	Positive	129	1	130
	Negative	0	370	370
Total Results		129	371	500

Relative Sensitivity: >99.9% (95%CI*: 97.7%~100%) *Confidence Intervals
Relative Specificity: 99.7% (95%CI*: 98.5%~100%)
Overall Accuracy: 99.8% (95%CI*: 98.9%~100%)

2. HCV

The recombinant antigen used for the HCV Rapid Test (Serum /Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test (Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens. The results show that the relative sensitivity of the HCV Rapid Test Cassette (Serum/Plasma) is 99.9%, and the relative specificity is 99.7%.

Method		EIA		Total Results
HCV Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	163	1	164
	Negative	0	336	336
Total Result		163	337	500

Relative Sensitivity: >99.9% (95%CI*: 98.2%~100 *Confidence Intervals
Relative Specificity: 99.7% (95%CI*: 98.4%~100%)
Overall Accuracy: 99.8% (95%CI*: 99.0%~100%).

3. HIV 1.2

The HIV 1.2 Rapid Test (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the relative sensitivity of the HIV 1.2

Rapid Test (Serum/Plasma) is >99.9% and the relative specificity is 99.8%.

Method		ELISA		Total Results
HIV 1.2 Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	100	1	101
	Negative	0	399	399
Total Result		100	400	500

Relative Sensitivity: >99.9% (95%CI*: 97.0%~100%) *Confidence Intervals
Relative Specificity: 99.8% (95%CI*: 98.6%~100%)
Overall Accuracy: 99.8% (95%CI*: 99.0%~100%)

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of four different specimens containing different concentrations of HBsAg, HCV antibody and HIV 1.2 antibody. The negative, positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same four different specimens containing different concentrations of HBsAg, HCV antibody and HIV 1.2 antibody. Three different lots of the HBsAg/HCV/HIV Combo Rapid Test (Serum/Plasma) have been tested over a 3-month period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

Cross-Reactivity

The HBsAg Rapid Test (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, *H. Pylori*, MONO, CMV, Rubella, HCV, HEV and TOXO positive specimens. The results showed no cross-reactivity.
The HCV Rapid Test (Serum /Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, *H. Pylori*, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.
The HIV 1.2Rapid Test(Serum /Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, Syphilis, *H. Pylori*, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HBsAg, HCV antibody and HIV 1.2 antibody negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin:	1000mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	60mg/dL

None of the substances at the concentration tested interfered in the assay.

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Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		

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