

Original Research Article

**ELISA versus Rapid test kits for screening of HIV and Hepatitis B and Hepatitis C among Blood donors in a tertiary care hospital****Dr Neetu Kukar<sup>1\*</sup>, Dr Ravinder Garg<sup>2\*</sup>, Dr R.N. Maharishi<sup>3\*</sup>, Dr Neha Syal<sup>4\*</sup>, Dr Harkiran Arora<sup>5#</sup>, Dr Anjali Handa<sup>6\*</sup>**<sup>1</sup>MD Pathology, Associate Prof, Department of Immunohematology and Blood Transfusion<sup>2</sup>MD Medicine, Prof. and Head, Department of Medicine<sup>3</sup>MD, Pathology, Prof. and Head, Department of Immunohematology and Blood Transfusion<sup>4</sup>PG Resident 3<sup>rd</sup> year, Department of Immunohematology and Blood Transfusion<sup>5</sup>MD IHBT, Senior Resident, Department of Transfusion Medicine<sup>6</sup>PG Resident 2<sup>nd</sup> year, Department of Immunohematology and Blood Transfusion

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**Abstract:** HIV, HBV and HCV pose a major public health problem through the world. Detection of infection markers for these agents is a major challenge in a resource poor setting. A blood transfusion service is a vital part of modern health care system. So it is mandatory to test each and every unit of donor blood for antibodies to HIV1 and 2, Hepatitis C, Hepatitis B surface agent, Syphilis and Malarial parasite. In our study 11879 donor samples were tested for HIV 1 and 2, HBsAg and HCV by ELISA and samples found reactive were again tested by rapid test kits. Out of these, 326 samples were reactive for HCV by ELISA but only 237 samples were reactive by RDT. On testing for HBsAg, 127 samples were reactive by ELISA but only 102 were reactive in Rapid tests and for HIV 43 samples were reactive by ELISA but only 18 samples were reactive by RDT.

**Keywords:** Transfusion Transmitted Infections (TTI), HIV 1 and 2, Hepatitis B, Hepatitis C, Rapid Detection Tests (RDT)

**INTRODUCTION**

Blood transfusion services are a vital part of modern health care system [1]. With every unit of blood there is 1% chance of transfusion associated problem including transfusion transmitted disease [2]. So it is mandatory to test each and every unit of donor blood for HIV 1 and 2, Hepatitis C, Hepatitis B surface antigen, syphilis and malarial parasite [3]. Conventional ELISA is regarded as the most commonly used screening technique for blood in Blood banks. But due to limitations of ELISA tests like high costs, unavailability in many blood banks and testing sites, involvement of costly instruments, time taking nature and requirement of highly skilled personnel for interpretation, rapid tests that are user friendly are gaining more importance and warrants comparison of performance [4]. The present study was conducted to compare the efficacy of ELISA test kits and Rapid test kits for screening of blood donors.

**MATERIAL AND METHODS**

This prospective study was conducted in the department of immuno haematology and Blood Transfusion from January 2014 to December 2014. During this period blood samples from 11879 blood donors were collected and tested for HIV 1& 2, HCV, Hepatitis B surface Antigen by third generation ELISA kits (SD Bio standard Diagnostics Pvt. Ltd.). The samples which were reactive by ELISA method were tested by rapid test kits (J.Mitra Co. Ltd.). The results of the reactive blood units by ELISA were compared with the rapid tests.

**Rapid test for HBsAg**

“Hepacard” (J. Mitra & Co. Ltd) is a one step immunoassay based on antigen capture sandwich principal. The method uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The

test sample introduced flows laterally through an absorbent pad where it mixes with the signal reagent. If the sample contains HBsAg, the colloidal gold antibody conjugate binds to the antigen, forming an antigen antibody colloidal gold complex. The complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the line of immobilized antibody (Test line), the complex is trapped forming an antibody-antigen-antibody colloidal gold complex, this forms a pink band indicating the sample is reactive for HBsAg.

**Rapid test for HIV**

HIV Tridot (J. Mitra & Co. Ltd). HIV antigens are immobilized on a porous immunofiltration membrane. Sample and solutions pass through the membrane and are absorbed into the underlying absorbent. As the patient’s sample passes through the membrane, HIV antibodies, if present, bind to the immobilized antigens. Conjugate binds to the Fc portion of the HIV antibodies to give distinct pinkish purple DOT(s) against a white background. It can differentiate between HIV 1&2.

