HBsAg RAPID TEST
(Serum / Plasma)

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

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 colored 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 colored band. The formation of first purple band (T zone) confirms a positive test result. Absence of this colored 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.

REAGENTS AND MATEREIALS PROVIDED
HBsAg test cards contain the following:
- Test Device with activated silica gel
- Plastic Dropper
- Package Insert (Instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDE
- Positive Control
- Negative Control
- Timer
- Digital Clock

WARNINGS AND PRECAUTIONS:
For professional in Vitro Diagnostic Use
- This pakage insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room tempreature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment,such as gloves and lab coats when handling kit reagents.wash hands thoroughly after performing the test.
- Do not smoke,drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to performe the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE
INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C; ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

SPECIMEN COLLECTION, STORAGE AND HANDLING
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

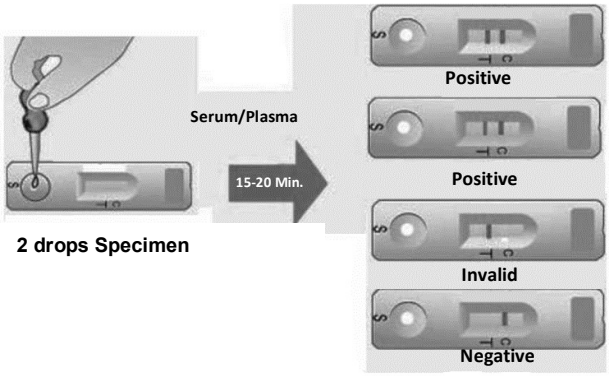
1. Plasma
- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new pre-labeled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

2. Serum
- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer®) by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store Specimens at 2-8°C if not tested immediately, for up to 5 days. The specimens should be frozen at -20°C for longer storage.

DIRECTIONS FOR USE
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on flat dry surface.
3. **For Serum or Plasma Specimen**: With a **25 µl** disposable dropper draw **Serum/Plasma** specimen and dispense **2 Drops (50 µl)** or with micropipette dispense **(50 µl)** into well(S) **(Don't add assay buffer in-case of Serum/Plasma)**.
4. Start the timer, see illustration below.
5. Wait for the colored line(s) to appear. The test result should be read at 15-20 minutes.
   Note. ***Do not interpret the result 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 is present in the specimen. The result is negative.



Positive Result: If the both control (C) and 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 color development on T bands. Repeat the assay with a new device.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control (containing 10ng/mL HBsAg) and a negative control (containing 0 ng/mL HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance.

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%.

Method		**ELISA**		**Total Results**
First View HBsAg Rapid Test Card (Serum/Plasma)	Results	Positive	Negative	
	Positive	200	0	200
	Negative	0	1000	1000
Total Results		200	1000	1200

Relative Sensitivity: 100%
Relative Specificity: 100%
Accuracy : 100%

2. Acceptance Criteria.

Sr. No.	**Test(s) Conducted**	**As per CDSCO´s Specifications for HBsAg Rapid Test.**
1	Sensitivity	100%
2	Specificity	>= 98%

3. Cross-reactivity

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, and Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

4. Interfering Substances

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipoid specimens. No interference was observed.
In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin,

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 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 analyst 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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