（FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !）

Human Hepatitis B Surface Antigen（HBsAg）Lateral Flow Assay Kit

Catalog No: E-HD-C105

20T/40T

Version Number:	V1.1
Replace version:	V1.0
Revision Date:	2023.03.10

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

This product is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-HBsAg antibody conjugated with colloid gold (HBsAg Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HBsAg antibody, and the C band is pre-coated with goat anti-mouse IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. If it is present in the specimen HBsAg will be bound to the HBsAg Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated non-conjugated HBsAg antibody, forming a burgundy colored T band, indicating a HBsAg positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG /HBsAg Ab-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	1 bottle
Dropper	20/40 pieces
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. It is a disposable reagent. Do not reuse it. Please use it within the validity date.
2. This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
3. Do not open the sealed pouch unless ready to conduct the assay.
4. Do not use expired devices.
5. Bring all test materials to room temperature (15-30 ℃) before use.
6. Do not use components from any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolized blood specimens for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.

12. The test result should be read at 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the result after 20 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
14. If you have any questions or suggestions during use, please contact the manufacturer.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment.

Expiry date: expiration date is on the packing box.

Requirements of sample

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

For plasma samples

1) Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture.
2) Separate the plasma by centrifugation.
3) Carefully withdraw the plasma into a new pre-labeled tube.

For serum samples

1) Collect blood specimen into a red top collection tube (containing no anticoagulants) by venipuncture.
2) Allow the blood to clot.
3) Separate the serum by centrifugation.
4) Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. If not tested immediately, store specimens at 2-8℃ for up to 5 days. For longer storage, specimens should be kept frozen at -20℃. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

For whole blood samples

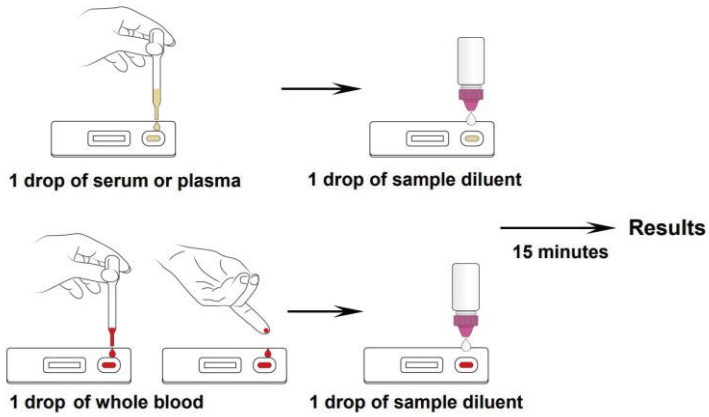
Drops of whole blood can be obtained by venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively). Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored at 2-8℃ if not tested immediately. The specimens must be tested within 24 hours of collection.

Assay procedure

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.
2. Remove the reagent card from the aluminum foil packaging bag and place it on a dry flat surface. Use the reagent card within 1 hour after unsealing to prevent moisture.

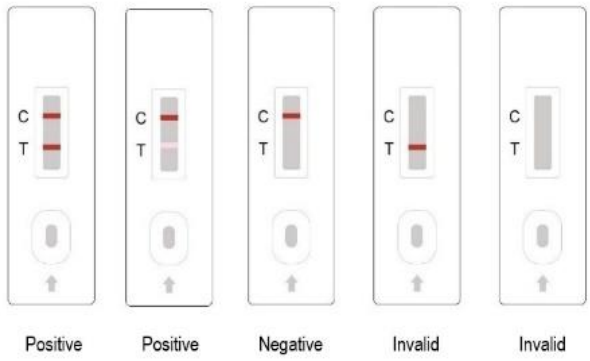
3. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop of serum/plasma (about 35-45 μL) or 1 drop of whole blood (about 40-50 μL) into the sample well, making sure there are no air bubbles. Immediately add 1 drop (about 30-50 μL) of sample diluent with the bottle positioned vertically.



4. Set up the timer.
5. Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.**Do not read the result after 20 minutes. To avoid confusion, discard the test cassette after interpreting the result.**

Interpretation of results

1. Positive: in addition to one purplish red line in the control line (C) region, an apparent colored line will also appear in the test line (T) region.
2. Negative: only one purplish red line appears in the control line (C) region. No line appears in the test line (T) region.
3. Invalid: no line appears in the control line (C) region. 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.



Note: this figure is only used as a reference.

Limitations of this test method

1. The Test Procedure and the Interpretation of Results sections must be followed closely when testing for the presence of HBsAg in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HBsAg Test Kit is limited to the qualitative detection of HBsAg in human serum, plasma or whole blood. The intensity of the test line does not have linear correlation with the HBsAg titer in the specimen.
3. A negative or non-reactive test result does not preclude the possibility of exposure to or infection with HBV.
4. A negative or non-reactive result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay or if the antibody that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptoms persist and the result from HBsAg Test Kit is nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative device.
7. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other procedures and findings.