EXPLANATION AND SUMMARY

[Introduction]

Hepatitis B virus (HBV) is one of several hepatitis viruses that can cause inflammation of the liver. It is currently endemic worldwide and commonly transmitted via body fluids such as blood, semen, and vaginal secretions. Acute HBV infection is a short-term viral infection, illness that occurs within the first 6 months after the person is exposed to the HBV. Acute HBV infection can be either asymptomatic or develop the signs and symptoms of viral hepatitis become noticeable. Most infected persons recover, but 5%-10% are unable to clear the virus and become chronically infected. Many chronically infected persons have mild liver disease with little or no long term morbidity or mortality. Other individuals with chronic HBV infection develop active disease, which can progress to cirrhosis and liver cancer. According to the World Health Organization, an estimated 240 million people are chronically infected with HBV and more than 780,000 people die every year due to complications of HBV infection, including cirrhosis and liver cancer. Given this urgent situation, rapid and accessible detection of HBV is important for efficient prevention and prompt treatment of it. Diagnosis of acute or chronic HBV infection is based on the presence of hepatitis B surface antigen (HBsAg), a protein on the surface of HBV, which can be detected in high levels during acute or chronic HBV infection. STANDARD Q HBsAg Test provides significantly fast, easy and accurate system to detect HBsAg in human serum, plasma or whole blood. It is essential for the reliable clinical diagnosis of HBV infection and enables supportive treatment decisions.

[Intended use]

STANDARD Q HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) present in serum or plasma. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of HBV infection in patient with clinical symptoms with HBV infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HBV infection.

[Test principle]

STANDARD Q HBsAg Test contains two pre-coated lines, "C" (Control line) and "T" (Test line) on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any samples. Monoclonal anti-Chicken IgY is coated on the control line region and monoclonal anti-HBS is coated on the test line region. Monoclonal anti-HBS conjugated with colloidal gold particles is used as a detector for HBsAg. During the test, Hepatitis B surface antigen (HBsAg) in the sample interacts with anti-HBS conjugated with colloidal gold particles making anti-HBS-HBsAg gold particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by monoclonal anti-HBS. A violet test line would be visible in the result window if HBsAg is present in the specimen. The intensity of violet test line will vary depending upon the amount HBsAg present in the specimen. If HBsAg is not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

ACTIVE INGREDIENTS OF MAIN COMPONENT

[Materials Provided]

Components	
Cassette	Specimen transfer device (50µl)
Instruction for use	

[Reagents composition]

Components	Composition
Cassette	· Gold conjugates - Monoclonal anti-HBS-gold - Chicken IgY-gold · Test line - Monoclonal anti-HBS · Control line - Monoclonal anti-Chicken IgY

KIT STORAGE AND STABILITY

Store the RDT Box at room temperature, 2-40°C / 36-104°F out of direct sunlight. Materials provided are stable until the expiration date printed on the RDT box. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube NOT containing anti-coagulant such as heparin or EDTA by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°F.
3. It should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin or EDTA by venipuncture and centrifuge blood to get plasma specimen.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°F.
3. It should be brought to room temperature prior to use.

CAUTION

- Anticoagulants such as heparin or EDTA do not affect the test result.
- As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair test results.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

[Preparation]

1. Carefully read the instruction for using the STANDARD Q HBsAg Test.
2. Look at the expiry date at the back of the cassette packaging. Use another lot, if expiry date has passed.
3. Open the cassette package, and check the cassette and the color indicator silica gel in cassette packaging.
4. Methods for following steps can be changed depending on the type of specimen and specimen transfer device.

[Test Procedure]

- **Using micropipette**

1. Collect 50µl of serum or plasma.
2. Add the collected specimen to the specimen well of the cassette.
3. Read the test results after 20 minutes. Test can be read up to 30 minutes.