**Rapid test for HCV**

HCV Tridot (J. Mitra & Co. Ltd). HCV antigens are immobilized on a porous immunofiltration

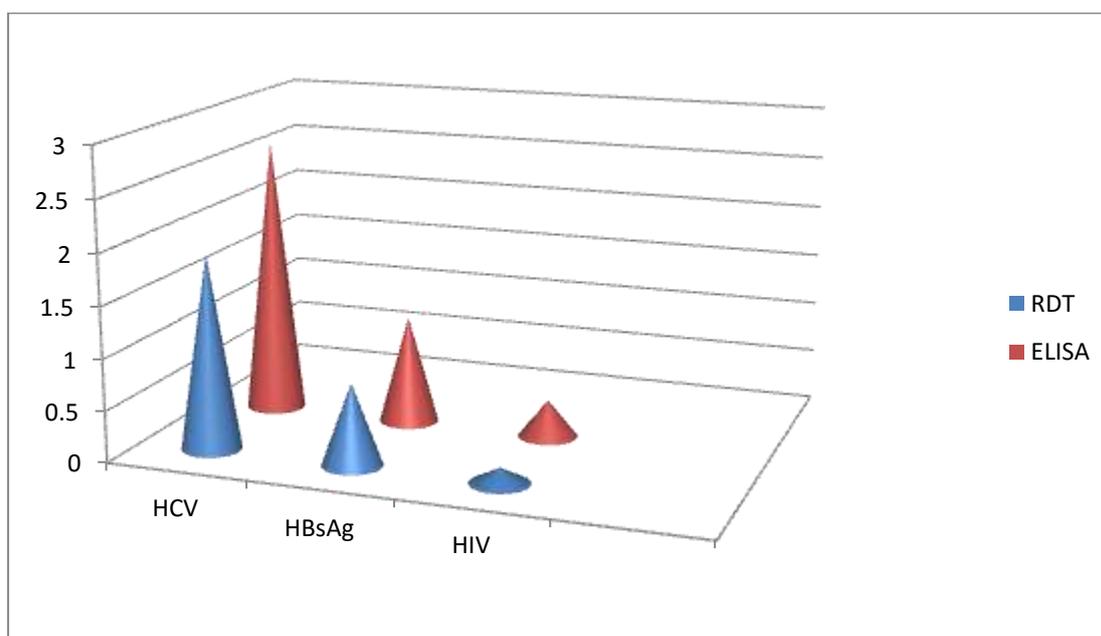
membrane. Sample and reagents pass through the membrane and are absorbed into the underlying absorbent pad. As the patient’s sample passes through the membrane, HCV antibodies, if present in serum/plasma, bind to the immobilized antigens. In the subsequent washing step, unbound serum/plasma proteins are removed. In the next step, the protein A conjugate is added which binds to the Fc portion of the HCV antibodies to give distinct pinkish purple DOT(s) against a white background near the test region.

**RESULTS**

A total of 11879 samples were tested for HCV, HBsAg and HIV 1 & 2 over a period of one year from January 2014 to December 2014. Out of these 326 samples were found to be reactive for HCV by ELISA but when these reactive samples were tested by Rapid tests only 237 samples were reactive. Thus Rapid tests had missed 89 samples and its sensitivity in comparison with ELISA was 72.6%. On testing for HBsAg, 127 samples were reactive by ELISA but only 102 were reactive in Rapid tests. Sensitivity of RDT was 80.3%. Likewise for HIV out of a total of 43 samples which were reactive by ELISA, only 18 samples were reactive by RDT thereby showing a sensitivity of 41.85 only.

**Table-1: Results of HCV, HBsAg and HIV 1 & 2 tests**

TTI	Reactive by ELISA	Percentage Reactivity	Reactive by RDT	Percentage Reactivity	False Negative by RDT
HCV	326	2.7%	237	1.9%	0.8%
HBsAg	127	1.06%	102	0.8%	0.26%
HIV	43	0.36%	18	0.15%	0.21%



**Fig-1: Results of HCV, HBsAg and HIV 1 & 2 tests**

## DISCUSSION

Detection of HIV, HBsAg and HCV infections and their diagnosis is mainly based on immunological assays amongst which ELISA and rapid tests are most common and widespread methods [5, 6]. An important problem encountered at this point is the discordance between the results of two assays [7]. Some studies suggest that the diagnostic performance of RDT is comparable to ELISA. However in our study we found ELISA to be much more sensitive than RDT. In a study by B Mehra *et al.* at Maulana Azad Medical College New Delhi, RDT for HIV 1 and 2 (SD Bio line) showed sensitivity and specificity of 77.5% and 99.3% respectively as compared to ELISA [8]. Inferior performance of RDT in comparison to ELISA has also been reported in another study by Torane where both modalities were used to screen healthy blood donors for HIV and RDT missed 17 out of 30 samples confirmed reactive by ELISA [9]. H. Kaur *et al.*; also in their study concluded low sensitivity of RDT [10]. This discordance may possibly be due to low antibody titers in sera especially in recent infections where the levels may be well below the detection limits of RDT but are picked up by the more sensitive enzyme immunoassays and its spectrophotometric format of result analysis. Another reason could be the difference in the nature of antigens used in RDT and ELISA especially in case of HCV where genetic heterogeneity can affect the serological response.

## CONCLUSION

ELISA is much more sensitive than rapid tests for screening of infections like HIV, HBsAg and HCV. The higher number of false negative results by RDT is of concern for blood banks, hence should not be recommended in transfusion centre for screening blood donors.

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