HCV Ab Rapid Test (WB,S,P)

Labgene biotech

INTENDED USE

Labgene HCV Ab Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection of antibodies against Hepatitis C Virus (HCV) in human whole blood/serum/plasma samples.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG002-10T	10	1 X 2 mL	01 in an individual pouch	-
LG002-25T	25	1 X 3 mL		
LG002-30T	30	1 X 3 mL		
LG002-40T	40	2 X 2 mL		
LG002-50T	50	2 X 3 mL		
LG002-100T	100	4 X 3 mL		
LG002LS-10T	10	1 X 2 mL		10
LG002LS-25T	25	1 X 3 mL		25
LG002LS-30T	30	1 X 3 mL		30
LG002LS-40T	40	2 X 2 mL		40
LG002LS-50T	50	2 X 3 mL		50
LG002LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

Hepatitis C virus (HCV) is now recognized as a major agent of chronic hepatitis transfusion acquired non-A,non-B hepatitis and liver disease throughout the world. HCV is a positive sense single stranded RNA virus. The major immunoreactive antigen of its protein have been reported as core, NS3, NS4 and NS5 regions of HCV genome, which are known as highly immunodominant regions. HCV infection frequently progresses to chronic liver disease. On the basis of phylogenetic analysis, HCV has been grouped into six major genotype each of which contain one or more subtype. The distribution of HCV genotype varies in different geographical areas.

PRINCIPLE

Labgene HCV Ab rapid test is a lateral flow chromatographic immunoassay based on a principle of double antigen sandwich. The test card contains a membrane strip, which is precoated with recombinant HCV capture antigen (core,NS3,NS4 and NS5) on the test band region. The HCV antigen-colloid gold conjugate and sample moves along the membrane chromatographically to test region (T) and form a visible band as the antigen-antibody-antigen gold particle complex forms. The development of a colored band in the test region indicate the presence of antibodies to HCV in the specimen. The unreacted gold conjugate and unbounded complex move further on membrane and are subsequently immobilized by the control reagent coated on the membrane at the control region(C) forming a colored band. control band is used for procedural control and should always appear if the procedure is performed correctly.

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 HCV 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 2-8°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.

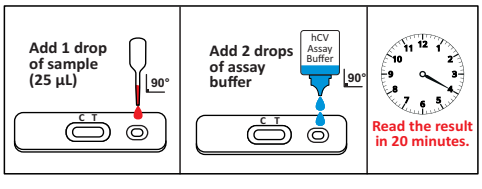
Whole Blood :

- 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 (2-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

PROCEDURE

- Allow test device, specimen, to reach room temperature (15°- 30°C) prior to testing.
- Place the test device on a clean and level surface.
- **For Serum/ Plasma/ Whole blood sample:** Hold the dropper vertically and **transfer 1 drop of sample (25 µL)** to the sample well of the test device, then **add 2 drops of assay buffer** and start the timer.
- Read the result in 20 minutes. Read results as shown under interpretation of Results
- **NOTE: Do not read the results after 25 minutes. For each sample, use a separate dropper and test cassette.**

WHOLE BLOOD / SERUM / PLASMA :

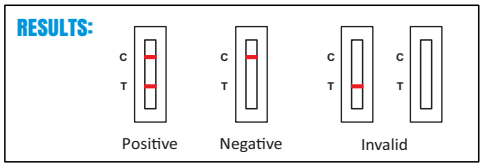


INTERPRETATION OF RESULTS

Positive Result : If the control (C) and HCV test band (T) are developed the test indicate for the presence of antibodies to Hepatitis C virus in the specimen, the result is reactive for anti-HCV antibodies.

Negative Result: If only the control (C) band is developed, the test indicate that no detectable antibodies to Hepatitis C virus are present in the specimen. The result is non-reactive for anti-HCV antibodies.

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



LIMITATIONS

- The HCV Ab rapid test is for in vitro diagnostic use only.
- Humidity and temperature can adversely affect results. This test should be used for the detection of antibodies against Hepatitis C virus in human whole blood, serum or plasma specimens only.
- 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 Hepatitis C virus 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.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

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

Status	Positive	Negative	Total
Positive	90	00	90
Negative	00	610	610
Total	90	610	700

External Evaluation

The external performance evaluation of the hCV 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	HCV Ab Reactivity
HBsAg Positive Serum	10	Negative
HIV Positive Serum	10	Negative
Syphilis Positive Serum	10	Negative

REFERENCES

1. Grakoul, A. R. A. S. H., et al. "Expression and indentification of hepatitis C virus polyprotein cleavage products," Journal of virology 67.3 (1993): 1385-1395
2. Cho, Young Gyu, et al. "Cloning and over expression of the highly immunogenic region of HCV genome from korean patients." Mol Cells 3 (1993): 407-416
3. Neville, J.A. et al. "Antigenic variation of core, NS3 and NS5 proteins amoung genotypes of hepatitis C virus." Journal of clinical microbiology 35.12(1997) : 3062-3070.
4. Yoshikawa, A., et al. "Serodiagnosis of hepatitis C virus infection by ELISA for antibodies against the putative core protein (p20c) expressed in Escherichia coll, "Journal of immunological methods 148. 1-2 (1992): 143-150.

INDEX OF SYMBOLS

REF	Product Reference No.	ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	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-002-03	

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