TEST IT
for healthy generations

INSTRUCTION FOR USE
HBsAg Test, WB/S/P
HBsAg Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: TIHB04

Hepatitis B Virus Surface Antigen Cassette Test

BACKGROUND INFORMATION

Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of different viruses such as hepatitis A, B, C, D and E. Of the many viral causes of human hepatitis few are of greater global importance than hepatitis B virus (HBV). Hepatitis B is a serious and common infectious disease of the liver, affecting millions of people throughout the world.

The severe pathological consequences of persistent HBV infections include the development of chronic hepatic insufficiency, cirrhosis, and hepatocellular carcinoma (HCC). In addition, HBV carriers can transmit the disease for many years. Infection occurs very often in early childhood when it is asymptomatic and often leads to the chronic carrier state. Detection of hepatitis B surface antigen (HBsAg) identifies individuals infected with the hepatitis B virus. Serum HBV DNA concentrations quantified by real-time polymerase chain reaction (PCR) correlate with disease progression and for decisions to treat and subsequent monitoring. HBsAg is typically detected by sensitive immunoassays that uses antibody to hepatitis B surface. Point-of-care testing offers significant advantages which include reduction of facility costs, rapid delivery of results, early diagnosis, nurses or technicians with a minimum of training, peripheral health care level and rapid initiation of treatment.

Interpretation of the Hepatitis B Panel		
Tests	Results	Interpretation
HBsAg, anti-HBc, anti-HBs	Negative, negative, negative	Susceptible
HBsAg, anti-HBc, anti-HBs	Negative, positive, positive	Immune due to natural infection
HBsAg, anti-HBc, anti-HBs	Negative, negative, positive	Immune due to hepatitis B vaccination **
HBsAg, anti-HBc, IgM anti-HBc, anti-HBs	Positive, positive, positive, negative	Acutely infected
HBsAg, anti-HBc, IgM anti-HBc, anti-HBs	Positive, positive, negative, negative	Chronically infected
HBsAg, anti-HBc, anti-HBs	Negative, positive, negative	Four interpretations possible *

* Four Interpretations: 1. Might be recovering from acute HBV infection. 2. Might be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum. 3. Might be susceptible with a false positive anti-HBc. 4. Might be undetectable level of HBsAg present in the serum and the person is actually chronically infected.

** Antibody response (anti-HBs) can be measured quantitatively or qualitatively. A protective antibody response is reported quantitatively as 10 or more milliinternational units (≥10mIU/mL) or qualitatively as positive. Post-vaccination testing should be completed 1-2 months after the third vaccine dose for results to be meaningful.

DEFINITIONS

* Hepatitis B Surface Antigen (HBsAg): A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis. The presence of HBsAg indicates that the person is infectious.
The body normally produces antibodies to HBsAg as part of the normal immune response to infection.
* Hepatitis B Surface Antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
* Total Hepatitis B Core Antibody (anti-HBc): Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus (HBV) in an undefined time frame.
* IgM Antibody to Hepatits B Core Antigen (IgM anti-HBc): This antibody appears during acute or recent HBV infection and is present for about 6 months.

INTENDED USE

HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood / serum / plasma.

REAGENTS

Anti-HBs monoclonal antibody, goat anti-mouse IgG polyclonal antibody and anti-HBs monoclonal antibody conjugated with colored particles.

METHOD

HBsAg Test uses immunochromatographic technology for the qualitative detection of HBsAg in human whole blood / serum / plasma. Sample is introduced from sampling pad. If there is HBsAg in the sample at detectable level, HBsAg binds to the mobile anti-HBs monoclonal antibodies conjugated with colored particles. Together they move to the test area "T". A visible colored signal due to the accumulation of colored particles in the test area "T" (a colored test line) indicates positive test result. If there is no HBsAg in the sample at detectable level then sample moves to the test area "T" together with unbound anti-HBs monoclonal antibodies conjugated with colored particles. Therefore, there is no visible colored signal in the test area "T" (no colored test line) be obtained, indicating negative test result. Regardless of HBsAg content of the liquid sample, accumulation of colored particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line always appears in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

