



Original Article

## Comparison of Rapid Immunochromatography and Enzyme-Linked Immunosorbent Assay Techniques for Hepatitis C Virus Serodiagnosis: A Study from Mumbai, Maharashtra

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### ABSTRACT

**Objectives:** Hepatitis C virus (HCV) belongs to the Flaviviridae family. It is a small, enveloped, positive-sense single-stranded ribonucleic acid (RNA) virus. It leads to both acute (30%) and chronic (70%) infections. The methods of HCV diagnosis are by detection of anti-HCV antibodies using immunoassays, followed by detection of HCV RNA in serum or plasma on those antibody-reactive specimens. Anti-HCV detection is done by rapid diagnostic test (RDT) and enzyme-linked immunosorbent assay (ELISA); both have different test principles with advantages and disadvantages.

**Material and Methods:** The aims and objectives of the study are to determine the sensitivity and specificity of RDT based on the principle of rapid immunochromatography and its comparison with ELISA for serodiagnosis of HCV, considering ELISA as the gold standard. Blood specimens of patients of both genders and all age groups received in the emergency laboratory for rapid anti-HCV testing were included; they were also tested by the ELISA method. After scrutinizing the laboratory registers, both the test results were recorded and analyzed.

**Results:** Out of the total 6955 samples tested, 77 (1.1%) were positive by RDT, while 46 (0.66%) were positive by the ELISA test. A total of 32 samples were both RDT and ELISA positive; of them, 22 (69%) were male and 10 (31%) were female with the most common age group affected being 41–60 years. As per this study, anti-HCV RDT had a sensitivity and specificity of 69.57% and 99.35% with positive predictive value of 41.55% and negative predictive value of 99.15%, while the kit manufacturer claimed relative sensitivity and specificity of 99.1% and 99.5%.

**Conclusion:** It is important to know the sensitivity and specificity of RDT kits used for interim reporting of HCV during emergency hours. This needs to be followed by an ELISA test which will help in confirmation and also prevent the complications associated with false negativity reported by the rapid assay.

**Keywords:** Hepatitis, Serology, Rapid, ELISA

### INTRODUCTION

Hepatitis C virus (HCV) belongs to the Flaviviridae family. It is a small, enveloped, positive-sense single-stranded ribonucleic acid (RNA) virus. It has 6 major and 1 minor genotype, with more than 50 subtypes leading to high mutability. The primary routes of HCV infection transmission are through exposure to contaminated blood, IV drugs, and men who have sex with men.<sup>[1]</sup>

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It leads to both acute (30%) and chronic (70%) infections. Around 30% acutely infected individuals clear the virus within 6 months without treatment; they are asymptomatic but a few complain of fever, loss of appetite, nausea, abdominal pain, and jaundice. Out of the remaining 70% chronic infections, 15–30% have a risk of developing hepatocellular carcinoma within 20 years. An estimated 50 million people have chronic HCV infection, with approximately 1.0 million new infections occurring per year globally.<sup>[2]</sup> As per the recommendation of the Centers for Disease Control (CDC) and Prevention, hepatitis C screening is to be done for all adults aged  $\geq 18$  years once in their lifetime and all pregnant women (regardless of age) during each pregnancy.<sup>[3]</sup> The HCV diagnosis is done by detection of anti-HCV antibodies using immunoassays, followed by HCV RNA detection in serum or plasma on those anti-HCV reactive specimens. If HCV RNA is detected, the patient is considered to have current HCV infection and treated with highly effective direct-acting antiviral drugs.<sup>[4]</sup> In patients infected with HCV, anti-HCV may persist throughout life, or decrease slightly while remaining at a detectable level, or disappear gradually after several years.<sup>[5]</sup> Methods for detecting anti-HCV are by rapid diagnostic test (RDT) and enzyme-linked immunosorbent assay (ELISA), both have different test principles with advantages and disadvantages.<sup>[6]</sup> The HCV diagnosis in this institute is carried out by serological assays, where ELISA is performed during routine working hours, while RDT is performed only during emergency hours. This study was conducted with the aim to determine the sensitivity and specificity of the RDT based on the principle of the rapid immunochromatography technique (ICT) and compared with ELISA, considering it as the gold standard.

