

## A cross sectional study on Evaluation of rapid diagnostic test for detection of hepatitis C at Integral Institute of Medical Sciences & Research, Lucknow

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### Abstract

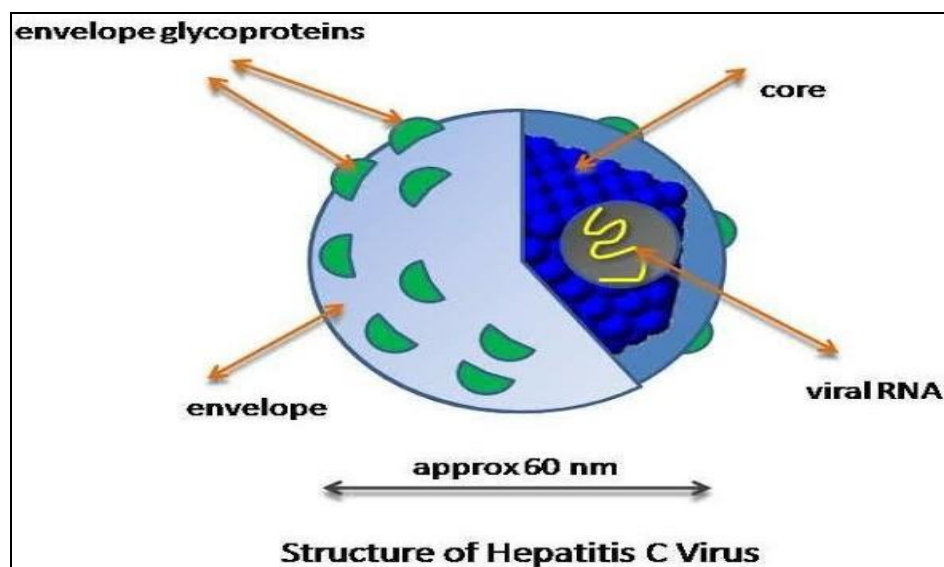
Background: Rapid diagnostic test needs highly trained healthcare worker, sample transport, provide fast TAT. The detection of HCV cannot be performed independently they can be approved for use in India by the drug controller general of India (DCGI). Hepatitis C is a positive sense ssRNA virus of family flaviviridae consist of non-coding regions and genes encoding the core E1 and E2. Aims- "To evaluate of Rapid Diagnostic Test for Detection of Hepatitis C at Integral Institute of Medical Sciences & Research, Lucknow." This study is a cross-sectional observational study conducted to evaluate the performance of rapid diagnostic tests (RDTs) for the detection of Hepatitis C virus (HCV) infection. The study was conducted in the Department of Microbiology, Integral Institute of Medical Sciences and Research (IIMSR), Lucknow. Final sample size is 80. Result - The results obtained in this study are consistent with findings reported in previously published literature. As per Wen-Ge-Xing (2020), the sensitivity of various HCV RDT kits ranged between 94% and 100%, while specificity varied from 96% to 100%. In our study, the RDT demonstrated high concordance with reference tests, suggesting strong potential for its use in clinical screening. The high Negative Predictive Value (NPV) further reinforces the RDT's utility in ruling out HCV infection in asymptomatic individual. Conclusion- The study concludes that RDTs can play a significant role in the early identification and management of HCV infections, thereby contributing to broader public health efforts aimed at controlling and eventually eliminating hepatitis C. However, further multi-centric studies with larger sample sizes are recommended to reinforce the findings and assess the generalizability and long-term impact of RDT-based screening strategies.

**Keywords:** Evaluation, Rapid diagnostic test, Hepatitis C.

### Introduction

Rapid diagnostic test need highly trained healthcare worker, sample transport, provide fast TAT. The detection of HCV cannot be performed independently they can be approved

for use in India by the drug controller general of India (DCGI). Hepatitis C is a positive sense ssRNA virus of family flaviviridae consist of non-coding regions and genes encoding the core E1 and E2.



There is high risk in individual for infection of HCV who are suffering from HIV infection due to receiving haemodialysis, IV drug user, multiple blood transfusion, individual with high-risk sexual behavior. Sexual transmitted disease has high prevalence of HCV ranging from 3.5% to 44.7%.

Hepatitis C virus (HCV) continues to be a pressing global health issue, with the World Health Organization (WHO) estimating that around 58 million people are living with the infection, and approximately 1.5 million new cases arise each year. HCV is a blood-transmitted virus that primarily impacts.

## **Aims**

"To evaluate of Rapid Diagnostic Test for Detection of Hepatitis C at Integral Institute of Medical Sciences & Research, Lucknow."

## **Objectives**

To estimate the number of Hepatitis C positive cases among the study population using a rapid diagnostic test.

To determine the association between Hepatitis C infection and selected demographic variables such as age, sex, residential area, occupation, and socio-economic status.

