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ORIGINAL ARTICLE

Evaluation of seven rapid diagnostic tests for detection of hepatitis C virus antibodies in China

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Abstract

Rapid diagnostic tests as an attractive alternative to enzyme immunoassay could identify hepatitis C virus (HCV) infected persons more expeditiously. The availability of high performing and quality-assured rapid diagnostic tests are essential to scale-up HCV screening. The study was undertaken to evaluate the performance of seven domestic HCV rapid diagnostic tests kits. The kits were evaluated by using HCV serum panels, including HCV basic panel, analytical specificity panel, mixed titre performance panel, characteristic panel, seroconversion panel, and genotype qualification panel. The results showed that clinical sensitivity, clinical specificity and analytical specificity of seven rapid diagnostic tests kits ranged from 94% (95% CI: 83.2–98.6) to 100% (95% CI: 91.5–100). Furthermore, specimens with HCV genotypes 1b, 2a, 3a, 4a, 5a, 6 could be detected by HCV rapid diagnostic tests kits, whereas specimens with genotypes 1a and 2b could not be detected. Additionally, most HCV rapid diagnostic tests kits had great performance in diagnosing different titres and/or different bands samples, but some low S/CO value specimens may not be fully detected by few rapid diagnostic test kits. In conclusion, seven HCV rapid diagnostic tests reagents presented high sensitivity, specificity, good anti-interference and detection ability of early infection, which could meet the requirements of clinical HCV antibody screening.

KEYWORDS
hepatitis C virus, rapid diagnostic test, sensitivity, serum panel, specificity

1 | INTRODUCTION

Hepatitis C virus (HCV) infection constitutes a global public health problem and a leading cause of chronic hepatitis, cirrhosis, and hepatocellular carcinoma.[1,2] Moreover, HCV infection is also a major contributor to mortality and morbidity worldwide.[3-5] In China, the prevalence of HCV is approximately 3%. It is estimated that grand total of 40 million individuals are infected with HCV in mainland China, and are one of the largest numbers of HCV infection in the world.[6,7] While most of persons with HCV infection are unaware of their infection status.[8,9] Therefore, large scale screening is critical to the success of HCV elimination targets, and early diagnosis and treatment of HCV infection are essential to prevent disease progression.

Conventional HCV testing is usually based on serological tests, including HCV-specific antibodies detection by means of chemiluminescent immunoassay (CLIA) or enzyme-linked immunosorbent assay (ELISA), performed in laboratories.[10] However, ELISA and CLIA assays are expensive, have long turnaround times, and require well-trained staff and well-equipped laboratory.[9] In contrast, rapid

diagnostic tests (RDTs) represent an attractive alternative for HCV screening and diagnosis, using various matrices, including serum and plasma, but also fingerstick capillary whole blood or oral fluid. Additionally, RDTs offer the advantage of simplicity, minimal training required, limited need for instrumentation, and rapid performance at room temperature.[10]

The objective of this study was to evaluate the performances of seven HCV RDTs approved by Chinese Food and Drug Administration (CFDA) HCV RDTs for the detection of HCV antibodies using multiple serum panels, and to provide references for testing selection in clinical application.

Highlights

- The availability of high performing and quality-assured HCV RDTs are essential to scale-up HCV screening.
- The HCV RDTs were evaluated using HCV serum panels.
- HCV RDTs presented high sensitivity, specificity, analytical specificity and detection ability of early infection.
- Some samples (such as HCV subtype 1a and/or 2b, low titre, single band) may not be detected by few HCV RDTs.

2 | MATERIALS AND METHODS

2.1 | Samples and kits

Serum samples were collected from intravenous drug users and blood donors in Yunnan Province and Gansu Province in China. The selected serum samples were diagnosed as HCV negative or positive by ELISA reagents (Murex, DiaSorin; Wantai BioPharm), RIBA reagents (Wantai BioPharm), and real-time PCR reagents (Cobas, Roche). The result judgement referred to per manufacturer's instructions of the testing reagents.

In this study, Seven HCV antibody RDT kits approved by CFDA were selected for performance evaluation, and the manufactures of HCV RDT kits include Kehua Bio-Engineering, Wantai BioPharm, Coretests, InTec Products, Newscan Coast, Wondfo, Biotest, which were represented by A, B, C, D, E, F, G, respectively. The detailed comparisons of selected HCV RDT kits were shown in supplementary material Table S1.

2.2 | Evaluation procedures

Before the evaluation of the experiment, all the operators were trained in performing and/or interpreting the HCV RDT assays. All specimens in all HCV serum panels were tested by the selected seven HCV RDT kits, and all assays were performed by one operator who was blinded to the reference results according to per manufacturer's instructions manuals. In addition, the results were visually interpreted by two others independently readers, and the readers were blinded to the reference results as well as the other's reading. Then, the results of different HCV RDT kits were recorded, compared and analysed with reference results in HCV serum panels.

