



## Comparative Evaluation Between ELISA And RAPID Immunochromatography Test For Detection Of Hepatitis C Virus

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**Received:** 16-11-2025

**Revised:** 03-12-2025

**Accepted:** 18-12-2025

**Published:** 31-12-2025

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**Abstract: Introduction:** Hepatitis C is an RNA virus that belongs to the flaviviridae family. It is a double-shelled, encapsulated, single-stranded RNA virus with a diameter of 50 to 60 nm. During acute and chronic infection, HCV replicates in the liver and is detectable in the blood. HCV replicates in the cytoplasm of hepatocytes, but is not directly cytopathic. Persistent infection appears to rely on rapid production of virus and continuous cell-to-cell spread, along with a lack of vigorous T-cell immune response to HCV antigens. The HCV turnover rate can be quite high with replication ranging between 10(10) to 10(12) virions per day, and a predicted viral half-life of 2 to 3 hours.

**Method:** ELISA was used as gold standard for comparative evaluation. Ninety two samples were collected and processed using ELISA and Rapid Immunochromatography assay. **Result:** Taking HCV microlisa as a standard reference test, out of 92 samples, 36 true positives were observed. In present study HCV tridot sensitivity was 100% and specificity was 82.1%. **Conclusion:** Rapid assays must be used with caution and it is also important to validate these rapid assays by testing them in a given population to assess the effectiveness of these assays in detecting the genotypes and subtypes of HCV circulating in the region before using these tests routinely in diagnostic laboratories.

**Keywords:** HCV, Rapid immunochromatography assay, ELISA

## INTRODUCTION

An estimated 170 million people worldwide are infected with the Hepatitis C virus (HCV), making it a viral pandemic five times larger than the infection with human immunodeficiency virus type 1. (HIV-1). Although blood-screening policies in affluent nations have eliminated the risk of transfusion-associated hepatitis, new instances still occur, mostly as a result of injection drug use and, to a lesser extent, other types of percutaneous or mucous-membrane exposure. The majority of HCV-infected individuals experience chronic sickness, and the virus is now the most frequent cause of liver transplantation(1) . Egypt

reports the highest number of HCV infections among countries around the world. The World Health Organization (WHO) estimates that approximately 3% of the world's population has HCV infection, with prevalence rates varying from 0.1 to 5% in various European countries. It is estimated that between 15 and 25 percent of HCV infections result in serious liver disease, which can take up to 30 years to appear.(2) The chronic hepatitis C virus is thought to infect 58 million individuals globally, and 1.5 million new cases are reported every year. Over 290 000 people with hepatitis C died in 2019, mostly from cirrhosis and hepatocellular carcinoma, according to the World

Health Organization (primary liver cancer) (3)

Different people develop hepatitis C at varying rates. It advances generally at a slow rate. About 15% of HCV-infected individuals recover on their own; another 25% have an asymptomatic sickness with persistently normal amino transferases and a generally benign histological lesion; hence, approximately 40% of patients recover or experience a benign outcome. Most persons with biochemical indications of chronic hepatitis only exhibit mild to moderate necro-inflammatory lesions and minimal fibrosis.(4)

## MATERIALS AND METHOD:

**Period of study:** February 2021 – January 2022

**Place of Study:** Department of Microbiology  
MGM Medical College and hospital  
Kamothe, Navi Mumbai

**Type of Study:** Descriptive and prospective study

**Sample Size:** All blood samples received in microbiology lab for HCV testing.

**Inclusion criteria:** All blood samples received in microbiology Lab for suspected HCV infection.

**Exclusion criteria:** 1. Repeat blood sample.  
2. Lipemic samples and haemolysed samples will be excluded from the studies.

**Sample collection and separation:** Blood samples approximately 3ml was collected from each patient under aseptic precautions into plain sample collection tubes and allowed to stand for 20 minutes at room temperature for clot formation. The serum was separated by centrifuging at 3000 rpm for 5 minutes. The separated serum was collected for the processing of HCV rapid tests.

## RESULT AND DISCUSSION

A total of 92 blood samples from patients were screened for anti-HCV antibody, out of which 46 were seropositive and 36 were positive by ELISA.

