Mansoura Nursing Journal (MNJ) Vol. 10. No. 1 – 2023 **Original Article**
Print ISSN: 2735 – 4121 Online ISSN : 2735 – 413X

Accuracy of Rapid Serological Test versus Reference Standard Test for Hepatitis C Virus among Blood Donors

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1.ABSTRACT

Hepatitis C Virus (HCV) is blood born pathogen with high incidence in Egypt. Early detection of HCV is an important step in preventing spread of infection. Serological detection of HCV infection in blood donor before donation process aims to decrease number of collected blood bag infected with the virus, decrease risk of transmitted infection to health care workers through wrong medical practices, and decrease reliance on blood donor's honesty of his/her HCV infection status. Therefore, the current study aimed to compare accuracy of rapid serological test versus reference standard test for HCV among blood donors. Through a diagnostic study on a convenient sample of 130 blood donors, by screened capillary finger stick blood using rapid serological test (Intec test [Advanced Quality™ test]). Results revealed that sensitivity and specificity of the rapid serological test were 50.00% and 97.66%, respectively, and its diagnostic accuracy was 96.92%. Concluded that rapid serological test has high percentage of diagnostic accuracy, but not as reference standard test; accordingly, cannot rely on it as a diagnostic test to HCV among blood donors. The researchers have recommended replicating the study on larger scale, and on different blood components to estimate effectiveness of the rapid serological test.

Key words: Diagnostic accuracy, Rapid test, Hepatitis C Virus, Incidence, Sensitivity, Specificity

2.Introduction:

Blood donor is a person, who gives human blood or its components for medical reason. Blood donor considers a source of Hepatitis C Virus (HCV) infection, so early detection of HCV is an important step in preventing spread of infection and ensuring that health care workers in blood banks are not acquiring infection during donation process (Bibi, Siddiqui, Ahmed & Jafry, 2019).

HCV is a nucleocapsid, human RNA contains single stranded genome, belongs to hepaciviruses genes, and is a blood borne pathogen causes chronic liver disease which may progresses to hepatocellular carcinoma. Chronically wise, an estimated 2% of the world population are infected with HCV, which is a silent course account for pathogenic potential of HCV, this includes extra hepatic manifestation, 20% of chronically people infected with HCV have liver cirrhosis, and 2%-5% of people infected with HCV progresses to hepatocellular carcinoma (Pawlotsky et al., 2018).

According to donation policy of National and Regional Blood Transfusion Centers affiliated to Egyptian Ministry of Health and Population, blood donors donate whole blood after verbal serological test; [health care workers ask blood donor, if he/she has HCV infection in the past or not]; reliance on blood donor's honesty of their HCV infection status puts health care workers to infection risk. When donated whole blood bag reaches to National and Regional Blood Transfusion Centers, transfers to two departments which are serological department to screening for blood borne pathogens and components department to separate whole blood to its components; once results of screening test release, components department accomplishes its duty. In case of negative results of screening test, the components of donated blood release for issuing, vice versa, if positive results of screening test, the components of donated blood discard. This policy assimilates burden on financial budget and increases risk of blood borne pathogens infection among health care workers (Yousef,

Hindawy & El-dansoury, 2012; Blaney & Howard, 2013).

Based on Institute of Blood Transfusion, Chengdu, China and Blood Work Center, US, donation screening process includes selection of blood donor with low HCV infection by using donation questionnaire and pre-donation physical examination. Donor's testing includes direct blood borne pathogens detection (serological test). Donor's screening and testing are conducted before donation process to determine who is eligible to donate. For ensuring the safety of blood, the collected blood must be examined for detection blood borne pathogens by nucleic acid test (NAT) technique after donation process. To combat this problem, lie study strategy aim to decrease number of contaminated blood with blood borne pathogens, decrease risk of blood borne pathogens transfusion by blood transfusion and decrease burden of budget through detection blood bag contaminated in first stage of blood collection (Li et al., 2017).

