Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD Q HBsAg

STANDARD™ Q HBsAg Test

Digitally signed by Bolea Petru
Date: 2022.07.25 08:53:15 EEST
Reason: MoldSign Signature
Location: Moldova

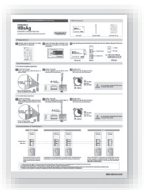
REF QHBS01G

PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

[Kit Contents]

Test device

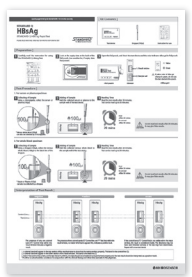
Disposable dropper (100µl)



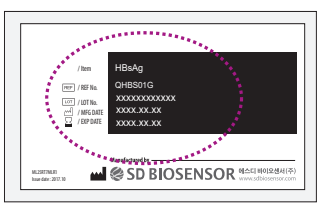
Instructions for use

[Preparation]

1 Carefully read the Instructions for using the STANDARD Q HBsAg Test.

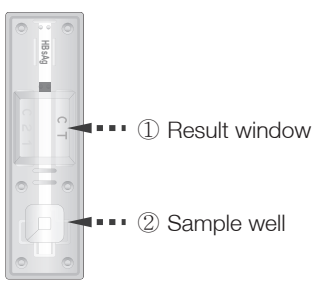


2 Look at the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.



3 Open the foil pouch, and check the test device and the silica gel pack inside the foil pouch.

<Foil pouch>



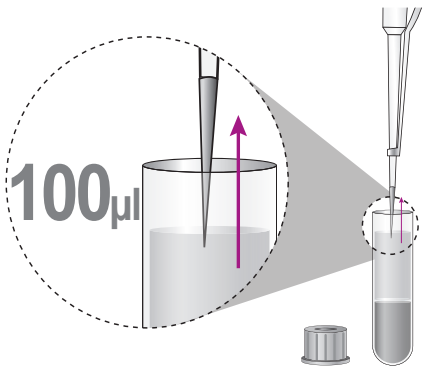
<Test device>

<Silica gel>

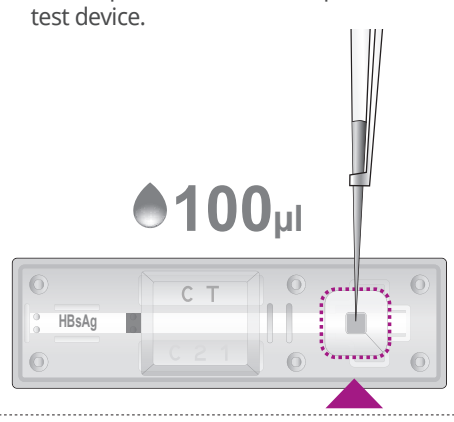
[Test Procedure]

1. Using a micropipette

1 Collecting of Specimen
Using a micropipette, collect 100µl of the serum, plasma or whole blood specimen.



2 Adding of Specimen
Add the collected serum, plasma or whole blood specimen to the sample well of the test device.



3 Reading Time
Read the test results after 20 minutes.
Test can be read up to 30 minutes.

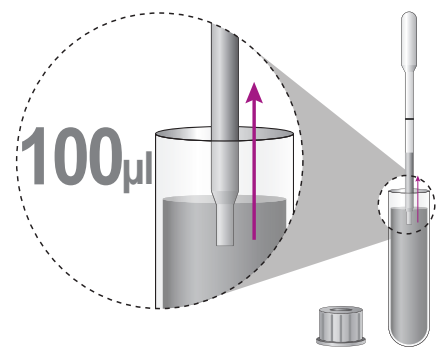
Read
After 20 mins
Do not read
After 30 mins

CAUTION

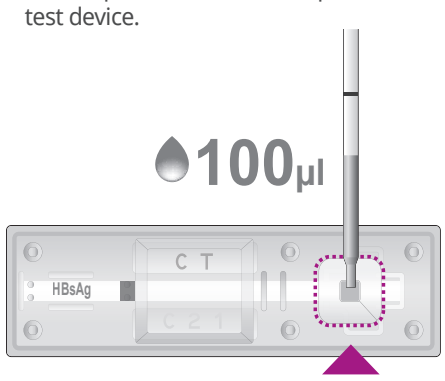
Do not read test results after 30 minutes. It may give false results.

2. Using a disposable dropper

1 Collecting of Specimen
Using a disposable dropper, collect 100µl of the serum, plasma or whole blood specimen to the black line.



