One Step Rapid Test For HCV

MERISCREEN HCV

Meril Diagnostics

Product code	Pack Size
RPDHCV - 01	50 Tests

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

INTENDED USE:
MERISCREEN HCV is a qualitative, *In-Vitro* diagnostic immunochromatography assay based on lateral flow technology for the detection of specific antibodies to Hepatitis-C in human serum/plasma or (venous) whole blood. This test is for healthcare professional diagnostic use and intended as an aid to the diagnosis of HCV infection in human. This is only a primary screening test. The positive results must be correlated with patient clinical history and more specific confirmatory test should be performed to obtain the confirmation of HCV infection. The assay is manual and does not require additional instruments.

INTRODUCTION:
Hepatitis C virus (HCV) is now recognised as the primary cause of transfusion associated hepatitis. HCV is a single stranded positive-sense RNA virus and is globally present. In acute presentation of HCV infection patients may develop jaundice, others may go on to develop chronic hepatitis with life threatening conditions such as cirrhosis and hepatocellular carcinoma.
Diagnosis of HCV is mainly done by either direct detection of viral RNA by PCR or by detection of anti-HCV antibodies. Recombinant DNA techniques have been used to develop structural and non-structural proteins derived from HCV RNA with utility for antibody screening. Anti-HCV assays have evolved as from first generation products, which used C-100-3 peptide. Second generation assay used recombinant viral proteins, Core, NS3 and NS4. Were as third generation anti HCV assay uses antigens from Core (structural), Ns3 protease/helicase (non-structural), NS4 (non-structural) and NS5 replicase (non-structural) proteins, which provides greater sensitivity and specificity.

PRINCIPLE:
MERISCREEN HCV is a qualitative rapid test based on immuno chromatography principle employs double antigen sandwich site immunoassay on nitrocellulose membrane. As the test sample flows through the membrane assembly of the test device, the recombinant Hepatitis C Virus antigens (Core, NS3, NS4 & NS5)-colloidal gold conjugate forms a complex with HCV specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant HCV antigens (Core, NS3, NS4 & NS5) coated on the membrane leading to the formation of a reddish purple coloured band at the test region 'T' which confirms a positive test result. Absence of this coloured band in test region 'T' indicates a negative test result.
At control region Goat anti-mouse IgG is immobilized and it binds to unreacted colloidal gold conjugate to give coloured band at Control region by turning pale blue to reddish purple colour. Control band will appear irrespective to the sample status. Control band is the procedural control and it has nothing to do with the intensity of test band.

REAGENTS AND MATERIALS PROVIDED:
Each kit contains:

1.	Individually Packed Test Devices	50
2.	Capillary Tubes	50
3.	Assay buffer	2.5 ml
4.	Sterile lancet	50
5.	Alcohol swab	50
6.	IFU	1

MATERIALS NEEDED BUT NOT PROVIDED:
1. Stop watch
2. Biohazard cover for disposal
3. Hand gloves

STORAGE AND STABILITY:
All reagents are ready to use as supplied. Store unopened test devices at 2-30°C. If stored at 2-8°C, allow test device to attain room temperature before opening. The test device is stable up to the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C. Once test device foil is opened, it gives accurate result till 24 hours. But, it is recommended that test device should be used immediately after opening the foil. After opening the Assay buffer bottle, the buffer is stable until the expiration date if kept at 2-30°C.

PRECAUTIONS:
1. For *in-vitro* diagnostics and professional use only.
2. Allow all reagents and sample(s) to attain room temperature (18°C to 30°C) before use.
3. Once test device foil is opened, it gives accurate result till 24 hours. But, it
4. is recommended that test device should be used immediately. Though performance of test device is not affected by the different range of humidity i.e., 40% RH, 60% RH and 75% RH, it is recommended that test device should be used in ambient humidity i.e., between 40% RH and 60% RH.
4. Do not use the kit contents beyond the expiry date.
5. Do not use test device if pouch is lack of desiccant.
6. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
7. Test Devices and assay buffers of different lot must not be mixed and used.
8. Perform the test by using kits assay buffers. Performing the test with any other buffer is not recommended
9. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
10. Do not use haemolysed specimen for testing.
11. Use sufficient volume of sample for testing.
12. Do not reuse the Test Devices, sample Capillary Tubes and pipette tips from the procedure may lead to aberrant results.
13. Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
14. Avoid contact of reagents with eyes and skin. If any reagents come into contact with the skin or eyes, wash thoroughly with water.
15. Wear protective clothing such as laboratory coats and disposable gloves and eye protection when specimens are assayed. Do not re- use used gloves or use of washed gloves.
16. Handle sample(s) and used materials as if it is capable of transmitting infection.
17. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. Remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121°C for 15 minutes or dipped in 6 % hypochlorite solution for 30 minutes prior to disposal.
18. Clean up spills thoroughly using an appropriate disinfectant.
19. The test device should remain in its original sealed pouch until usage. Do not use the test device if the seal is broken or the pouch is damaged. In case desiccant pouch changes colour from blue to light pink colour or test device pouch is lack of desiccant then test device should not be used.