## MATERIAL AND METHODS

This retrospective observational study was carried out in the, Department of Microbiology, Maharashtra, from August 2023 to July 2024. Blood specimens of patients of both genders and all age groups received in the emergency laboratory for rapid anti-HCV testing were included; they were also tested by the ELISA method on the next working day. After scrutinizing the laboratory registers, both the test results were recorded and analyzed.

### Anti-HCV RDT

The one-step card test for HCV antibody is based on the principle of ICT. The method uses multiple epitope HCV recombinant peptides conjugated to colloidal gold and immobilized on nitrocellulose strip in a thin line. The assay was performed as per the manufacturer's instructions that claimed relative sensitivity and specificity of 99.1% and 99.5%, with overall agreement of 99.3% (one-step HCV card test, manufactured by Sidak Life Care, India).

### Anti-HCV ELISA

This is a third-generation sandwich format microplate enzyme-linked immunoassay for the detection of antibodies to HCV. The microwells are coated with HCV-specific recombinant proteins, i.e., core, NS 3,4,5 derived from HCV RNA. The assay was performed as per the manufacturer's instructions: Blank = 0, Negative control (NC)  $< 0.5$ , Positive control  $> 1.0$ , Cut off = Mean of NC + 0.2, and Grey zone = Cut off  $\times 0.9$ . The values lying in the Grey zone were considered indeterminate or equivocal, and retesting was done for them. The kit has a sensitivity of 100% and specificity of  $\geq 99.5\%$  (Merilisa HCV, manufactured by Meril Diagnostics, India).

### Statistical analysis

Both the test results were entered in a Microsoft Excel spreadsheet. Correlation tables were made and sensitivity and specificity were calculated by  $2 \times 2$  tables considering ELISA as the gold standard against RDT. Chi-square test was used for statistical analysis and  $P < 0.05$  was considered statistically significant.

### Ethics approval

This study was approved by the institutional ethics committee IEC EC/OA-126/2024 (IEC(III)/OUT/635/2024). The waiver of patient consent was granted by the IEC.

## RESULTS

Out of the total 6955 samples tested, 77 (1.1%) were positive by RDT, while 46 (0.66%) were positive by the ELISA test. A total of 32 samples were both RDT and ELISA positive, of them 22 (69%) were male and 10 (31%) were female with the most common age group affected being 41–60 years. As per the study, HCV RDT had a sensitivity and specificity of 69.57% and 99.35% with positive predictive value (PPV) of 41.55% and negative predictive value (NPV) of 99.15%, while the kit manufacturer claimed relative sensitivity and specificity of 99.1% and 99.5%.

## DISCUSSION

In our study, anti-HCV seropositivity was found to be 0.66% by ELISA and 1.10% by RDT [Table 1]. The percentage positivity by ELISA is similar to the meta-analysis by Goel *et al.*<sup>[7]</sup> where the pooled prevalence of anti-HCV was reported as 0.6% (0.20–1.20%), while 1.57% was reported by Mishra *et al.*,<sup>[8]</sup> 2.3% by Kumar *et al.*,<sup>[9]</sup> and 4.8% by Bhattacharya *et al.*<sup>[10]</sup> among hospital-based studies across India. The prevalence rate of HCV infection varies in different countries, ranging from 0.23% in Sri Lanka to 2.65% in Myanmar among South-East Asian countries<sup>[11]</sup> and  $< 0.5\%$