Egypt has high prevalence of HCV infection among general population as ongoing unsafe medical practices (Hagan & Schinazi, 2013). Egyptian Liver Research Institute and Hospital has established a program to test and treat HCV through perform HCV antibody test screening by using a rapid immune-chromatographic assay [(Rapid serological test, (Advanced QualityTM , InTec product, China)] (Shiha, Soliman, Mikhail & Easterbrook, 2020).

Since, the virus replicates mainly in the hepatocytes of the liver, where it is estimated that daily each infected cell produces approximately fifty virus particles with a calculated total of one trillion virus particles generated. The reason of the high levels of immunological disorders in chronically infected HCV patients is that HCV may also replicates in peripheral blood mononuclear cells. In the liver, the HCV particles are brought into the hepatic sinusoids by blood flow. These sinusoids neighbor hepatocyte cells. HCV can pass through the endothelium of the sinusoids and take its way to the basolateral surface of the hepatocyte cells (Dubuisson & Cosset, 2014).

Antibody of HCV is an immune response of the host and the window period (WP) of the virus is 65 days for detecting antibody by rapid serological test-using nucleic acid test technology (NAT) detection of HCV infection, window period decreases to 44 days. NAT detects infection as early as possible, to reduce the residual risk of viral transmission linked to window period. NAT with high sensitivity relies on amplification of intended target region of viral nucleic acid (NA) for detection. There are three heading influence high sensitivity of nucleic acid assay involving: sample preparation, amplification, and detection. Typically, NAT blood screening assay are qualitative assay scoring for reactive (Shymala, 2014).

Screening assay test has used to detect antigens, anti-bodies, nucleic acid of the infectious agent. Simple single use test (rapid serological test) is a discrete, individual, and disposable use. This test based on immune chromatography (highly specific biological reaction) of added sample that flow down strip and react with fixed reagent. Simple qualitative result reads visually from this test (WHO, 2010).

2.1Aim of the Study

Compare accuracy of rapid serological test versus reference standard test for HCV among blood donors.

2.2Research Questions

1. What is sensitivity of rapid serological test versus reference standard test for HCV among blood donors?
2. What is specificity of rapid serological test versus reference standard test for HCV among blood donors?
3. To what extent rapid serological test for HCV reduce donated blood bags contaminated with this virus?

3. Method

3.1Study Design

This study used diagnostic design. Diagnostic accuracy study, also called clinical validity studies, evaluates the test's accuracy

in discriminating between donor with or without the target condition (disease) (Mallett, Halligan, Thompson, Collins & Altman, 2012).

3.2Setting

This study was conducted at donation department, Mansoura Regional Blood Transfusion Center Services (MRBTCs), affiliated to Egyptian Ministry of Health, and Population.

3.3Participants

Blood donors had attended to donation department, MRBTCs, affiliated to Egyptian Ministry of Health, and Population, during 2021-2022, under the following eligibility criteria:

Table 1 *Inclusion and exclusion criteria to enrollee blood donors*

Inclusion criteria	Exclusion criteria
▪ Both sex ▪ Age from 18 to 60 years old	▪ Had performed any of the following, within six months preceding: o Surgical operation o Fracture o Teeth treatment o Open an abscess o Tattooing ▪ With any of the following: o Uncontrolled hypertension o Heart disease o Thyroid disease (hypothyroidism or hyperthyroidism) o Diabetic mellitus type one (insulin dependent diabetic ellitus) o Kidney diseases (acute or chronic kidney diseases) o Cancer (benign or malignant) o Blood diseases ▪ Person with infectious diseases (blood borne diseases): o Hepatitis C Virus o Hepatitis B Virus o HIV (human immune deficiency virus) o Syphilis ▪ Pregnant woman ▪ Lactating woman ▪ Person receiving any of the following: o Chemotherapy o Immunosuppressive drugs

3.4 Sampling Size

Average number of blood donors was 900 per month. Sample size was calculated using sample size calculator software application, (2018) by relief applications version 2.0.4. When population size 1000, confidential level 95%, and precision rate 0.1; required sample size had to be 98 blood donors. This number had incremented to be 130 donors.

