HBsAg RAPID TEST
(Serum / Plasma / Whole Blood)

INTENDED USE
First View HBsAg Rapid test card is a lateral flow immunoassay and qualitative screening, In-Vitro diagnostic immune-chromatographic assay for detection of antigen specific to HBsAg Antibodies in human serum/plasma or whole blood.

INTRODUCTION
Hepatitis B surface antigen ("Australis Antigen") consists of lipid, carbohydrate and protein elements; the protein moiety provides a marker for identification of chronic, infectious HBV infections. Hepatitis B is transmitted sexually or intravenously and has an incubation period of six months. If not diagnosed properly and in time, it can develop into acute or chronic infection, liver cirrhosis and fulminant Hepatitis. This test is very useful for screening blood donors, to find out whether they are HBsAg positive before collection of blood.

PRINCIPLE OF TEST
HBsAg card test utilizes the principle of immunochromatography, a unique assay based on antigen capture or sandwich principle. The method uses monoclonal antibody conjugated to colloidal gold and polyclonal antibodies immobilized on nitrocellulose strip in thin line. As the test sample flows through the membrane assembly of the test device, the coloured monoclonal anti-HBsAg-colloidal gold conjugate complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by a polyclonal anti HBsAg antiserum coated on the membrane leading to formation of pink-purple coloured band. The formation of first purple band (T zone) confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result. The unreacted conjugate and unbound complex, if any, move further on the membrane subsequently immobilized by the anti-rabbit IgG coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test results.

ACTIVE INGREDINTS OF MAIN COMPONENT
First View HBsAg test kit contain the following:
- Test Device with activated silica gel
- Plastic dropper.
- Assay Buffer Bottle
- Instruction for use.

MATERIALS MAY BE REQUIRED AND NOT PROVIDED
- Positive Control.
- Negative Control.

MATERIALS REQUIRED BUT NOT PROVIDED
- Digital Clock
- Timer

KIT STORAE AND STABILITY
- For the reproducible results, users should be aware of the following:
- Store the kit box at room temperature, 2-30°C.
- Do not freeze.
- The test device is sensitive to humidity as well as heat
- Perform the test immediately after removing the device from the pouch.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not mix reagents of different lots.
- Do not use the kit beyond the expiration date.
- To verify a higher than expected frequency of positive or negative results.
- To investigate the cause of repeated invalid results.
- The shelf-life of the kit is as indicated on the outer package.
- When transporting or storing the kits, avoid exposure to high temperature (over 30°C).

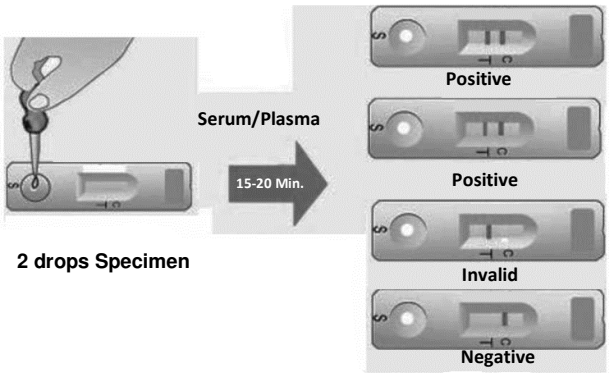
QUALITY CONTROL
Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen and assay buffer. If the C line does not develop, review the entire procedure and repeat the test with a new device.

