LordsMed HCV Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
HCVLMR01	25 Test Device	WholeBlood/Serum/Plasma
HCVLMR02	50 Test Device	WholeBlood/Serum/Plasma
HCVLMR03	25 Test Device	Serum/Plasma
HCVLMR04	50 Test Device	Serum/Plasma

INTENDED USE

LordsMed HCV Rapid test is rapid qualitative lateral flow immunoassays for detection of total antibodies specific to Hepatitis C Virus in human serum /plasma / whole blood. The double antigen sandwich system ensures detection of all anti-HCV- antibody isotypes (viz., IgG, IgM, IgA etc.) to all major HCV genotypes. It is prelimary screening test the sample should be confirmed by confirmatory test such as ELISA. It is intended for professional use.

TEST PRINCIPLE

Highly purified antigens of HCV (CORE, NS3,NS4 & NS5) are coated on the nitrocellulose membrane at test region "T" and goat anti-rabbit IgG/mouse IgG at control line region "C". the gold conjugate pad contains recombinant proteins of HCV representing core,NS3,NS4,NS5 and rabbit/mouse IgG.

When a test specimen containing HCV antibodies is added to the sample well along with the required volume of assay buffer, it makes an immune complex with recombinant antigen of HCV conjugated with colloidal gold. The complex moves further on the nitrocellulose membrane to the test line region "T", where it is capture by HCV antigens coated on the membrane and leads to the formation of purplish pink coloured band. The presence of coloured bands in the test regions "T" indicates the presence of antibodies to HCV in the test specimen. Appearance of no purplish pink coloured band at the test line region "T", indicates absence of HCV antibodies or level of the antibodies are below detection limit.

The unreacted conjugate and unbound complex, if any, along with rabbit IgG/mouse IgG conjugate moves further on the membrane and are subsequently captured by the goat anti-rabbit IgG/mouse IgG coated at the control line region "c" forming an additional purplish pink coloured band. This control band acts as an procedural control and serves to validate the result.

MATERIAL PROVIDED

1. Test device.
2. Desiccant.
3. Plastic dropper.
4. Assay Buffer.
5. Pack insert.

PRECAUTION

1. For *In - vitro* diagnose only.
2 .Do not use after the expiration date.
3. The test result is invalid over 20 minutes.
4. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.
5. Do not smoke, drink, or eat in areas were specimens or kit reagents are being handled.

STORAGE AND STABILITY

1.The test can be used for the human serum, plasma, and whole blood specimen.

2.A serum / plasma / whole blood specimen must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the, anticoagulants. Detect immediately after collecting blood. If blood coagulation occurs serum sample is to use. Use the fresh whole blood samples.

3. Samples may be stored at 2-8℃ for 1 week prior to assay, and at 20 ℃ for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times. Samples exhibiting visible precipitates, stink or muddy should not be used. Instead, it should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing

PROCEDURE

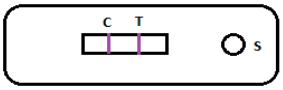
For LordsMed HCV Rapid Test

1. Instructions must be read entirely before taking the test.
2. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)
3. Take off the outer packing, put the cassette onto the Desk. And label the device with patient's ID number.
4.**(a) For Wholeblood :** Dispense 2 drop (about 40-50 µL) of the whole blood specimen into the sample well and then add 1 drop (about 35 -50 µL) of assay buffer immediately.
4.**(b) For Serum/Plasma :** Dispense 1 drop (25 µL) of the specimen into the sample well and then add 2 drops (about 70-100 µL) of assay buffer immediately.
5. Set up timer.
6. Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

TEST INTERPRETATION (REFER TO FIGURE)

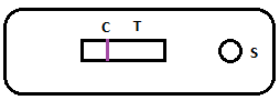
POSITIVE:

Two distinct purplish pink colour lines appear. One line should be in the control region (C) and the other line should be in the (T) test region



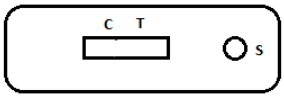
NEGATIVE:

One purplish pink colour line appears in the control region(C). No apparent purplish pink colour line appears in the test region (T).



INVALID: The test should be considered invalid if,

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

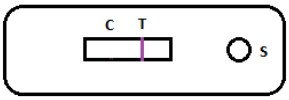


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(Wholeblood/Serum/Plasma)

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



LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of HCV cannot be determined by this qualitative test.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of HCV does not exist, or the concentration is below detection limit.
4. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
5. Abnormal results may occur according to operator error or drug use. If HCV infection is still suspected, the sample should be collected later and carry the parallel detection with the first sample.

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	54	00	99.39% (Sensitivity)
Negative sample	01	20	100% (Specificity)
Total	55	20	99.56% (Total accuracy)

BIBLIOGRAPHY

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(4) Principle and Practice of Infectious Diseases, Mandell, Burnett and Dolin, 5th Edn., Vol. 1 Part-II, 1307-1331, 2000, Churchill Livingstone Publications.
(5) Marisol Deves Arlette De Saez, Graciela Leon, Firelei Sirit, Clarisa Coson, Henry Bermudez, Ferdinando Liprandi, Oscar Noya, Flor H. Pujol. Restricted Isotypic Antibody reactivity to Hepatitis C Virus Synthetic Peptides in Immunocompromised Patients, Clinical and Diagnostic Laboratory Immunology, Vol.6 No.2, 279-281, May 1999.
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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/HCV/01 Rev No.: 01 Dated.:15/07/2024

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