Research Article

iMedPub Journals
www.imedpub.com

Health Science Journal
ISSN 1791-809X

2022
Vol. 16 No. 7: 960

DOI: 10.36648/1791-809X.16.7.960

HCV Antibody Rapid Test is Expected to Accelerate the Detection Accuracy of the Hepatitis C Virus

Zhang Lei[1*], Yang Feng[2], Zhu Junzhe[3]

1 Zhejiang Gongshang University

2 Community Health Service Center, Yipeng Street, Qiantang District, Hangzhou

3 Wenzhou Medical University

***Corresponding author:**
Zhang Lei

zhanglei@zjgsu.edu

Tel: +13588036333

Zhejiang Gongshang University

Citation: Lei Z, Feng Y, Junzhe Z (2022) HCV Antibody Rapid Test is Expected to Accelerate the Detection Accuracy of the Hepatitis C Virus. Health Sci J. Vol. 16 No. 7: 960.

Abstract

Background: Hepatitis C virus (HCV) infection is mostly asymptomatic in its early stages, but long-term infection can lead to liver fibrosis, cirrhosis, and even liver cancer. Traditional antibody serology test for detecting a HCV infection in the window, real-time fluorescent quantitative PCR operation is relatively complicated. Moreover, clinical laboratory technicians require advanced training and large capital investments are required to procure and operate laboratory equipment. Therefore, it is important to establish a new rapid test method for HCV with high accuracy, sensitivity and specificity for early diagnosis of HCV.

Purpose: This evaluation aimed to evaluate the accuracy and performance of the All Test HCV Rapid Test Cassette. It is a rapid chromatographic immunoassay for the qualitative detection of antibody to HCV in whole blood, serum or plasma to aid in the diagnosis of HCV infection.

Method: Run a rapid in vitro diagnostic test device for detection of antibody to HCV in whole blood, serum or plasma and compare to a leading commercial ELISA HCV test using clinical specimens for validation of the performance.

Results: The assay showed that the relative sensitivity of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.8%, the relative specificity is 99.1%, and the relative accuracy is 99.0%.

Conclusion: The All Test HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to HCV in whole blood, serum or plasma. The test is accurate with simple operation, low contamination risk, easy visual interpretation and fast results. The HCV Rapid Test Kits manufactured by All Test are an important diagnostic tool for the early diagnosis of HCV.

Keywords: Hepatitis C Virus; Antibody; Rapid Test; Chromatographic Immunoassay

Received: 28-Jun-2022, Manuscript No. Iphsj-22-12834; **Editor assigned:** 30-Jun-2022, PreQC No. Iphsj-22-12834; **Reviewed:** 14-Jul-2022, QC No. Iphsj-22-12834 **Revised:** 19-Jul-2022, Manuscript No. Iphsj-22-12834 (R); **Published:** 27-Jul-2022, DOI: 10.36648/1791-809X.16.7.960

Introduction

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA virus. HCV is now known to be the major cause of parentally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens [1, 2]. Compared to the first-generation HCV ELISA using a single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests [3, 4].

The All Test HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in whole blood, serum or plasma specimens. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in whole blood, serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

HCV Prevention

Currently there is no vaccine to protect against hepatitis C [5]

Table 1: All Test HCV Rapid Test Compared to ELISA HCV Test Kit.

Method		ELISA		Total Results
HCV Rapid Test (Whole Blood/Serum/Plasma)	**Results**	**Positive**	**Negative**	
	Positive	252	7	259
	Negative	3	731	734
Total Results		255	738	1158

Prevention of hepatitis C is the same as that of hepatitis B. HCV is primarily spread through blood contact associated with injected drug use, poorly sterilized medical devices, needle stick injuries in health care, and blood transfusions [6]. With blood screening, the risk of transfusion is less than 1 in 2 million [7].

HCV Rapid Test Kit Materials and Method

Materials

The HCV Rapid Test Kit consists of a test cassette, a dropper, a buffer and a package insert.

Method

The All Test HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial HCV ELISA test using clinical specimens.

Before testing, all test kits were stored in a room temperature environment (15-30°C) prior to performing the comparison test. The test material was used as soon as the contents were removed from the sealed bag. The most accurate results are obtained by completing the experiment within one hour.

The All Test HCV Rapid Test Kit is suitable for testing three different types of samples (whole blood, serum or plasma). The three specific operation methods are as follows:

For Serum or Plasma specimen

The first step is to separate serum or plasma as soon as possible to avoid hemolysis. The instructions note to only use clear non-haemolysed specimens. Next, transfer 1 drop of serum or plasma to the specimen area and then 2 drops of buffer solution, and start the timer.

For Venipuncture Whole Blood specimen

Hold the dropper vertically and transfer 2 drops of whole blood to the specimen area, then add 2 drops of buffer, and start the timer.

For Finger stick Whole Blood specimen

To use a capillary tube: Fill the capillary tube and transfer approximately 50µl of finger stick whole blood specimen to the specimen area of test cassette, then add drops of buffer, and start the timer.

The intensity of the color in the Test line region (T) will vary depending on the concentration of HCV antibodies present in the specimen. Therefore, any shade of color in the Test line region (T) should be considered a positive result. A colored line will always appear at the Control (C) location on the cassette to indicate that the assay worked correctly. The test result is obtained in 10 minutes. Do not interpret the result after 20 minutes.

These comparative tests show that the relative sensitivity of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.8%, and the relative specificity is 99.1% (**Table 1**).

Precision of the Test

Within-run precision has been determined by using 20 replicates of three specimens: a negative, an HCV low titer positive and an HCV high titer positive. The negative, HCV low titer positive and HCV high titer positive values were correctly identified 100% of the time.

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a HCV low titer positive and a HCV high titer positive. Three different lots of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified 100% of the time.

Summary

The All Test HCV Rapid Test Kits tested in this evaluation performed well. In particular, the relative accuracy of the kits was 99.0%. Also, the test kits showed both excellent sensitivity and specificity. However, the laboratory evaluation could differ from test performance outside of a laboratory due to the limited sample range and close monitoring and expertise that is carried out by laboratory technicians.

From the results of tested samples, it presents that the HCV Rapid Test Kit developed by Hangzhou All Test Biotech Co., Ltd meets the requirements of intended use. The HCV Rapid Test Kits is expected to improve the accuracy of HCV testing and could be an effective preventive tool for hepatitis C.

References

1 Choo Q L, Kuo A J, Weiner L R, Bradley D W, Houghton M (1989) Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 244:359.

2 Kuo G, Choo Q L, Alter H J, Houghton M (1989) an assay for circulating antibodies to a major etiologic Virus of human non A, non-B hepatitis. Science 244:362.

3 Van der Poel C L, Cuypers H T M, Reesink H W, Lelie P N (1991) Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 337:317.

4 Wilber J C (1993) Development and use of laboratory tests for hepatitis C infection: a review. J Clin Immunoassay 16:204.

5 Abdelwahab KS, Ahmed Said ZN (2016) Status of hepatitis C virus vaccination: Recent update. World J Gastroenterol 22:862-873.

6 Maheshwari A, Thuluvath PJ (2010) Management of acute hepatitis C. Clin Liver Dis 14:169-176.

7 Q&A for Health Professionals (2020) Viral Hepatitis. Centers for Disease Control and Prevention.