3.5 Sampling Technique

A convenient sampling technique had used to enrollee 130 donors.

3.6Tools of Data Collection

The researchers developed five tools for data collection according to Egyptian Ministry of Health, and Population, and American Association of Blood Bank (AABB) (Blaney & Howard, 2013; Youssef, Hindawy & El-dansoury, 2012); as the following:

Tool (I) Blood donors' registration and demographic characteristics structured interview questionnaire. This questionnaire included documentation data, and prescreening blood donors' eligibility status through computerized database (health informatics

technology E-delphyn software program), that included: full name, serial number of blood bag, permanent address, date of birth, sex, material status, educational level, and occupation.

Tool (II) Blood donors' health history structured interview questionnaire. This questionnaire used to collect blood donors' health history, aimed to protect them, and patients who would receive the donated blood. It included six parts as the following:

1. Donation history: number of donation times, duration since last donation, complication occurred after donation process. Date of last donation:
   - 12 weeks must elapse after whole blood donation for males.
   - 16 weeks must elapse after whole blood donation for females.
   - Four weeks must elapse after plasma apheresis.
2. History within six months preceding donation, to exclude carry out any procedure via them transmission of blood borne pathogens could occur, as: surgical operations, fractures, teeth treatments, open abscess, acupunctures, and tattoos.
3. History of chronic diseases prevents donation process, as: heart diseases, thyroid gland diseases, liver diseases, diabetes mellitus, kidney diseases, blood diseases.
4. Family health history: family member with any blood borne diseases such as: HCV, HBV, AIDs, and Syphilis.
5. Obstetric history: current; lactating, or pregnancy.
6. Current respiratory system disorders' signs, and symptoms, as: chesty cough, sore throat, active cold sore.

Tool (III) Blood donors' physical examination questionnaire. The researchers observed and measured the following:

- Blood donors' general appearance: pall, jaundice, flushed, sunken eye, allergy, chickenpox.
- Temperature measured by infrared thermometer, it should not exceed 37.5˚c. Hyperthermia could indicate possibility of infectious disease, which pose dangerous to recipient.
- Blood pressure measured by electrical sphygmomanometer, normal systolic blood pressure 120 mm Hg and diastolic blood pressure 80 mm Hg.
- Heart rate normal 60-90 beat per minute.
- Weight measured by electronic platform scale, its measurement per kilogram (kg). Blood donors' minimum weighing 50 kg, as collection of 10.5 ml of blood per kg, with donor weighing 50 kg could tolerance a maximum withdrawal of 525 ml.

Tool (IV) Blood donors' laboratory investigation. Hemoglobin estimated by spectrophotometric method, which is screened capillary finger stick blood. For whole blood donation, the minimum hemoglobin level should be 12.5 g/dl; this requirement ensures a sufficient hemoglobin level to allow the removal of maximum of 525 ml, included sample drawn for tests without harming donor. Female donors should be 12.0 to 15.5 gram per deciliter while, male donors should be 13.5 to 17.5 gram per deciliter.

Tool (V) Rapid serological test for HCV. The researchers had screened blood donors for HCV infection by rapid serological test (Intec test [Advanced Quality™ test]) which had high sensitivity, and specificity. Sensitivity of test is the ability of assay to identify samples from infected individual as positive (to correctly identify those with disease [true positive] and its efficacy to avoid false negative result. An ideal test was 100% sensitivity with means that all sick individual were correctly identified as sick) (Yousef, Hindawy & El-dansoury, 2012; Blaney & Howard, 2013).

Specificity of test is the ability of assay to identify sample from non-infected individual as negative (to designate an individual who doesn't have the disease as negative. An ideal test was 100 % specific test mean that on healthy person were in correctly

identified as a sick) (Yousef, Hindawy & El-dansoury, 2012; Blaney & Howard, 2013).