**Table 1:** Anti-HCV results by rapid and ELISA techniques.

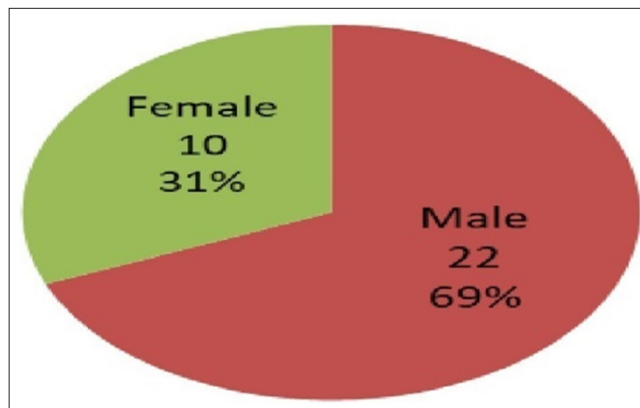
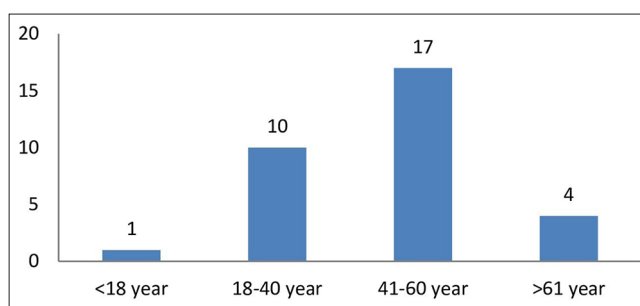
	ELISA positive	ELISA negative	Total
RDT positive	32	45	77
RDT negative	14	6864	6898
Total	46	6909	6955

HCV: Hepatitis C virus, ELISA: Enzyme-linked immunosorbent assay, RDT: Rapid diagnostic test

of the population in western, northern, and central Europe to 3–5% in eastern Europe and central Asia,<sup>[2]</sup> and this variation may be due to traditional factors, genetics, immunity difference, and community habits that affect its spread. In the current study, among true positives ( $n = 32$ ) which are rapid and ELISA positives, 22 (69%) were male and 10 (31%) were female. A similar male preponderance was observed by Agarwal *et al.*<sup>[12]</sup> and Irshad *et al.*<sup>[13]</sup> where HCV acquisition in males was 39 (69.64%), and 250 (58%) compared to 17 (30.4%) and 176 (42%) in females, respectively [Figure 1]. In the present study, the most common age group affected among true positive cases ( $n = 32$ ) was 41–60 years. Bula and Gaddam<sup>[14]</sup> also reported the highest seroprevalence at 41–50 years. In contrast, Singh *et al.*,<sup>[15]</sup> Kulkarni and Chillarge,<sup>[16]</sup> Patel *et al.*<sup>[17]</sup> reported it at 18–40 years, Patil *et al.*<sup>[18]</sup> reported it at 51–60 years, while 61–80 years was reported by Bhaumik *et al.*<sup>[19]</sup> [Figure 2].

The National Viral Hepatitis Control Program (NVHCP) was launched by the Government of India on 28<sup>th</sup> July 2018 to provide free diagnosis and treatment.<sup>[20]</sup> The aim of this program is to end hepatitis C by 2030 and, to achieve this aim, there is a need to expand HCV diagnostics. The tests used for the antibody detection are RDT and ELISA; both have their advantages and disadvantages. The serological window period is the time duration between infection and the appearance of antibody. ELISA test has undergone modification from 1<sup>st</sup> to 3<sup>rd</sup> generation, reducing the window period from 16 weeks to 8 weeks. There is also availability of the 4<sup>th</sup> generation ELISA that detects both HCV core antigen and HCV antibodies within 28 days of infection.<sup>[21]</sup> ELISA test requires skilled personnel, standard laboratory setup with ELISA reader and washer, and longer turn-around times. Conversely, RDT, which does not need automated machines or highly trained laboratory technicians, and generates results within half an hour, can be used for point-of-care testing.<sup>[22]</sup> Owing to cheaper cost and ease of use, these rapid tests can be used at all primary and most secondary healthcare facilities in India under the NVHCP.<sup>[23]</sup>

According to European Union standards, anti-HCV assays must have 100% sensitivity and 99.5% specificity for the market approval.<sup>[24]</sup> And as per the Drug Controller General of India guidelines, anti-HCV rapid immunodiagnostic kits must meet sensitivity and specificity requirements of

**Figure 1:** Gender distribution of true positives ( $n = 32$ ).**Figure 2:** Age distribution of true positives ( $n = 32$ ).