SPECIMEN COLLECTION AND PREPARATION:
Consider any materials of human origin as infectious and handle them using standard bio safety procedures.

A. WHOLE BLOOD: Collect Blood specimen in to collection tube containing EDTA, Citrate or Heparin.
B. PLASMA: Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
1. Separate the plasma by centrifugation (Centrifugation time & speed: 2350-3150 x g for~ 10 minutes).
2. Carefully withdraw the plasma into new pre-labelled tube.

C. SERUM:
1. Collect blood specimen into a collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Separate the serum by centrifugation (Centrifugation time & speed: 2350-3150xg for~10 minutes).
4. Carefully withdraw the serum into a new pre-labelled tube. Test the specimens as soon as possible after collection.

Stored serum/plasma/Whole Blood specimens at 2-8°C up to 3 days can be used for testing. Serum/Plasma specimens should be frozen at -20°C for longer storage

TEST PROCEDURE:
1. Bring all reagents (and specimens) to attain room temperature.
2. Open the pouch and remove the test device from it. Place device on a flat surface.
3. Dispense 10 µL serum/plasma or 20 µL Whole blood sample through Capillary Tubes on to the sample port ('S').
4. Dispense three drops of the assay buffer into the sample port ('S').
5. At the end of 20 minutes, read the results. Do not read results after 30 minutes. INTERPRET THE TEST RESULTS AT THE END OF 20 MINUTES. DO NOT READ THE RESULTS AFTER 30 MINUTES AND READING TOO LATE CAN GIVE FALSE RESULTS.

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Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com
Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. +(32) 2 732-59-54 (32) 2 732-60-03, mail@obelis.net

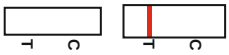
INTERPRETATION OF RESULTS
Notes: The faint blue line at "Control" position is always visible before testing.

This faint blue line should not be interpreted as control line during result interpretation. Expected results are as follows:

NEGATIVE RESULT: If only the Control (C) band is developed, the test indicates that no detectable antibodies to Hepatitis C Virus are present in the specimen. The result is non-reactive for Anti-HCV.

POSITIVE RESULT: If no Control (C) band is developed, the assay is invalid regardless of colour development on 'Test' band as indicated below. Repeat the assay with a new device.

INVALID RESULT: If no Control (C) band is developed, the assay is invalid regardless of colour development on 'Test' band as indicated below. Repeat the assay with a new device.



As shown in below images, appearance of faint blue line at control band even after addition of samples and assay buffer and no color development at control band, the assay is invalid regardless of color development on test bands. Repeat the assay with a new device.

PERFORMANCE CHARACTERSTICS:
The performance of MERISCREEN HCV has been demonstrated by testing samples of anti-HCV positive and HCV negative samples. In addition, its performance on commercially available seroconversion has been evaluated.

DIAGNOSTIC SENSITIVITY:
In-house testing: Diagnostic sensitivity of MERISCREEN HCV was evaluated using 400 anti- HCVpositive samples including 21 samples of Genotype 1, 21 samples of Genotype2, 21 samples of Genotype 3, 21 samples of Genotype 4, 21 Samples ofGenotype 4 non-A, 6 samples of Genotype 5 and 1 sample of Genotype 6. Allsamples were identified as positive when tested with MERISCREEN HCV.Diagnostic sensitivity of MERISCREEN HCV was calculated as 100% (95% CI:99.08% to 100.00%) and positive predicted value was calculated as 100%.
Testing at National Institutes of Biologicals, India:
Three lots of MERISCREEN HCV were tested at National Institute of Biologicals, India to find out the diagnostic sensitivity. Diagnostic sensitivity of all three lots of MERISCREEN HCV was found as 100%.
Overall Diagnostic Sensitivity of MERISCREEN HCV:
Total 700 anti-HCV positive samples were tested with MERISCREEN HCV and all samples were detected as positive. So, Diagnostic sensitivity of MERISCREEN HCV is calculated as 100% (95% CI: 99.47% to 100.00%).