Screening reagents and assay system. The most common anti –HCV EIA kits manufactured in China, distributed by BETA trade were used in the current study as interest test for vitro diagnostic use. The kits consist of rapid anti HCV test (Intec products, INC) with lot number: GJ21070855, Advanced quality trademark, STORED AT 2-30˚C as recommended by the manufacturer. In vitro, qualitative, immune –chromatographic, single use, disposable chamber test that provide visual result within 20 minutes for anti HCV detection, Advanced Quality kit uses the NS3 region antigens.

The assay used as a reference standard test is Ultrio Elite, version: 2.6.5 (for in vitro diagnostic use), work list ID: 002878-20210915-02. This test is for nucleic acid virus RNA. It had been used to assess diagnostic accuracy of the rapid test through comparing result of rapid test (Test searching for antibodies of HCV in blood) with reference standard test (Test searching nucleus acid of HCV in blood).

3.7Phases of the Study

Administrative phase. Vice dean of postgraduate and research, Faculty of Nursing, Mansoura University issued an official letter to the director of MRBTCs, affiliated to Ministry of Health, and Population, to permit the researchers conducting the current study.

Ethical considerations. The researchers obtained approval from Research Ethics Committee, Faculty of Nursing, Mansoura University.

The researchers obtained written informed consent from each blood donor before starting of the study; the researchers introduce themselves and explained the aim of the study. The researchers had emphasized that the study causes no physiological or psychological harm to the donors; assured them that rapid serological test for HCV cost and procedure were the responsibility of the researchers considering infection prevention, and control measures.

The researchers emphasized to blood donors' privacy, and confidentiality of the collected data, and they used only for research purpose. Any blood donor had the right to ask any question related to the study, as well they had the right to withdraw from the study at any time without any responsibility.

Review of literature. A review of the past, current national, regional, and international related literature using available books, articles, periodicals, and magazines were necessary to be acquainted with all aspects of the study problem, and in order to develop relevant tools for data collection.

Development of the study tools. The researchers developed tools of data collection supported by reviewing Egyptian Ministry of Health, and Population, and American Association of Blood Bank (AABB) (Blaney & Howard, 2013; Youssef, Hindawy & El-dansoury, 2012).

Content validity. Five experts in the field of community health nursing tested the study tools for content validity and the required modifications were carried out.

Face validity. The researchers carried out a pilot study on 10 % of the study participants (13 blood donors) selected conveniently from the same settings. Participants in the pilot study were included in the main sample of the study.

Fieldwork phase. The study started from the beginning of February 2021 and ended in May, 2021. This phase was considered the following:

Data collection schedule. The researchers visited donation department, MRBTCs, affiliated to Ministry of Health, and Population, three days per week from 09:00Am to 01:00Pm. The researchers had assessed from 20 to 30 blood donors per day, till enrolling the required number; each blood donor consumed from eight to 12 minutes; the researchers enrolled 130 blood donors out of screened 1397.

According to Yousef, Hindawy and El-dansoury, (2012); Blaney and Howard, (2013) blood donation process included

two parts donors screening, and phlebotomy.

First part: donors screening.

The researchers coded each donor, and assessed his/her registration, and demographic characteristics, using tool I.

Registration. The blood donors' registration process included document data that fully identify him/her on an individual registration record; this record included prescreening to assess donor eligibility status; through computerized database (E-delphyn program), which allowed health care members to confirm that: donor's data was correct, sufficient time had passed since the last donation, and donor had not been deferred from donation based on a previous donation history. Correct identification of blood donor was essential to prevent ineligible donor from donation, as well to ensure issuing test's result own to each donor.

The researchers assessed each donor for; health history, physical examination, and laboratory investigation, using tools (II, III, and IV).