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PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
4. Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
5. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
6. Use a new pipette for each sample. Close the buffer bottle cap after using. Buffer is stable until expiry date after the first use in routine.
7. Adequate lighting is required to read the test results.
8. The test device should be discarded in a proper biohazard container after testing.
9. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. Do not freeze and thaw the serum, plasma samples repeatedly. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
12. Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
13. Hemolytic samples should not be used since they can lead to invalid or false results.
14. A negative result does not exclude the possibility of HBV infection. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is required.
15. A false negative result can occur in the following a recent exposure to HBV; the recent exposure may take several months to reach detectable levels due to recent infection. In exceptional cases; presence of mutant virus and infection with a variant of the virus may lead to observation of false negative results.
16. Positive samples should be retested using another method and the results should not be used as the only basis for the diagnosis of hepatitis viral infection.
17. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze. The test in the original packaging retains stable until expiry date at storage conditions.
The test device should be used in maximum one hour after the foil is opened.
Kit components : Test cassettes, pipettes, diluents (for whole blood samples only) and instructions for use.
Additional materials required but not provided : Sample collection tube, centrifuge, timer, for fingerstick whole blood: sterile lancet and capillary tubes.
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood (venous blood and capillary blood), serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible and tested immediately after collection. If the sample cannot be tested on the day of collection, serum or plasma samples should be refrigerated at 2 to 8°C for up to 3 days prior to testing. If testing within 3 days is not possible, serum or plasma samples should be frozen at -20°C or colder. Frozen serum, plasma samples must be completely thawed and mixed well prior to testing. Bring the samples to room temperature before testing.
Plasma and venous blood can be collected with the following anticoagulants: K3EDTA, K2EDTA, sodium citrate (3,2%), sodium citrate (3,8%), lithium heparin, sodium heparin.
Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Plasma Samples: Collect blood into a collection tube with anticoagulants to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Whole Blood Samples: Collect venous blood into a collection tube with anticoagulants to avoid coagulation, test should preferably be performed immediately. Otherwise, whole blood samples should be stored at 2 - 8 °C until they are being tested in a period of 2 days after collection. Do not freeze whole blood sample.
For Capillary Blood; according to the laboratory practice, use a sterile lancet and an appropriate capillary tube to collect blood by capillary action. Test should be performed immediately.

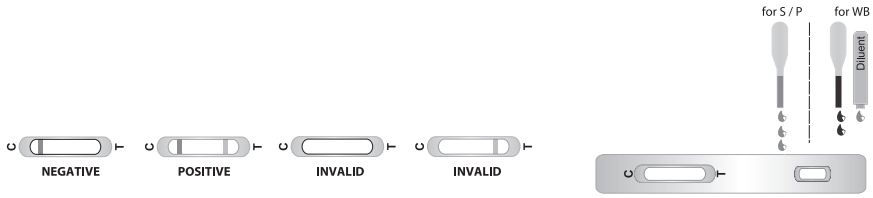
TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. **For Serum / Plasma Samples:** Draw serum / plasma into pipette and put 3 drops (75 µl) into the sample well of the cassette. Do not use diluent for serum / plasma samples.
   For Whole Blood Samples: Draw whole blood into pipette and put 2 drops (50 µl) into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.
   When using Capillary Blood Samples: Collect 50 µl of fingerstick whole blood using the capillary tube (not provided) and transfer it into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.
   Avoid the formation of any air bubbles.
3. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area.
Positive: Two colored lines are visible in "C" and "T" areas.
Low concentration of hepatitis B surface antigen may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

HBsAg Test can detect all subtypes of hepatitis B virus surface antigens.

Sample Status	Sample HBsAg Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Naturally acute or chronic infected	Positive	536	EIA	100 %	411	EIA	100 %
Blood donors	Negative	1041	EIA	99,8 %	-	-	-
Clinical samples	Negative	225	EIA	100 %	225	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity and Specificity

Using results of positive samples (947/947) and negative samples (1799/1801); sensitivity, specificity with the 95% confidence interval values are calculated as;

Sensitivity : 100 % [95% CI = 99,61% - 100%] Specificity : 99,89 % [95% CI = 99,60% - 99,99%]

Analytical Sensitivity Cut-off: 0,26 IU/mL

Seroconversion panels: 30 seroconversion panels were studied with Türklab HBsAg Test and compared to results from CE Marked EIAs as reference assays. Türklab HBsAg Test was capable of detecting antigens of HBsAg in a similar manner of the CE Marked EIA tests.

Interferences: Following potentially interfering substances were tested with HBsAg Test: Hemoglobin, Bilirubin, Triglycerides, Rheumatoid Factor (RF). No interference was observed.

Hemolytic samples should not be used since they can lead to invalid or false results.

Cross Reactivity: Cross reactivity has been tested with below samples, no cross reactivity was found with the HBsAg Test.

- Anti-HCV serum / plasma samples,
- Anti-HBs serum / plasma samples,
- Whole blood / serum / plasma samples from pregnant women.

Capillary Blood: Positive and negative capillary whole blood specimens collected by fingerstick were performed with HBsAg Test. The results showed that there was a good correlation of testing results between venous whole blood and capillary blood.

REFERENCES

1. "Hepatitis B", *World Health Organization Department of Communicable Diseases Surveillance and Response*, WHO/CDS/CSR/LYO/2002.2:Hepatitis B.
2. "Hepatitis B", *WHO, Media Centre.*
3. "Facts and Figures", *The Hepatitis B Foundation.*
4. Interpretation of Hepatitis B Serologic Test Results, *Centers for Disease Control and Prevention (CDC).*
5. Guidelines fort he prevention, care and treatment of persons with chronic hepatitis infection, *World Health Organization*, 2015.
6. Khuroo MS, Khuroo NS, Khuroo MS. (2014). "Accuracy of Rapid Point-of-Care Diagnostic Tests for Hepatitis B Surface Antigen—A Systematic Review and Meta-analysis". *Journal of Clinical and Experimental Hepatology.* doi:10.1016/j.jceh.2014.07.008.
7. WHO Guidelines on Hepatitis B and C Testing. Geneva: World Health Organization; 2017 Feb. ANNEX 4, *PICO Questions and Decision-Making Tables.*

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