>99% and  $\geq 98\%$ , respectively.<sup>[25]</sup> Even though there are many commercially available RDT kits, the quality of their performance is not independently assessed. This could be the reason for certain samples being reactive by ELISA and non-reactive by RDT. Hence, RDT should have a high degree of sensitivity and specificity to minimize false-positive and false-negative results.<sup>[26]</sup>

As per this study, HCV RDT had a sensitivity and specificity of 69.57% and 99.35% with PPV of 41.55% and NPV of 99.79% [Table 2]. These findings align with those of Farooqui<sup>[23]</sup> who reported sensitivity and specificity of 70.58% and 93.61%, indicating a relatively lower ability to detect true positives while maintaining high specificity in confirming negative cases. A study by Kumar *et al.*<sup>[27]</sup> reported a higher sensitivity and specificity of the rapid ICT as 86.96%, 100% and PPV and NPV as 100% and 99.83% while Khan *et al.*<sup>[28]</sup> reported a lower sensitivity and specificity of 66% and 45% with PPV and NPV of 96% and 97% [Table 3].

The reasons for poor diagnostic accuracy may be divided into viral factors, patient factors, and test kit-related factors. False negativity is the inability of screening kits to detect HCV-reactive specimens. This could be due to inadequate coating of the antigen, the nature of antigen used, and the genetic heterogeneity of virus. Rapid test assays use recombinant proteins from the prototype virus,

**Table 2:** Evaluation of rapid anti-HCV kits with ELISA.

RDT	ELISA		Total	Sensitivity	Specificity	PPV	NPV	Accuracy	P-value
	Positive	Negative							
Positive	32	45	77	69.57%	99.35%	41.55%	99.79%	99.15%	<0.05
Negative	14	6864	6878						
Total	46	6909	6955						

RDT: Rapid diagnostic test, PPV: Positive predictive value, NPV: Negative predictive value, ELISA: Enzyme-linked immunosorbent assay, HCV: Hepatitis C virus

**Table 3:** Comparison of sensitivity and specificity of different studies.

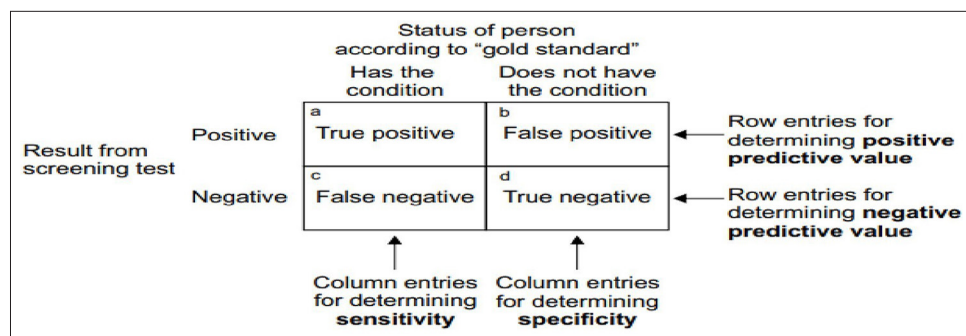
The date of publication	Current study	Farooqui <sup>[23]</sup> Haryana, India February 2016	Arora <i>et al.</i> <sup>[26]</sup> New Delhi, India March 2021	Agarwal <i>et al.</i> <sup>[12]</sup> U.P, India January 2022	Kumar <i>et al.</i> <sup>[27]</sup> Telangana, India December 2024	Irshad <i>et al.</i> <sup>[13]</sup> Karachi, Pakistan September 2019	Khan <i>et al.</i> <sup>[28]</sup> Lahore, Pakistan March 2010
Details of kit used for the Rapid test.	One-step HCV card test, by Sidak Life Care, India.	Virucheck anti-HCV by Orchid Biomedical System.	Not Mentioned	IS IT HCV ONE PLUS by Medsource Ozone Biomedicals.	Not Mentioned	Multi-Sure HCV Antibody Assay by MP/ Diagnostic.	1. Rapid anti-HCV test One Check 2. Anti-HCV by Accurate.
Details of kit and generation of ELISA test - used as a gold standard.	3 <sup>rd</sup> generation Sandwich ELISA. Merilisa HCV by Meril Diagnostics, India.	3 <sup>rd</sup> generation Indirect ELISA. Hepa Scan HCV by Bhat Bio-Tech, India.	4 <sup>th</sup> generation ELISA. Manufacturer-not mentioned.	3 <sup>rd</sup> generation ELISA. HCV microlisa by J. Mitra, India.	3 <sup>rd</sup> generation ELISA. Manufacturer-not mentioned.	4 <sup>th</sup> generation ELISA by Murex.	Not mentioned.
Sensitivity (%)	69.57	70.58	76.01	85.71	86.96	87.2	45 66
Specificity (%)	99.35	93.61	100	99.91	100	89.3	93 93
Positive predictive value (%)	41.55	66.66	100	96	100	82.8	96 97
Negative predictive value (%)	99.79	94.62	80.65	99.64	99.83	98.9	35 43