The researchers obtained blood required for rapid serological test (Intec test [Advanced Quality™ test]) from finger stick; synchronous with hemoglobin level estimation; its result was qualitative. This test based on immune chromatography (highly specific biological reaction such as between antigens and anti–bodies of infectious agent) of added sample that flow down strip and react with fixed reagent. Simple qualitative result read visually from this test (WHO, 2010).

Second part: phlebotomy.

Health care members belonged to MRBTCs, affiliated to Ministry of Health, and Population continued donation process. This part included: identification, bag labeling, arm preparation, vein puncture, and post donation care.

Identification. Blood donor's identification was confirmed at each step of donation process; as there were different health care members at each step, the blood donor's identification was important before vein puncture by the phlebotomist.

Next, the antecubital area, both blood donor's arms were checked to select the arm with best vein, the inspection enable the phlebotomist to check any skin lesion, and intravenous drug use.

Bag labeling. The primary bag for blood collection, all attached satellite bags, samples tubes, and blood donor's registration form; were labeled with a unique identification number (serial number). Use of identification number allowed the collected blood, and prepared component, samples tests' results; to be traced back on the blood donor's registration form.

- *Arm preparation, and vein puncture.* Blood drawn from the antecubital area consider the best vein. The following steps were carried out as the following:
- The drawing skin site must be free from skin lesions, was not sterilized, but disinfected.
- The vein puncture site was scrubbed with alcohol swab in circular manner from inside to outside, in case of site was visually clean. If site visually dirty, was cleaned with soap and water.
- A tourniquet made vein more prominent for vein puncture.
- A gauge needle 16 attached to primary blood bag was inserted into large, and firm vein.
- The usual donation time for whole blood is 8 to 12 minutes.
- Frequent mixing blood with anticoagulant / preservative in the bag was critical during donation time to avoid clotting blood, it could be performed manual or with mechanical device.
- Electronic scale used to monitor volume of drawn blood.

- Either before or after termination donation process, two blood samples drawn for reference test (NAT).
- After the needle was removed, pressure applied to the vein puncture site over the gauge, and the arm was elevated.
- The needle discarded in an appropriate biohazard container.
- *Post donation* instruction*, and care.* Blood donor informed about post donation instruction as follow:
- Avoid smoking for 30 minutes until something had been eaten.
- Post donation fluid replacement began in the donation department, MRBTCs, affiliated to Ministry of Health, and Population.
- Drink more fluid than usual in the next four hours. Inform donor that total fluid volume replacement usually restored within 72 hours of donation.
- If dizziness or fainting occurs, lie down, or sit with head between the knees.
- Remove the bandage after few hours.
- Inform the donation department, MRBTCs, affiliated to Ministry of Health, and Population if any symptoms persist.

Evaluation phase. The researchers compared results identified from rapid serological test (Intec test [Advanced Quality™ test]); with those from reference standard test relation to sensitivity, and specificity. Accordingly, evaluate to what extent rapid serological test for HCV reduce donated blood bags contaminated with the virus.

3.8Statistical Analysis

The collected data was analyzed by IBM's SPSS statistics (Stand for Statistical Product and Service Solutions) for windows (Version 20). Data were tabulated in descriptive frequency and, percentage. The following statistical tests were used mean, Standard Deviation, minimum and maximum. To calculate positive and negative, predictive values used chi-square test, risk estimate. To calculate sensitivity and specificity used descriptive statistics, cross tab test.

4. Results

Table 2 represents that; minimum age of blood donors was 19 years and maximum age was 48 years, with a mean of 33.02±7.961 years. In relation to sex, residence, and marital status 87.7%, 73.1%, and 77.7% of blood donors are male, resident in rural areas, and married, respectively. Concerning to educational level, 52.3% of blood donors had secondary level, while 39.8% had bachelor´s degree.

Figure 1 shows that; 43%, 35%, 17%, 16%, 14% and 5% of blood donors were skillful manual workers, clerks, manual workers, semiprofessionals, professionals, and students, respectively.

