LordsMed HBsAg Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
HBSLMR01	25 Test Device	WholeBlood/Serum/Plasma
HBSLMR02	50 Test Device	WholeBlood/Serum/Plasma
HBSLMR03	25 Test Device	Serum/Plasma
HBSLMR04	50 Test Device	Serum/Plasma

INTENDED USE

LordsMed HBsAg Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum/plasma/whole blood at a level equal to or higher than 1 ng/mL. It is intended to be used as a screening test and as an aid in the diagnosis of infection with hepatitis B virus (HBV). It is intended for professional use.

TEST PRINCIPLE

The HBsAg Rapid Test is a lateral flow chromatographic immunoassay. Each test contains a strip composed with absorbent pad, nitrocellulose membrane, conjugate pad and sample pad. After addition of the serum/plasma/whole blood sample and Assay buffer (for whole blood) to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with HBsAg specific Antibody and Rabbit IgG. If the sample contains detectable levels of the HBsAg Antigen, it reacts with the gold conjugated HBsAg specific Antibody to form a complex. This complex moves further and reacts with HBsAg specific Antibody coated as test line on the nitrocellulose membrane to form colored band (test line). The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat anti-rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

MATERIALS PROVIDED

1. Test device.
2. Desiccant.
3. Plastic dropper.
4. Buffer Bottle (Only for Wholeblood Specimen)
5. Package insert (instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Do not use the components in any other type of test kit as a substitute for the components in this kit.
5. Do not use haemolysed blood specimens for testing.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens.
Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV, and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens.

SPECIMEN COLLECTION AND STORAGE

Store serum/plasma specimens at 2-8°C if not tested immediately. Fresh wholeblood specimen is required. Serum/plasma specimens can be stored at 2-8°C for up to 5 days. The serum/plasma specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Serum/plasma Specimens containing visible particulate matter should be clarified by centrifugation before testing.

PROCEDURE

For LordsMed HBsAg Rapid Test

1. Bring the specimen and test components to room temperature if refrigerated or frozen.
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Be sure to label the device with the specimen ID number.
4**(a). Serum/Plasma:** Place the device on flat plane surface & add 2 drops (Approx. 60 µl) of serum or plasma sample in well “S”.
4**(b). Wholeblood:** Place the device on flat plane surface & add 2 drops (Approx.60 µl) of whole blood sample in well “S” & Add 1 drop of Assay buffer in well “S”.
5. Set up timer.
6. Read the result at 15 minutes. Do not read the result after 20 minutes.

Note: Use assay buffer for wholeblood samples only.

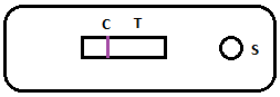
Lord's Mark Industries Ltd., Plot No. A71, Royal Ind. Hub, Poman, Kaman-Bhiwandi Road, Taluka -Vasai, Palghar- 401208, Maharashtra (India). Customer Care No.: 8425982321. Email: ivdcare@lordsmark.com; Website:www.lordsmed.com

LordsMed HBsAg Rapid Test

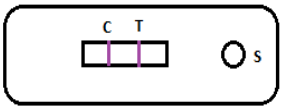
(Wholeblood/Serum/Plasma)

TEST INTERPRETATION (REFER TO FIGURE)

NEGATIVE RESULT: One distinct purplish pink coloured line appeared in control line 'C'. The result is negative or non-reactive.

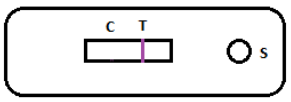


POSITIVE RESULT: Two distinct purplish pink coloured line appeared in both the Control line 'C' and the Test line 'T'. The result is positive or reactive.

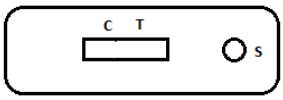


INVALID:

- No purplish pink colour line appears in 'C' region and line appear only in 'T' region



- No purplish pink colour line appears in 'C' region and 'T' region



PERFORMANCE CHARACTERISTICS

As per National Institute of Biologicals – Noida, (NIB) the sensitivity is 100% and specificity is 100%

AS PER NABL LAB SENSITIVITY & SPECIFICITY

	Positive sample	Negative sample	Rate
Positive sample	34	00	100% (Sensitivity)
Negative sample	00	20	100% (Specificity)
Total	34	20	100% (Total accuracy)

LMITATION

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely. Failure to follow the procedure may give inaccurate results.
2. LINEAR HBsAg is a screening test. This screening test should be used for the detection of HBsAg in serum or plasma specimen. Neither the quantitative value nor the rate of HbsAg concentration can be determined by this qualitative test.
3. A non-reactive test result does not preclude the possibility of exposure to or infection with HBV.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of HBsAg in blood, as HBsAg may be present below the minimum detection level of the test.

BIBLIOGRAPHY

1. Emanuel Rubin and John Farber. The liver and biliary system. Acute viral hepatitis P 721-729. Rubin E, Farber JL ed. Pathology 2nd ed.1994. J.B. Lippincott, Philadelphia.
2. Kaplan PM, Greenman RL, Gerin JL, Purcell RH, Robinson WS. DNA polymerase associated with human hepatitis B antigen. J Virol. 1973 12(5):995-1005.
3. Dane DS, Cameron CH, Briggs M. Virus-like particles in serum of patients with Australia-antigen-associated hepatitis. Lancet. 1970;1(7649):695-8.
4. Magnius LO, Espmark A. A new antigen complex co-occurring with Australia antigen. ActaPathol Microbiol Scand [B] MicrobiolImmunol. 1972;80(2):335-7.

REF	Catalog No		Attention Caution
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer	Σ	No. of Tests

IFU/HBS/01 Rev No.: 01 Dated.:15/07/2024

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