HCV: Hepatitis C virus, ELISA: Enzyme-linked immunosorbent assay

and as HCV has a high nucleotide sequence diversity, rapid tests may not yield positive results.<sup>[12]</sup> Another reason could be that, during the early phase of infection, antibody titers are below the detectable limits of RDT but detected by more sensitive assays as enzyme immunoassays in their spectrophotometric format. Also, RDT gets a shorter exposure time to react with antibodies while ELISA assay gets good long incubation period with antibodies till the reaction proceeds to completion.<sup>[29]</sup> The chances of missing the diagnosis are higher with these false-negative results. Hence, if rapid card tests are done, they should be confirmed with ELISA. During the screening of populations, false-positive results are preferred over false-negative results as positive test results indicate additional

testing using a different technique to confirm the diagnosis [Figure 3].

The important finding of this study is the high false positives with low sensitivity and very low positive predictive value, which is lower than other similar studies. The possible reasons for higher false positives could be lower specificity of RDT, presence and interaction of non-specific antibodies and technical variations. Lower specificity of RDT will mislabel non-infected individuals as positive; various studies have mentioned that the presence of high prevalence of certain endemic diseases, like malaria or autoimmune diseases or hypergammaglobulinemia, may cross-react and give false-positive results.<sup>[30-32]</sup> The other reason could be a technical error as subjective interpretation, where light test band



**Figure 3:** Diagram demonstrating the basis for deriving sensitivity, specificity, and positive and negative predictive values (Sensitivity =  $[a/(a + c)] \times 100$ , Specificity =  $[d/(b + d)] \times 100$ , Positive predictive value =  $[a/(a + b)] \times 100$ , Negative predictive value =  $[d/(c + d)] \times 100$ ).

is mistakenly considered as positive when it is actually negative. The current study entails performing ELISA during regular working hours where quality control measures being followed under vigilance, while RDT is performed during emergency hours where possibility of deviation from standardized laboratory practices can't be ruled out. Furthermore, ELISA provides a semi-quantitative signal-to-cutoff ratio where results slightly above the cut-off might be considered a weak-positive requiring cautious confirmation, whereas RDT simply provides a positive or negative result, possibly leading to more assumed false positives.

There are various RDTs available in the market claiming to have 100% sensitivity and specificity. The base for these claims is largely the studies conducted by workers who maintain ideal conditions for manufacture, transportation, and storage, but these favorable conditions may not always be achievable in developing or underdeveloped countries, where financial aspects also play a significant role. The superior performance of advanced immunological and molecular techniques over rapid testing devices is well-documented. Hence, it is advisable to validate the RDT with ELISA before approval and implementation. More studies need to be conducted to compare the performance of such rapid tests with ELISA in different groups and geographical locations.

## CONCLUSION

HCV diagnosis is done by detection of anti-HCV antibodies using immunoassays, followed by detecting of HCV RNA in serum or plasma. Methods for detecting anti-HCV are RDT and ELISA; both have different test principles with advantages and disadvantages. It is important to know the sensitivity and specificity of RDT kits used for interim reporting of HCV during emergency hours. This needs to be followed by ELISA test which will help in confirmation and also prevent the complications associated with false negativity reported by the rapid assay.

**Ethical approval:** The research/study was approved by the Institutional Review Board at Seth GS Medical College and KEM Hospital, Parel, Mumbai, number EC/OA-126/2024, dated 13th September, 2024.

**Declaration of patient consent:** Patient's consent is not required as there are no patients in this study.

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