Table 3 illustrates that; minimum blood donors' hemoglobin level was 13.2 g/dl while, maximum level was18.1g/dl, with mean of 15.60±0.997 g/dl. It was documented that; minimum heart rate count of blood donors was 70 beat per minute while, maximum count was ≥97 beat per minute. Related to systolic and diastolic blood pressures means were 127.00±9.454 mm/hg and 78.69±6.396 mm/hg, respectively. Finally, blood donors' minimum weight was 58 kg, with mean of 93.63±17.212 kg while, maximum weight was140 kg, with mean of 93.63±17.212 kg.

Table 4 demonstrates that; only 50.0% positive (true positive) results from reference standard test, identified by rapid serological test, while detected 50.0% as false negative results. In addition to 97.7% negative (true negative) results from reference standard test, identified by rapid serological test, while detected 2.3% as false positive results.

Table 5 reveals that; sensitivity and specificity of a rapid serological test were 50.00% and 97.66%, respectively. Concerning positive and negative likelihood ratios of rapid serological test were 21.33% and 0.51%, respectively. Identified incidence by rapid serological test was 1.54%. Related to positive and negative predictive values of rapid serological test were 25.00% and 99.21%,

respectively. Finally diagnostic accuracy of rapid serological test (Advanced Quality™ test) was 96.92%.

Table 2 *Registration and demographic characteristics of blood donors (n= 130)*

Items	N=130	%
Age in Years		
Minimum19	x̄±SD	
Maximum48	33.02±7.961	
Sex		
Male	114	87.7
Female	16	12.3
Residence		
Rural	95	73.1
Urban	35	26.9
Marital status		
Married	101	77.7
Single	27	20.8
Widow, divorced	2	1.5
Educational level		
Illiterate, primary, and preparatory	11	8.5
Secondary		
University and postgraduate	68	52.3
	51	39.2

Figure 1. Occupations of blood donors (n= 130)

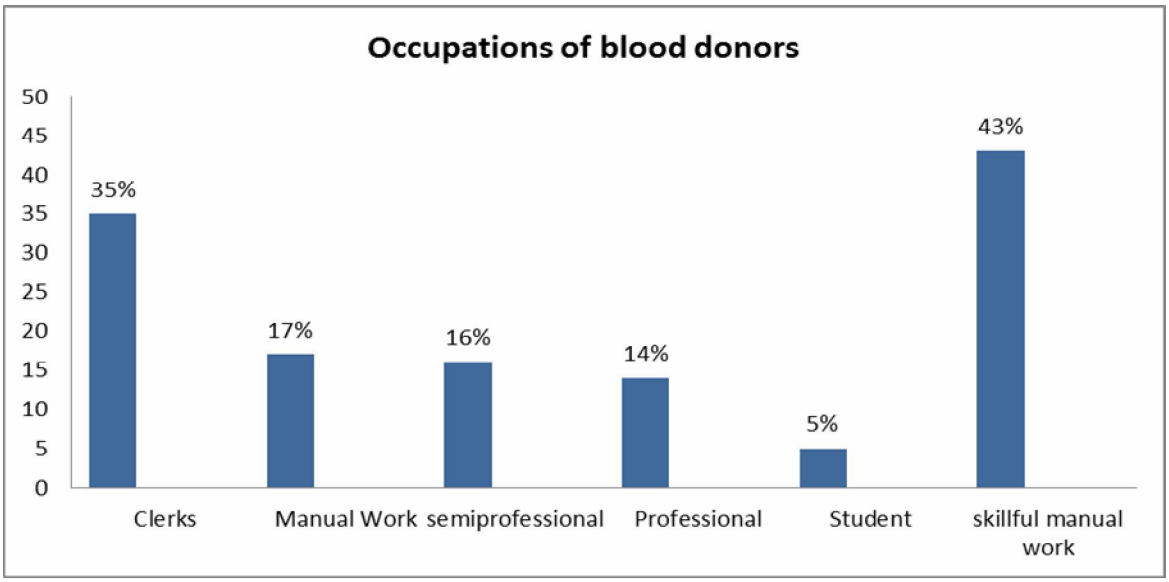

Table 3 *Laboratory investigation and physical examination of blood donors (n= 130)*

