

HBsAg Rapid Test (WB,S,P)

INTENDED USE

Labgene HBsAg Rapid Test kit is a lateral flow chromatographic immunoassay designed for qualitative determination of Hepatitis B surface antigen (HBsAg) in human whole blood, serum and plasma .

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG003-10T	10	1 X 2 mL	01 in an individual pouch	
LG003-25T	25	1 X 3 mL		
LG003-30T	30	1 X 3 mL		
LG003-40T	40	2 X 2 mL		
LG003-50T	50	2 X 3 mL		
LG003-100T	100	4 X 3 mL		
LG003LS-10T	10	1 X 2 mL		10
LG003LS-25T	25	1 X 3 mL		25
LG003LS-30T	30	1 X 3 mL		30
LG003LS-40T	40	2 X 2 mL		40
LG003LS-50T	50	2 X 3 mL		50
LG003LS-100T	100	4 X 3 mL		100
*IFU: 01 in an individual carton box				

INTRODUCTION

Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease. The hepatitis B virus can survive outside the body for at least 7 days. The complex antigen found on the surface of HBV is called HBsAg, previously known as Australian antigen. The presences of HBsAg in serum/plasma/whole blood is an indication of an active Hepatitis B infection, either acute or chronic. The incubation period of the hepatitis B virus is 120 days on average, but can vary from 45 to 160 days. Hepatitis B virus (HBV) is a global health problem. It is a major cause of chronic hepatitis, liver cirrhosis and hepatocellular carcinoma.

PRINCIPLE

Labgene HBsAg Rapid Test kit is a lateral flow chromatographic immunoassay test which contains 1) A nitrocellulose membrane strip containing a test band (T) and control band ©. The T band is pre-coated with monoclonal antibody covering all subtypes and variants of HBsAg 2) A conjugate pad containing monoclonal antibody, specific to HBsAg and polyclonal antibody colloidal gold conjugate. The colloidal gold conjugate and sample moves along the membrane chromatographically to test region (T) and control region (C) and forms a visible band as the antibody-antigen-antibody gold particle complex forms. The HBsAg test cassette has a letter of T and C as "Test band" and "control band" on the surface of the cassette. Both the test and control band in result window are not visible before applying any sample. The control band is used for procedural control. The control band should always appear if the test procedure is performed properly and the reagents of control band are working.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.

- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

The HBsAg Rapid Test can be performed using either serum, plasma or whole blood.

Plasma :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- 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,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2°C-8°C for up to three days if the tests cannot be performed immediately. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature and mix gently. Do not use haemolysed sample.

Whole Blood :

Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

Collection using a lancet:

- Clean the area to be lanced with the alcohol swab
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

PROCEDURE

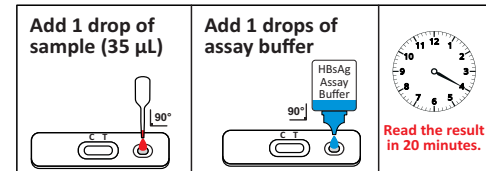
- Follow the same procedure for serum/plasma and whole blood
- Allow the kit component and specimen to attain room temperature prior to testing.
- Remove the test cassette from foil pouch and place it on flat dry surface.
- With disposable dropper draw **serum/plasma or whole blood** specimen and dispense **1 drop (35-40 µL)** or with **micropipette dispense 35-40 µL into the sample well**.
- Add **1 drops of Assay buffer** into the well. wait for 20 minutes and read the results.

Do not read the result after 25 minutes, as it can give false results.



Strong positive specimens may produce positive result in as little as 1 minutes.

SERUM/PLASMA/WHOLE BLOOD:



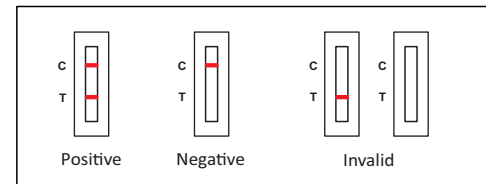
INTERPRETATION OF RESULTS

Positive Result : The presence of both band control band (C) and test band (T) within the result window indicate presence of HBsAg antigen in specimen .The result is positive for HBsAg.

Negative Result: If only the control (C) band is developed, within the result window the test indicate that no HBsAg antigen is present in specimen. The result is negative for HBsAg.

Invalid Result: if the control (C) band is not visible in the result window after performing the test, the result is considered invalid. The specimen must be tested using a new test device.

RESULTS:



LIMITATIONS

- This assay is intended as an aid for the clinical diagnosis. Conduct this assay in conjunction with clinical examination, patient's medical history and other test results.
- If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result. A negative result does not preclude the possibility of HBsAg infection. This assay is a screening assays and any positive result should be confirmed by Western Blot method or other confirmatory methods.
- As with all diagnostic assays, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

HBsAg rapid test has been tested using in-house clinical sample confirmed by leading commercial HBsAg ELISA and Lateral flow test & NIB panel of positive and negative samples. The correlation between these two systems was found to be 100%.

SAMPLES	Positive	Negative	Total
Positive	166	00	166
Negative	0	560	560
Total	166	560	726

Relative Sensitivity: 100%

Relative Specificity: 100%,

External Evaluation

The external performance evaluation of the HBsAg rapid test has been done by National Institute of Biologicals (NIB), India. The results are shown in following table:

Sensitivity	100%
Specificity	100%

CROSS REACTIVITY WITH OTHER INFECTIOUS DISEASES

Specimen	Sample Size	HBsAg Reactivity
HIV Positive Serum	10	Negative
HCV Positive Serum	10	Negative
Syphilis Positive Serum	10	Negative

REFERENCES

1. Blumberg, B. S.; Sutnick, A. I.; & London, W. T. (1969). Australia antigen and hepatitis. *Jama*, 207 (10), 1895-1896.
2. Block, T. M.; Guo, J. T. (2007). Molecular virology of hepatitis B virus for clinicians. *Clinics in liver disease*, 11(4), 685-706.
3. Zampini, R.; Boemio, A.; Sagnelli, C.; Alessio, L.; Adinolfi, L.; Esagnelli, E.; & Coppola, N. (2015). Hepatitis B virus burden in developing countries.
4. Blumberg, B.; Alter, H. J.; & Visnich, S. (1984). A New antigen in Leukemia Sera. *JAMA*, 252 (2), 252-257.
5. Posthuma-Trumple, G. A., & van Amerongen, A. (2012). Lateral flow assays. In *Antibodies: Applications and New Development (Vol. 2012, pp. 175-183)*. Bentham eBooks: Bussum, The Netherlands.

INDEX OF SYMBOLS

	Product Reference No.		International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date		For invitro diagnostic use only
	Lot (batch) number		Read product insert before use.
	Store between 2-30°C		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-003-04	

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