LumiQuick

DIAGNOSTICS, INC.

QuickProfile™ HCV ANTIBODY TEST

FOR THE QUALITATIVE ASSESSMENT OF HCV ANTIBODY
IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

REF 71027 HCV Test Strip
REF 71030 HCV Test Card

For In Vitro Diagnostic Use Only

INTENDED USE

QuickProfile™ HCV Ab Test is a chromatographic immunoassay for qualitative detection of the antibodies against hepatitis C virus (HCV Ab) in human serum, plasma or whole blood samples. It is intended for professional use as an aid for diagnosis and management of patients related to infection with hepatitis C as well for primary screening of blood from volunteer donors.

SUMMARY

Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA (9.5 kb) virus belonging to the family of Flaviviridae. Six major genotypes and series of subtypes of HCV have been identified. Isolated in 1989, HCV is now recognized as the major cause for transfusion associated non-A, non-B hepatitis. The disease is characterized with acute and chronic form. More than 50% of the infected individuals develop severe, life threatening chronic hepatitis with liver cirrhosis and hepatocellular carcinomas. Since the introduction in 1990 of anti-HCV screening of blood donations, the incidence of this infection in transfusion recipients has been significantly reduced. Clinical studies show that significant amount of HCV infected individuals develop antibodies to NS5 non-structural protein of the virus. For this, the third generation tests include antigens from the NS5 region of the viral genome in addition to NS3 (c200), NS4 (c200) and the Core (c22). Third generation tests have improved sensitivity and shorten the time between infection with HCV and the appearance of detectable antibodies (window period) to 60 days.

TEST PRINCIPLE

QuickProfile™ HCV Ab Test employs a chromatographic lateral flow device in a strip or cassette format. Recombinant HCV antigens are immobilized at the Test Zone (T) and goat anti mouse IgG antibodies are immobilized at the Control Zone (C) on the nitrocellulose membrane. When the sample is added, it migrates by capillary diffusion and rehydrating the colloidal gold conjugated recombinant HCV antigens (Au-Ag) dried onto the fiberglass strip. If present in sample, HCV antibodies will bind the gold conjugated antigens forming complexes. These complexes will continue to migrate along the strip until the Test Zone (T) zone where they are captured by the HCV antigens to form a visible red line. The colloidal gold-mouse IgG is used as the indictor for control line. A red line formed by gold-mouse IgG and goat anti-mouse IgG at the Control Zone (C) indicates the validity of the test.

MATERIAL PROVIDED

1. QuickProfile™ HCV Ab Test
2. Sample buffer
3. Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or timer
Specimen collection container
Centrifuge
Biohazard waste container

STORAGE

The sealed pouches in the test kit may be stored between 4-30ºC for the duration of the shelf life as indicated on the pouch. The test must be used immediately after being removed from the sealed pouch.

PRECAUTIONS

1. This kit is for ***in vitro*** diagnostic use only.
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose of specimens after autoclaving them at 121º C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and do not no smoke, eat or drink while performing assays.
9. Wear gloves during the whole procedure.

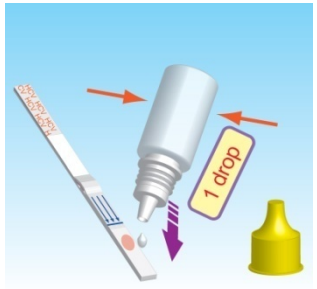
SPECIMEN COLLECTION AND PREPARATION

Fresh serum, plasma or whole blood samples can be used for this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum/plasma must be separated from the clot as early as possible as to avoid hemolysis of the red blood cell. Care should be taken to ensure that the serum samples are clear and not contaminated by microorganisms. Any visible particulate matter in the sample should be removed by centrifugation at 3000 RPM for at least 20 minutes at room temperature, or by filtration with 0.22u filters. Plasma samples collected into EDTA, sodium citrate or heparin may be tested, but highly lipaemic, icteric, or hemolized samples should not be used as they could give erroneous results in the assay. Do not inactivate samples by heat. This can cause deterioration of the target proteins in the sample.

ASSAY PROCEDURE

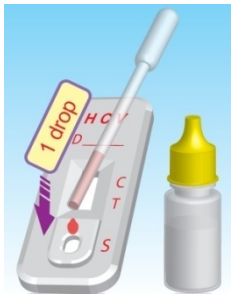
For HCV Test Strip (Catalog Number: 71027)

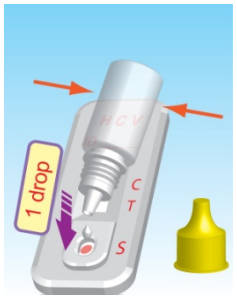
1. Allow the test strip and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test strip and transfer pipet.
3. Using the transfer pipet to draw up the sample, dispense one drop (approx 40µl) specimen to the sample pad as shown in the illustration, and wait for a few seconds until the sample is completely absorbed by sample pad.
4. Add one drop (approx 40µl) sample buffer to the sample pad as shown in the illustration.
5. Read the results at 20 minutes.