Item	Minimum	Maximum	x̄±SD
Hemoglobin level	13.2	18.1	15.60±.997
Heart rate	70	97	82.03±5.560
Systolic blood pressure	100	150	127.00±9.454
Diastolic blood pressure	70	90	78.69±6.396
Weight	58	140	93.63±17.212

Table 4*Results of rapid serological test versus reference standard test (n= 130)*

Rapid serological test * versus reference standard test**					
			Reference standard test		Total
			Positive	Negative	
Rapid serological test	Positive	Count	1	3	4
		% Within reference standard test	50.0%	2.3%	3.1%
	Negative	Count	1	125	126
		% within reference standard test	50.0%	97.7%	96.9%
Total	Count		2	128	130
	% Within reference standard test		100	100	100

*Intec test. ** Nucleic acid virus RNA test.

Table 5*Performance of rapid serological test (n= 130)*

Statistic	Value	95% CI
Sensitivity	50.00%	1.26% to 98.74%
Specificity	97.66%	93.30% to 99.51%
Positive likelihood ratio	21.33	3.59 to 126.61
Negative likelihood ratio	0.51	0.13 to 2.05
Disease incidence	1.54%	0.19% to 5.45%
Positive predictive value	25.00%	5.32% to 66.42%
Negative predictive value	99.21%	96.90% to 99.80%
Accuracy*	96.92%	92.31% to 99.16%

*Advanced Quality™ test.

5. Discussion

Screening of blood donor is the first step to determine that blood does not react to specific markers of infection with blood borne pathogens, and safe for clinical use. Each country should decide screening blood donation program that included transmitted infections through blood transfusion, since each program influenced by prevalence of infection. Screening assay is test used to detect antigens, anti-bodies, and nucleic acid of the infectious agent. Simple single use test (rapid test) is a discrete, individual, and disposable use. This test based on immune chromatography (highly specific biological reaction such as between antigens and antibodies of infectious agent) of added sample that flow down strip and react with fixed reagent. Simple qualitative result read visually from this test (WHO, 2010).

According to WHO (2019), prequalification in vitro diagnostic public report on May 2019, Rapid Anti-HCV test manufactured by Intec product, INC, Rest of world regulatory version is rapid, lateral flow immune-chromatographic assay for the detection of antibodies to HCV in human serum, plasma, and whole blood.

The advanced quality of rapid anti-HCV test is evaluated by WHO in the 3rd quarter of 2018 at the virus reference department, public health England, UK. This evaluation is on 466 plasma specimen, compared to the reference diagnostics algorithm (Ortho- HCV ELISA test system with enhanced save, ortho-clinical diagnostics and Monolisa anti –HCV pus, BIO-RAD, in parallel; followed by Chiron Riba HCV 3.0 strips immunoassay, the following criteria is found: sensitivity of Intec rapid test is 100%, specificity of test is 99.7%, in valid rate is 0%, inter-reader variability is 0% and Intec test able to detect low titer of HCV antibodies (WHO, 2019).

Results of the current study reveal that rapid serological test (Intec test [Advanced Quality™ test]) has half sensitivity (true positive) of reference standard test (Nucleic acid virus RNA test). These results are consistent with the results of diagnostic study carries out by Mane et al. (2019), in India, investigated the Advanced Quality™ test kits as a rapid diagnostic test versus two high characteristic serum/plasma panel, one from Indian population and other from United State Center of Disease Control (US CDC).