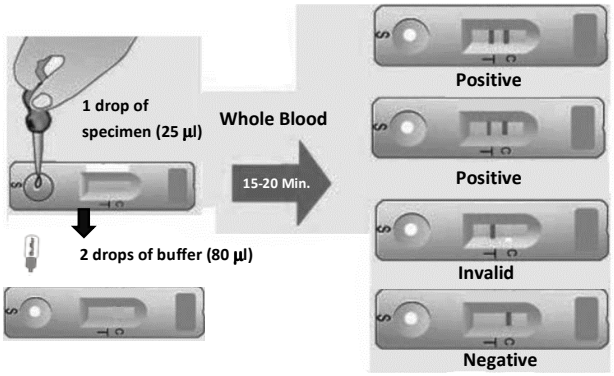
SPECIMEN COLLECTION, STORAGE AND HANDLING
Plasma: Collect blood specimen into collection tube containing EDTA, Citrate or Heparin. Separate the plasma by centrifugation, 1500 RPM for 10 minutes. Carefully withdraw the plasma into a new pre-labeled tube.
Serum: Collect blood specimen into a collection tube containing no anticoagulants. Allow the blood to clot. Separate the serum by centrifugation; 1500 RPM for 10 minutes. Carefully withdraw the serum into a new pre-labeled tube. Test the specimens as soon as possible after collection.
Whole Blood: Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
Storage: Stored serum/plasma or whole blood specimens at 2-8°C up to 3 days can be used for testing Serum/plasma or whole blood. Specimens should be frozen at -20°C for storage longer than 2 weeks.

HANDLING
- Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- As known for relevant interference, hemolytic samples, rheumatoid factors containing samples and lipaemic, icteric samples can lead to impairment of the test results.
- Use separate disposable dropper or pipette tips for each sample in order to avoid cross contamination of either samples which could cause erroneous results.

ASSAY PROCEDURE
- Allow the kit components and specimens to attain room temperature prior to testing.
- Remove the test device from foil pouch and place it on flat dry surface.
- With a **25 µl** disposable dropper draw **serum/plasma** specimen and dispense **two drops (50 µl)** or with micropipette dispense 50 **µ**l into well(S) **(don't add assay buffer in-case of serum/plasma)**.
- With a 25 **µ**l disposable dropper draw **whole blood** specimen and dispense **one drop (25 µl)** or with micropipette dispense 25 µl into well(S).
- Add 2 drops (80 µl) of Assay Buffer into the well (S).
- Wait for 15-20 minutes and read the results. Do not read the results after 30 minutes.

INTERPRETATION OF ASSAY RESULT
Negative Result: If only the control (C) band is developed, the test indicates that no detectable HBsAg antigen are present in the specimen. The result is negative.





Positive Result: If the both control(C), test band (T) are developed, The test indicates for the presence of HBsAg antigen in specimen. The result is HBsAg Positive.

Invalid Result: If no control band is developed the assay is invalid regardless of colour development on T bands. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

First View HBsAg test has been tested using in-house panel of positive and negative clinical samples confirmed by leading commercial anti HBsAg ELISA and lateral Flow test and the correlation between these two systems was found to be 100%.

First View HBsAg Rapid test			
Status	**Positive**	**Negative**	**Total**
Positive	200	0	200
Negative	0	1000	1000
Total			1200
Sensitivity-100%		Specificity-100%	

LIMITATIONS AND INTERFERENCS

- This is only a screening test to detect the presence of antigen against HBsAg antibodies. All specimens detected reactive must be cross checked by using other techniques like ELISA, PCR.
- A definitive clinical diagnosis should not be based on the single test. But should only be made by the physician after all clinical and laboratory findings have been evaluated.
- A positive test result must be verified with a confirmatory test.
- This test is designed for use with serum/plasma or whole blood samples only. Use of other body fluids, including urine or saliva has not been established.
- A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected and not present during the stage of disease in which a sample is collected.

WASTE MANAGEMENT OR DISPOSABLE

The contents of RDTs can be divided into:

Infectious waste:

- sharps (lancets, needles, scalpel blades)
- blood collection devices (tubes, straws, and loops); gloves; swabs; and cotton
- Used cassettes.

Non-infectious waste (Recyclable):

- Packaging materials, desiccant, buffer, and unused or unusable RDTs. **"You must collect and dispose each type of waste in separate containers as per your waste management policies".**

LIMITED EXPRESS WARRANTY DISCLAIMER

Bioline Diagnostics LLP. Products are warranted to meet the applicable product specifications described. Notice of non-conforming products should be made to Bioline Diagnostics LLP. For which liability is limited to either replacement of the product and in no case liable to for claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. Bioline Diagnostics LLP. Disclaims any and all responsibility for any injury or damage or legal implications which may be caused by the fault of the user or buyer in accordance with the limitations and specifications here in.

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