One Step HCV Rapid Test

For detection of Hepatitis C Virus antibodies in Human Serum, Plasma or Whole Blood.

IVD *In-vitro diagnostic use only* *Not reuse*

Introduction

Hepatitis C virus (HCV) now is recognized as a major agent of chronic hepatitis, transfusionacquired non-A, non-B hepatitis and liver disease throughout the world. HCV is an enveloped positive-sense, single-stranded RNA virus. Clinical diagnostic issues related to HCV is the detection of HCV antibodies in human serum, plasma or whole blood by immunoassay. We have constructed HCV genes for the expression of recombinant antigens in bacterium systems such as E. coli and focused on structural and non-structural regions of HCV-encoded polyprotein, which are definitely immunogenic. The major immunoreactive antigens of these proteins have been reported as core, NS3, NS4 and NS5 regions of HCV genome, which are known to be highly immunodominant regions. For diagnosis of HCV infection, these recombinant proteins were used as capture materials of a immunochromatographic (rapid) test. Compared to the first generation HCV test using single recombinant antigens, multiple antigens using recombinant proteins have been added in new serologic tests to avoid nonspecific cross-activity and to increase the sensitivity of the HCV antibody test.

Intended Use

The One Step HCV Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus (HCV) in Whole Blood /Serum / Plasma to aid in the diagnosis of Hepatitis C Virus infection

Principle

The One Step HCV Test is a qualitative membrane strip based immunoassay for the detection of HCV antibodies in Whole Blood /Serum / Plasma. In this test procedure, recombinant HCV antigen is immobilized in the test line region of the device. After a Whole Blood /Serum / Plasma specimen is placed in the specimen well, it reacts with HCV antigen coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized HCV antigen. If the specimen contains HCV antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain HCV antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials Included

1) HCV Ab test kit contains the following items to perform the assay.
- HCV Ab test device foil pouched with a desiccant
- Assay diluents
- Instruction for use

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
9) Store kit at room temperature (2 -30 ^{o}C). Do not expose the kit to temperature over 30 ^{o}C.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card. Preferably, collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. If blood specimens are not immediately tested, they should be refrigerated at 2~8˚C . When stored at 2~8˚C, the blood specimens should be used within 3 days. For storage period longer than 3 days, freezing is recommended. They should be brought to room temperature (1~30˚C) prior to use. Using the blood specimens in the long-term keeping more than 3 days can cause nonspecific reaction.
4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8˚C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30˚C) prior to use.
5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure (Refer to Figure)

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) For serum or plasma specimen: With a micropipette (not provided) or a disposable dropper, add about 100 µL of serum/ plasma specimen into the sample well marked “S”.
4) For whole blood specimens: Hold the dropper vertically and transfer 1 drop of whole blood(approximately 35 µL) to the specimen well (S) of the test device. **Allow about 30 seconds for the specimen to be absorbed totally**. Then add 2 drops of buffer (approximately 70 µl) and start the timer. See illustration below.
5) As the test begins to work, you will see red color move across the result window in the center of the test

device.

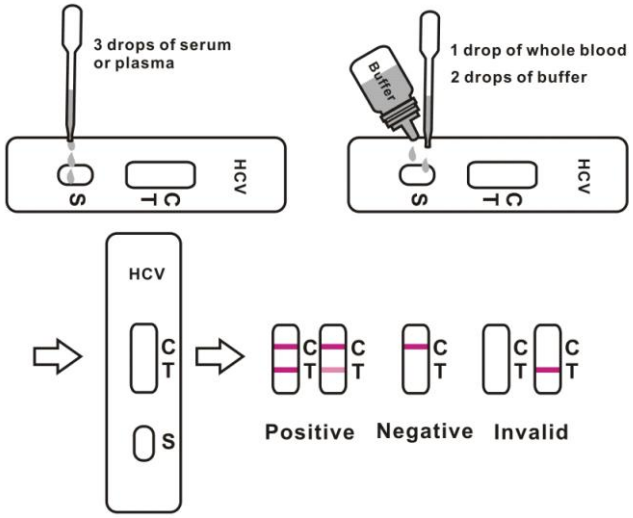
6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Limitations of the Test

1. The One Step HCV Test is for in vitro diagnostic use only. The test should be used for the detection of HCV antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in HCV antibodies can be determined by this qualitative test.
2. The One Step HCV Test will only indicate the presence of HCV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C Virus infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
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 any time preclude the possibility of HCV infection.

Internal Quality Control

The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

Suggested Reading List

1) Arash G., Czeslaw W., Chao Lin, Stephen M. Feinstone, and Charles M. Rice : Expression and Identification of Hepatitis C Virus Polyprotein Clevage Products. Journal of Virology, March. 1993, p.1385-1395

2) Young Gyu Cho, Min Kyung Yi, Kyung Lib jang, Chang Min Kim and Young Chul Sung : Cloning and Overexpression of the Highly Immunogenic Region of HCV Genome from Korean Patients. Mol. Cells, Vol. 3, 4-7 - 416

3) S. Osborne, E. Cecconato, S. Griva, F. Garetto, R. Calogero, C. Rosa and F. Bonelli : Expression in E. coli and purification of a chimeric p22-NS3 recombinant antigen of Hepatitis C Virus (HCV). Federation of European Biochemical Societies, Volume 324, number 3, 253-257

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