Results of the present study illustrate that rapid serological test (Intec test [Advanced Quality™ test]) has high percentage of specificity (true negative), but is not as reference standard test, with the highest percentage belonged to negative predictive values rather than positive one. These results are contradict with a literature review of guidelines for Laboratory Testing and Result Reporting of Antibody to HCV, found that to say the anti –HCV rapid diagnostic test accurate in detecting its infection must be has positive predictive value≥95 %.(CDC, 2003; Alter, Kuhnert & Finelli, 2003). Furthermore, results of the present study are opposite with a study carries out by Wu et al. (2011), in China, the researchers in this study found that Intec product, are accurate with positive predictive value 96.4 %.

Based on Ren et al. (2005), variation of rapid anti HCV test's results due to the different prevalence sub- types of HCV from area to another, and differences of manufacture test companies. Chinese Blood Center gives support for accurate diagnosis of HCV and don't use diagnostic assay with low quality and low diagnostic accuracy, as false positive result demonstrates by these tests lead to decreased number of collected blood bags and psychological burden on blood donor.

In addition to, variation of test's results may be due to objective of test design, which is detecting HCV in human blood specimen and don't give attention to the user misconduct with test. Negative result of sample is not mean ruling out the potentiality of HCV infection. When sample result shows purplish mark on (T) band and not shows mark on control band (C) , is not mean invalidity of test, but may refers to high concentration of HCV antibody over maximum level to test design ("WHO Prequalification of In Vitro Diagnostics PUBLIC REPORT Product", 2019). From the researchers view of point, small sample has recruited in the current study as well; discrepancy in screened blood components with applied rapid serological test (Intec test [Advanced Quality™ test] can interpret the variance of the present study's findings and the findings of others.

Results of the current study demonstrate rapid serological test (Intec test [Advanced Quality™ test]) has diagnosed blood samples of two donors with HCV out of 130 donors, with most diagnostic accuracy. As well a Waheed et al. (2019) study conducted in Pakistan to evaluate rapid serological test for detecting HCV antibodies to meet the goals of the US CDC global viral hepatitis strategy. The study results indicate that Advanced Quality™ test (rapid serological test) is effective in detecting HCV infection as it agrees with acceptance criteria set by US CDC, the specificity of advanced quality™ rapid test (Intec product, China) is 98.91%, this sensitivity 98.56%, positive predictive value 99.51%, and negative predictive value 96.8%.

Results of the present study indicate that rapid serological test (Intec test [Advanced Quality™ test]) is not as reference standard test; accordingly, cannot rely on it as a diagnostic test to HCV among blood donors. This stand in the same side with, CDC, (2017) explains Anti-HCV rapid test's results and the correct actions to perform. If result of test is negative, no future action taken. But if person lately has expose to HCV risk; the result is doubts and HCV RNA test requires. If result of test is positive HCVRNA test requires. If HCVRNA test result is positive, appropriate counseling for treatment must be provided to the blood donor. If HCVRNA is not detected, follow up and repeated HCVRNA test is recommended.

Although the researchers unable to prove accuracy of rapid serological test versus reference standard test for HCV among blood

donors, but it stills promising area for further research, since it is an important issue to decrease number of collected blood bag infected with the virus, decrease risk of transmitted infection to health care workers through wrong medical practices, and decrease reliance on blood donor honesty of his/her HCV infection status.

6. Conclusion

The researchers has concluded that rapid serological test (Intec test [Advanced Quality™ test]) has half sensitivity (true positive) of reference standard test (Nucleic acid virus RNA test), as well, rapid serological test has high percentage of specificity (true negative), but is not as reference standard test, with the highest percentage belonged to negative predictive values rather than positive one. Finally, rapid serological test has high percentage of diagnostic accuracy, but is not as reference standard test; accordingly, cannot rely on it as a diagnostic test to HCV among blood donors.

7.Recommendations

On light of the study results, the researchers are suggested the following recommendations:

- Replicate the study on larger scale to estimate effectiveness of the rapid serological test.
- Replicate the study on different blood components to compare their results.
- Conducted further studies to compare different type of rapid serological test to detect HCV antibodies in human blood specimens.

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