The study, there were 13,699 total samples of HCV suspected cases, of which 36 (0.2%) were found to be seropositive by ICT. 500 total HCV suspected samples were taken in another study by E.I. Bigwan et al. in Nigeria titled "Evaluation of Two Commonly Used Commercial Immunochromatographic and ELISA Screening Kits for the Detection of Anti-HCV Antibodies among Patients in North Central Nigeria," out of which 45 (9.0 percent) were only positive by ICT. Due to the fact that both studies' observations differ significantly, it is likely that our samples mainly include patients who had pre-operative workups.(5)

The study displays the distribution of reactive samples by gender. It revealed that, out of 36 samples, 23 (63.8%) were men and 13 (36.1%) were women. An additional study by Swapna S. et al., "Comparison of two fast immunoassays for screening of hcv infection in dialysis patients," conducted in Visakhapatnam, revealed that out of 92 patients, 64 (69.5%) were men and 28 (30.5%) were women. In both investigations, male infection dominance is evident, which are consistent with the results of our investigation.(Table 1)(6)

The study displays the age-wise distribution of reactive patients, and it reveals that the age range from 21 to 40 years accounts for the majority of HCV reactive patients (55.5%). Prevalence and Genotypic Distribution of Hepatitis C Virus in Peshawar KPK" is another study. Nazir Ahmad and colleagues' research in Pakistan revealed that the highest prevalence of the following age groups showed evidence of HCV RNA: 41–50 years (33.3 percent). The One explanation could be that people between the ages of 20 and 50 are more likely to engage in sexual activity. And also to get a blood transfusion, which are HCV transmission methods. (7)

The my study represents department wise distribution of HCV reactive patient from different wards. The maximum number of reactive patients were from medicine opd (out patient department) which is 10(27.7%) followed by surgery department which is 5(13.8%), Casualty department which is 04(11.1%). This can be because most symptomatic patients visit medicine OPD for consultation.. Which is almost similar to the study "A Brief Study on the Seroprevalence of Hepatitis C Infection in a Tertiary Care Hospital in Kolkata." carried out in Kolkata by Dr.Sanjeev Das et.al, who obtained 39% from paediatric ward and 25% from Medicine opd.(8)

The study shows the result with ICT and ELISA test, out of total 92 samples where 46 (50%) were positive by ICT and 36(39.1%) were positive by ELISA. In another study " comparison between ELISA and ICT techniques for the Detection of Anti HCV antibody among blood donors" carried out in Lahore, Pakistan by Zameer M et.al where they showed 30(23.1%) samples screened as HCV positive by ICT and only 1 (1%) showed positive result by ELISA. These findings shows that false positives were seen when ICT tests were used.(Table 2) (9)

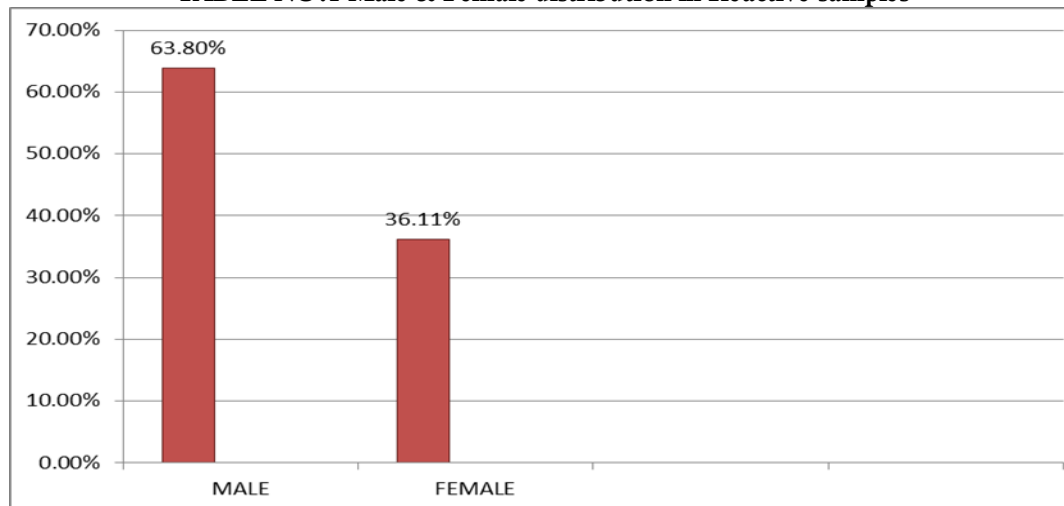
The study shows the result of false positive and false negative result on ICT, in my study false negative was (0%) and false positive was (0.1%). In another study "comparison between ELISA and ICT techniques for the Detection of Anti HCV antibody among blood donors" carried out in Lahore, Pakistan by Zameer M et.al where they showed the rate of false negative was

(1%) and false positive was (3.3%) which is more than my observation.(Table 3) (9)