## **Methodology**

### **Type of Study**

This study is a cross-sectional observational study conducted to evaluate the performance of rapid diagnostic tests (RDTs) for the detection of Hepatitis C virus (HCV) infection.

### **Place of Study**

The study was conducted in the Department of Microbiology, Integral Institute of Medical Sciences and Research (IIMSR), Lucknow.

### **Study Period**

The study was carried out over a period of six months, commencing from the date of ethical clearance issued by the Institutional Ethics Committee.

### **Inclusion Criteria**

All relevant clinical samples received in the Department of Microbiology, IIMSR, Lucknow for HCV testing during the study period were included.

### **Exclusion Criteria**

1. Patients or their guardians/attendants not providing informed consent for participation in the study.
2. Improperly labeled, leaking, or otherwise unacceptable samples as per laboratory standards.
3. Patients who were already undergoing anti-hepatitic treatment or were on medications targeting Hepatitis C virus at the time of sample collection.

### **Sample size**

Final sample size is 80

## **Result & Discussion**

The present study was conducted as a cross-sectional investigation in the Department of Microbiology at Integral Institute of Medical Sciences & Research (IIMSR), Lucknow, with the aim of evaluating the efficacy of a Rapid Diagnostic Test (RDT) for the detection of Hepatitis C Virus (HCV) infection. The study was carried out over a period of six months following ethical clearance, and a total of 80 clinical samples were collected and analyzed. Among the 80 samples tested using the RDT kit, 6 samples (7.5%) were found to be reactive (positive), while 74 samples (92.5%) were non-reactive (negative). These results were subsequently compared with the reference standard tests (Enzyme-Linked Immunosorbent Assay [ELISA] and/or Polymerase Chain Reaction [PCR]) to assess the diagnostic accuracy of the RDT.

## **Performance of RDT**

The results obtained in this study are consistent with findings reported in previously published literature. As per Wen-Ge-Xing (2020), the sensitivity of various HCV RDT kits ranged between 94% and 100%, while specificity varied from 96% to 100%. In our study, the RDT demonstrated high concordance with reference tests, suggesting strong potential for its use in clinical screening. The high Negative Predictive Value (NPV) further reinforces the RDT's utility in ruling out HCV infection in asymptomatic individuals.

## **Gender Distribution**

Among the 6 reactive cases, 3 were male (50%), 2 were female (33.3%), and 1 was unspecified (16.7%). This distribution is in line with national trends where male subjects often exhibit higher prevalence due to increased risk factors such as intravenous drug use, occupational exposures, and unsafe sexual practices.

## **Age Distribution**

The majority of HCV-positive individuals belonged to the 31–40 years age group. This was followed by individuals in the 21–30 years category. These findings suggest that HCV predominantly affects adults in the economically productive age range, which carries implications for workforce productivity and overall family health dynamics.

## **Occupational Profile**

A breakdown of occupational background revealed that laborers formed the largest group among HCV-positive individuals (n=2), followed by healthcare workers, housewives, and others (n=1 each). These results are consistent with studies indicating higher exposure among manual laborers and healthcare personnel due to potential contact with infected blood or needles.

## **Comparison with Previous Studies**

Carvalho *et al.* (2019) highlighted that approximately six million individuals in India are HCV-infected, with the majority unaware of their infection status. Their study underlined the significance of RDTs in large-scale screening programs. Our findings complement this, demonstrating that high-performing, quality-assured RDTs are essential tools in the early diagnosis and containment of HCV.

Abhinav Anand and Shalimar (2021) reported a national prevalence of 0.5% to 0.85% in community-based studies. The slightly higher prevalence (7.5%) observed in our study could be attributed to the clinical nature of the sample population, which included individuals presenting with symptoms or belonging to high-risk categories.

## **Conclusion**

The present cross-sectional study entitled "Evaluation of Rapid Diagnostic Test for Detection of Hepatitis C at Integral Institute of Medical Sciences and Research" was conducted with the objective of assessing the diagnostic performance of a rapid diagnostic test (RDT) for Hepatitis C virus (HCV) detection.

Based on the findings of the study, it was observed that the RDT demonstrated a satisfactory level of sensitivity and specificity when compared with standard reference methods such as ELISA or PCR. The rapid diagnostic test proved to be a valuable screening tool, particularly in low-resource

settings, due to its affordability, ease of use, minimal training requirement, and quick result turnaround.

Despite its advantages, certain limitations were noted, including the occurrence of false positives and false negatives. This suggests that RDTs should be primarily utilized for screening purposes, and any positive result should be subsequently confirmed by more specific diagnostic assays.

The study concludes that RDTs can play a significant role in the early identification and management of HCV infections, thereby contributing to broader public health efforts aimed at controlling and eventually eliminating hepatitis C. However, further multi-centric studies with larger sample sizes are recommended to reinforce the findings and assess the generalizability and long-term impact of RDT-based screening strategies.

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