2 Adding of Specimen
Add the collected serum, plasma or whole blood specimen to the sample well of the test device.



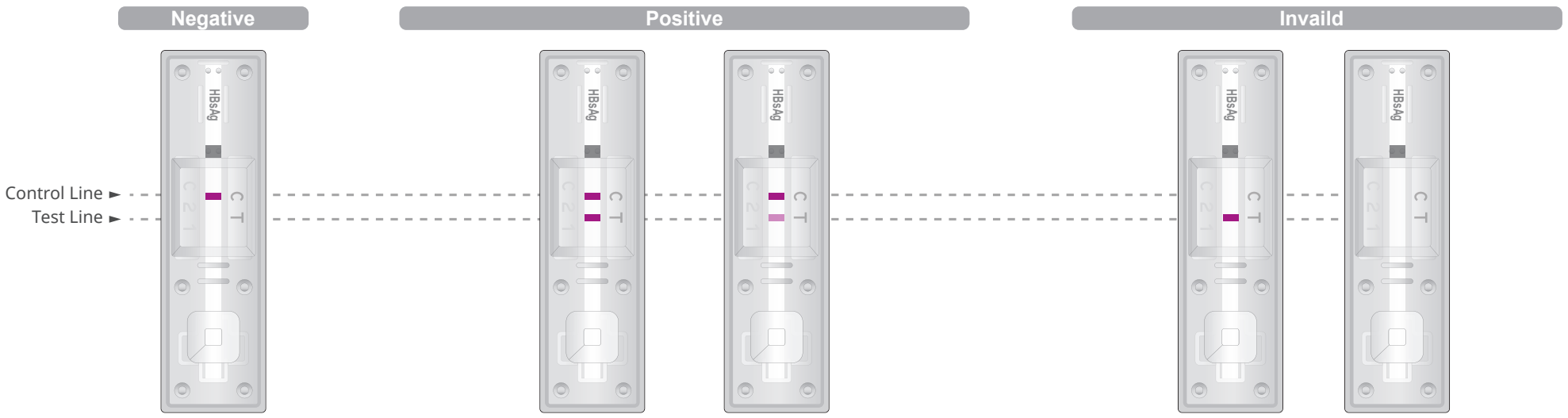
3 Reading Time
Read the test results after 20 minutes.
Test can be read up to 30 minutes.

Read
After 20 mins
Do not read
After 30 mins

CAUTION

Do not read test results after 30 minutes. It may give false results.

[Interpretation of Test Result]



The presence of only one colored band ("C" Control line) within the result window indicates a negative 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 HBsAg positive 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 patient specimen and a new test device.

1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is the control line (C).
2. A colored band will appear in the lower section of the result window. This band is the test line (T).
3. Even if the test 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 positive result.

*** This test only indicates the presence of HBsAg in human serum, plasma or whole blood specimen and should not be used as the sole criteria for the diagnosis of HBV. As with other diagnostic tests, all test results should be considered with other clinical history available to the physician.**

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 (WHO), 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, plasma or whole blood. 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 has 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 antibody-antigen 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 sample. The intensity of violet test line will vary depending upon the amount HBsAg present in the sample. If HBsAg is not present in the sample, 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.

[Kit contents]

① Test device ② Disposable dropper (100µl) ③ Instructions for use

KIT STORAGE AND STABILITY

Store the kit at 2-40°C / 36-104°F out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use after the 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 of 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 foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube NOT containing anti-coagulant such as heparin, EDTA or sodium citrate 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 -40°C / -40°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, EDTA or sodium citrate 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 -40°C / -40°F.
3. It should be brought to room temperature prior to use.

[Whole blood]

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood 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 1-2 days after collection.
3. Do not use hemolyzed blood samples.

CAUTION

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

TEST PROCEDURE

[Preparation]

1. Carefully read the instructions for using the STANDARD Q HBsAg Test.
2. Look at the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
3. Allow the STANDARD Q HBsAg Test components and specimen to room temperature (15-30°C/59-86°F) prior to testing.
4. Open the foil pouch, and check the test device and the silica gel pack inside the foil pouch.
5. Methods for following procedures can be changed depending on the type of specimen applicator.

[Test Procedure]

- **Using a micropipette**

1. Using a micropipette, collect 100µl of the serum, plasma or whole blood specimen.
2. Add the collected serum, plasma or whole blood specimen to the sample well of the test device.
3. Read the test results after 20 minutes. Test can be read up to 30 minutes.

- **Using a disposable dropper**

1. Using a disposable dropper, collect 100µl of the serum, plasma or whole blood specimen to the black line.
2. Add the collected serum, plasma or whole blood specimen to the sample well of the test device.
3. Read the test results after 20 minutes. Test can be read up to 30 minutes.

CAUTION

- Read the test result after 30 minutes. It may give false results.

INTERPRETATION OF TEST RESULT

1. Negative result: The presence of only one colored band ("C" Control line) within the result window indicates a negative result.
2. Positive 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 positive 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 HBsAg positive result.
3. 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 patient specimen and a new test device.

CAUTION

- This test only indicates the presence of HBsAg in human serum, plasma or whole blood specimen and should not be used as the sole criteria for the diagnosis of HBV. As with other diagnostic tests, all test results should be considered with other clinical history available to the physician.

LIMITATION OF TEST

1. The test should be used for the detection of HBsAg in human serum, plasma or whole blood specimens.
2. Neither the quantitative value nor the rate of HBsAg concentration 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 negative test result may occur if the level of extracted antigen in a sample 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.

QUALITY CONTROL

1. A colored line appearing in the control line is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagent are reactive.
2. Control materials are not supplied with this test kit. However, it is recommended that the positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

1. Clinical sensitivity : 43 Clinical specimens determined to be positive using CLIA analyzer were tested using the STANDARD Q HBsAg Test to determine clinical sensitivity of the test. In a comparison of STANDARD Q HBsAg Test against CLIA, results yielded clinical sensitivity of 100% (43/43).

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

2. Clinical specificity : 162 Clinical specimens determined to be negative using CLIA analyzer were tested using the STANDARD Q HBsAg Test to determine clinical specificity of the test. In a comparison of STANDARD Q HBsAg Test against CLIA, results yielded clinical specificity of 100% (162/162).

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

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 B 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.

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

Manufactured by SD BIOSENSOR
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Any inquiries regarding the instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L23HBS1ENR2
Issue date: 2018.02

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
Note
Do not re-use.
To indicate the temperature limitations in which the transport package has to be kept and handled.
Use by
LOT Batch code
Manufacturer
Date of manufacture