The study shows the result of sensitivity and specificity of ICT while using ELISA as Gold standard. Our ICT shows the sensitivity of 100% and specificity of 82.1%. In another study “Role of rapid

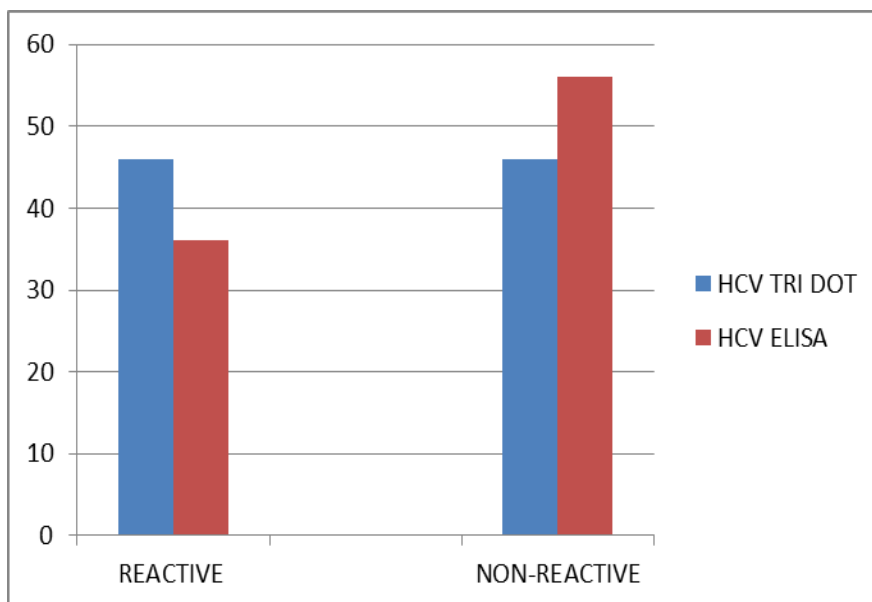
test and ELISA in the diagnosis of HCV in Haemodialysis patients” carried out in Asaripallam, India by Kanaga Priya Muthiah et.al where they showed the sensitivity of ICT 85.7% and specificity of 100% which is exactly opposite to our findings.(Table4)(10)

**TABLE NO.1 Male & Female distribution in Reactive samples**



**TABLE 2 RESULTS WITH ICTAND ELISA TESTS**

| V SCREENING | V TRI DOT | V ELISA |
|-------------|-----------|---------|
| ACTIVE      |           |         |
| N-REACTIVE  |           |         |
| TAL         |           |         |



**TABLE NO 3 FASLE POSITIVE AND FALSE NEGATIVE RESULTS ON ICT IN THIS STUDY**

|              | TRUE POSITIVE | TRUE NEGATIVE | FALSE POSITIVE | FALSE NEGATIVE |
|--------------|---------------|---------------|----------------|----------------|
| ICT          | 36            | 56            | 10             | NIL            |
| LSE NEGATIVE |               |               | 00 (NIL)       |                |
| LSE POSITIVE |               |               | 100 (0.1%)     |                |

**TABLE NO 4 SENSITIVITY AND SPECIFICITY OF ICT WHILE USING ELISA AS GOLD STANDARD**

|             |       |
|-------------|-------|
| SENSITIVITY | 100%  |
| SPECIFICITY | 82.1% |

## CONCLUSION

The study was performed in MGM Medical College within the period of February 2021 to April 2022.

1. Our study shows out of 13,699 HCV suspected cases only 0.2% were reactive to HCV antigen.(Table 1)
2. Present study shows out of 92 blood samples 46 were seropositive by ICT out of which 23 (63.8%) were males and 13 (36.1%) were Females i.e the infection was more supremacy in males than females.(Table 2)
3. Maximum of HCV positive patients belong to age group 21-40 years of age wick was 55.5%(20/36) ,5%(2/36) were of age group 0-20 years of age , 33.3%(12/36) were of age group 41-60, 2.7%(11/36) were of age group 61-80 years of age ,2.7% (1/36) were of age group 80 & above.(Table 3)
4. Out of 46 seropositive patients from ICT , 36 were Positive by ELISA , as per the result
5. ICT showed 10 false positive result .

The published literature show that ELISA is more sensitive but ICT specificity is comparable with ELISA. However, our results while using J.Mitra ICT tests was observed to be completely opposite. Hence, rapid assays must be used with caution and it is also important to validate these rapid assays by testing them in a given population to assess the effectiveness of these assays in detecting the genotypes and subtypes of HCV circulating in the region before using these tests routinely in diagnostic laboratories.

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