For HCV Test Card (*Catalog Number: 71030*)

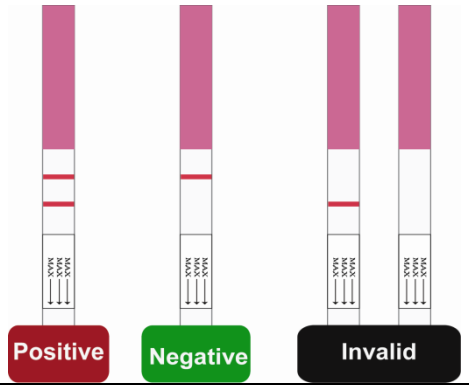
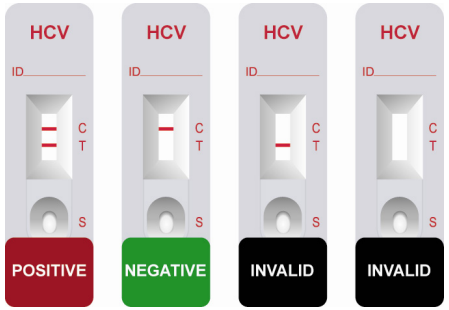
1. Allow the test card and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test card and transfer pipet..
3. Using the transfer pipet to draw up the sample, dispense one drop (approximately 40µl) of specimen to the sample well marked as "**S**" and wait for a few seconds until the sample is completely absorbed by sample pad.
4. Add one drop (approx. 40 µl) sample buffer into the sample well marked as "**S**".
5. Read the results at 20 minutes.





Some positive samples may show positive results before 20 minutes.
Results after 30 minutes may not be accurate.

INTERPRETATION OF RESULTS

TEST STRIP		**Positive** If two color bands are visible within 20 minutes, the test is positive and valid. The test result can be read as soon as a distinct colored band appears in test zone and control zone respectively. It indicates that HCV Ab has been detected using QuickProfile™ HCV Ab Test.
TEST CARD		**NEGATIVE** Only one red line appears in the Control Zone (C), indicating that no HCV Ab have been detected with QuickProfile™ HCV Ab Test. However, this does not exclude the possibility for infection with HCV. **INVALID** One red line should always appear at Control Zone (C) if no red line appears in the Control Zone (C), the test is invalid. The sample must be re-tested using a new device

QUALITY CONTROL

1. The control band is an internal reagent for procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials are not provided with this test kit but may be commercially available.

LIMITATIONS

1. The test is for in vitro diagnostic use only.
2. Negative results do not rule out the possibility of hepatitis C exposure or infection. Infection through recent exposure to HCV may not be detectable.
3. The positive result obtained with QuickProfile™ HCV Ab Test alone cannot be the final diagnosis of hepatitis C infection. As in the case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.
4. This test is intended ONLY for testing of individual serum, plasma or whole blood samples. DO NOT use it for testing of other body fluids or pooled blood samples.
5. The test is for qualitative detection of anti-HCV antibody in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.

PERFORMANCE CHARACTERISTICS:

1. Accuracy

In clinical evaluation of the QuickProfile™ HCV Ab Test, 727 confirmed negative and 327 positive samples were tested. A sensitivity of 99.08% (324/327) and a specificity of 99.17% (721/727) were obtained.Overall, agreement with the Predicate Test is 99.15%.

	Predicate HCV Ab Test		
QuickProfile™ HCV Ab Test		Positive	Negative
	Positive	324	6
	Negative	3	721
	Agreement	99.08%	99.17%

2. Interference

No cross reactivity was observed with specimens from patients infected with HAV, HBV, HIV, HTLV, CMV, and TP.

REFERENCES

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2. Alter HJ., Purcell RH, Holland PV, et al. (1978) Transmissible agent in non-A, non-B hepatitis. Lancet I: 459-463.
3. Choo Q-L,Weiner AJ, Overby LR, Kuo G, Houghton M. (1990) Hepatitis C Virus: the major causative agent of viral non-A, non-B hepatitis. Br Med Bull 46: 423-441.
4. Engvall E, Perlmann P. (1971) Enzyme linked immunosorbent assay (ELISA): qualitative assay of IgG. Immunochemistry 8:871-874.

IVD 4°C 30°C

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