- **Using specimen transfer device (50µl)**

1. Collect 50µl of serum or plasma till black line of the specimen transfer device.
2. Add the collected specimen to the specimen well of the cassette.
3. Read the test results after 20 minutes. Test can be read up to 30 minutes.

CAUTION

- Do not Read the test result after 30 minutes. It may give false results.

INTERPRETATION OF TEST RESULTS

Non reactive result The presence of only one colored band ("C" Control line) within the result window indicates a non reactive result.

Reactive result The presence of two colored bands ("C" Control line and "T" Test line) within the result window, no matter which band appears first, indicates a reactive result. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.

Invalid result If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new cassette.

CAUTION

- Reactive results should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

1. The test should be used for the detection of HBsAg in human serum or plasma specimens.
2. Neither the quantitative value nor the concentration of HBsAg can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A non-reactive test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

PERFORMANCE CHARACTERISTICS

1. Sensitivity : In this multi-site evaluation of 43 specimen, we found the relative sensitivity is 100% (43/43). The results are summarized in the following table.

Reference		STANDARD Q HBsAg Test		Total Result
		Reactive	Non reactive	
CLIA Analyzer	Positive	43	0	43
	Negative	0	0	0
Total Result		43	0	43
Sensitivity		43/43 x 100=100%		

2. Specificity : In this multi-site evaluation of 162 specimen, we found the relative specificity is 100% (162/162). The results are summarized in the following table.

Reference		STANDARD Q HBsAg Test		Total Result
		Reactive	Non reactive	
CLIA Analyzer	Positive	0	0	0
	Negative	0	162	162
Total Result		0	162	162
Specificity		162/162 x 100=100%		

WARNINGS

1. Do not re-use the kit.
2. Do not use the kit if the cassette package is damaged or the seal is broken.
3. Do not use the kit after expiration date.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose off all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Silica gel in cassette packaging is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the cassette in the cassette packaging should be discarded.
11. Discard the cassette immediately after reading result.

BIBLIOGRAPHY

1. Tabor E, Gerety RJ. Smallwood LA, Barker LF. Coincident hepatitis B surface antigen and antibodies of different subtypes in human serum. J Immunol 1977;118:369-70.
2. Mesenas SJ, Chow WC, Zhao Y, Lim GK, Oon CJ, Ng HS. Wild type and "a" epitope variants in chronic hepatitis B virus carriers positive for hepatitis B surface antigen and antibody. J Gastroenterol Hepatol 2002; 17:148-52.
3. Shiels MT, Taswell HF, Czaja AJ, Nelson C, Swenke P. Frequency and significance of concurrent hepatitis surface antigen and antibody in acute and chronic hepatitis B virus. Gastroenterology 1987; 93:675-80.
4. Voller A, Bartlett A, and Bidwell D. Zuckerman AJ: Viral hepatitis with special reference to hepatitis B. Immunoassays for the 80's. eds University Park Press. 1981;361-373.
5. Weinbaum, C.M., Williams, I., Mast, E.E., Wang, S.A., Finelli, L., Wasley, A. et al, Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. MMWR Recomm Rep. 2008; 57:1-20.
6. Randrianirina, F., Carod, J.F., Ratsima, E., Chretien, J.B., Richard, V., Talarmin, A. Evaluation of the performance of four rapid tests for detection of hepatitis B surface antigen in Antananarivo, Madagascar. J Virol Methods. 2008; 151:294-297.

Issue date : 2018. 06

SD/026/IN/01-00

Manufactured by

SD BIOSENSOR HEALTHCARE PVT. LTD.

Corporate Office
Unit No-202 A-D, 2nd Floor, Tower-A, Unitech Signature Towers South City 1, Gurugram, Haryana-122001, India

Manufacturing site
Plot No. 38, Sector - 4, IMT Manesar, Gurugram, Haryana-122052, India

Any inquiries regarding the instruction provided should be addressed to:
care@sdbiosensor.co.in

Toll Free No.
1800-10-23105