DIAGNOSTIC SPECIFICITY:
In-house testing:
Diagnostic specificity of MERISCREEN HCV was evaluated using 1961 HCV negative samples including 1450 healthy blood donor samples, 204 pregnant women samples, 207 hospitalized (clinical) samples and 100 Interfering substances. All samples were identified as negative when tested with MERISCREEN HCV. Diagnostic specificity of MERISCREEN HCV was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%.
Testing at National Institutes of Biologicals, India:
Three lots of MERISCREEN HCV were tested at National Institute of Biologicals, India to find out the diagnostic specificity. Diagnostic specificity of three lots of MERISCREEN HCV was found as 100%.
Overall Diagnostic Specificity of MERISCREEN HCV:
Total 3404 HCV negative samples were tested with MERISCREEN HCV. All samples were identified as negative when tested with MERISCREEN HCV. So, overall Diagnostic specificity of MERISCREEN HCV is calculated as 100.00% (95% CI: 99.89% to 100%).
Sensitivity in Seroconversion Panels:
MERISCREEN HCV was tested with 35 HCV seroconversion panels to evaluate the sensitivity in seroconversion panels. From the results, it can be concluded that MERISCREEN HCV has relatively comparable sensitivity when compared with CE marked comparator assay kit i.e., Turklab's Rapidan® Tester Anti-HCV Test, WB/S/P.

Repeatability & Reproducibility:
Inter-day, inter-lot, inter-operator, within-run variability were assessed by testing samples in replicates of 3 by three operators over the five days. The results have shown 100% agreement with the sample status when tested with anti-HCV positive samples and HCV negative samples. The results and data analysis showed 100% sensitivity for anti-HCV positive samples and 100% specificity for HCV negative samples.

Hook effect:
30 anti-HCV high-titer positive samples were diluted to generate moderate titer and weak titer anti-HCV positive samples and these samples were tested in replicates of three (03) with MERISCREEN HCV to check whether MERISCREEN HCV exhibit hook effect or not. There was no intensity drop observed anywhere with high-titer anti-HCV positive samples. So, it is concluded that MERISCREEN HCV does not exhibit hook effect.

DISPOSAL:
Discard the test device immediately after reading the results. Add few drops of disinfectant on the device and items used for the handling of serum, plasma, Whole blood. Dispose all the items as per the standard QC norms.

LIMITATIONS OF THE TEST
1. This is only a screening test. All Specimens detected reactive must be cross checked by using other techniques like HCV EIA, PCR or NAAT.
2. As with all diagnostic tests, the test result must always be co-related with clinical findings.
3. Presence of heterophile antibodies in patient's sample with Rheumatic diseases, Renal failure, Kidney dysfunction and autoimmune disorder may lead to false results need to be reconfirmed with confirmatory tests.
4. 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 analyte of interest that are tested are not present during the stage of disease in which a sample is collected.
5. A negative result at any time does not preclude the possibility of exposure or infection.
6. Repeat the test in case of very faint band or if have any doubt for test band.
7. Although the test is accurate in detecting Antibodies specific to HCV in Serum/Plasma low incidence of false results may occur. Reactive samples should be confirmed by EIA and RNA HCV test or Western Blot.
8. Interpret the results of the test in immunocompromised patients with caution. For example, it was observed during performance testing that, faint test line/band was developed when tested with HIV co- infected samples.

REFERENCES

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Product disclaimer:
Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.
Warning:
The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whetherpositive or negative, in the use of this product

Symbols used on Meril Diagnostics labels:

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Storage temperature
Consult instruction for use
For single use only do not reuse
Keep away from direct sunlight
CE marking of Conformity
Device not for near-patient testing
Device not for self-testing
UDI Unique Device Identi· er
Do not use if package is damaged and consult *instructions for use*