2.3 | Construction of HCV serum panel

2.3.1 | HCV basic panel

HCV basic panel was mainly used to evaluate the clinical sensitivity, clinical specificity, positive predictive value (PPV) and negative predictive value (NPV) of HCV RDT kits. And the basic panel consisted of 100 serum samples, including 50 HCV antibody-positive samples and 50 HCV-negative samples.

2.3.2 | HCV seroconversion panel

HCV seroconversion panel was a series of samples, continuously collected over a period of time, from a HCV infected individual during the period between primary infection and HCV antibody production. And it was used to evaluate the sensitivity of HCV RDT kits in early infection of HCV. A total of 40 samples from four seroconversion panels (PHV906, PHV908, PHV914, PHV921; Seracare Life Sciences) were tested on each of the seven HCV RDT kits evaluated.

2.3.3 | HCV analytical specificity panel

HCV analytical specificity panel was used to evaluate the analytical specificity of HCV RDT kits. This set of serum panel consisted of 45 HCV antibody-negative samples, but these samples have multiple potentially interference factors in immunoassays. For example, these samples had haemoglobin, triglycerides, and other viral infections, such as HIV, HBV and syphilis antibody positive.

2.3.4 | HCV mixed titre performance panel

HCV mixed titre performance panel was used to evaluate the different antibodies titres of HCV RDT kits. This serum panel was composed of 16 undiluted and naturally occurring serum samples, which had antibodies reactivity ranging from negative to strongly positive for anti-HCV. One negative serum has been included as nonreactive controls.

2.3.5 | HCV genotype qualification panel

HCV genotype qualification panel was used to evaluate the ability of different genotypes detection of HCV RDT kits. Commercially HCV genotype qualification panel (Panel: 2400–0182) was purchased

from Seracare Company, which consists of eight HCV RNA positive and one HCV RNA negative. Single-positive samples from different infected patients. HCV genotypes (subtypes) of the eight HCV RNA-positive samples were HCV 1a, 1b, 2a, 2b, 3a, 4a, 5a, 6, respectively.

2.3.6 | HCV characteristic panel

HCV characteristic panel was used to evaluate the ability of different bands detection of HCV RDT kits. And this serum panel was composed of 20 serum samples, which had a single band, two bands, three bands, four bands, and whole bands, respectively. The background information of HCV characteristic panel shows in Table S2.

2.4 | Statistical analysis

Data analyses were performed using GraphPad PRISM 8.0. Clinical sensitivity and clinical specificity with confidence intervals (CIs) for each HCV RDT kit were calculated by comparing results obtained using the RDT with the reference result.

3 | RESULTS

3.1 | Results of HCV basic serum panel

The set of HCV basic panel was used to evaluate clinical sensitivity, clinical specificity, PPV and NPV of HCV RDT kits. As shown in Table 1, the results showed that the clinical sensitivity of all HCV RDT reagents were between 94% (95% CI: 83.2–98.6) and 100% (95% CI: 91.5–100), and the clinical specificity ranged from 96% (95% CI: 85.8–99.7) to 100% (95% CI: 91.5–100). Moreover, the PPV and NPV were calculated according to clinical sensitivity, clinical specificity, and HCV prevalence in different population. The results showed that the NPV of all RDT reagents were higher than 99.9% at different HCV prevalence. And the PPV of C and D reagents was 100% in different prevalence, while the PPV of the other five reagents was lower than 25% when the HCV prevalence was 0.5%, the PPV ranged from 20.16% to 33.56% in 1.0% prevalence of HCV, and the PPV ranged from 73.53% to 84.75% in 10.0% prevalence of HCV (Table 1).

3.2 | Results of HCV seroconversion panel

The HCV seroconversion panel was used to evaluate analytical sensitivity of HCV RDT reagents in early detection of antibodies. For each seroconversion panel, the first specimen in the sequence to become reactive with Murex4.0 HCV was assigned the value '0'. Results from HCV RDT under evaluation were compared with Murex4.0 HCV by the relative position. If a HCV RDT reagent became reactive one specimen earlier in a seroconversion panel than Murex 4.0 HCV, the value assigned for this panel in the RDT reagent was '+1'. Similarly, if a RDT reagent became reactive two specimens later than Murex 4.0 HCV, the value assigned was '−2'. As shown in Figure 1. It can be found that the E and G reagents were more sensitive in early detection of antibodies compared with the other five HCV RDT reagents and compared to the reference assays. While the early detection of B, C, D and F reagents was weak, which was less than the detection time of Murex HCV 4.0.

3.3 | Results of HCV analytical specificity panel

The set of HCV analytical specificity panel was used to evaluate analytical specificity of HCV RDT kits. The results showed that the analytical specificity of A, B, D, E, F, and G kits were all 100% (95% CI: 90.6–100), and no false-positive result was found. While the analytical specificity of C kit was 97.8% (95% CI: 87.4–100), and the result of a haemolytic specimen was false positive by C kit. Thus,

TABLE 1 Results of HCV basic panel with different HCV RDT kits

	A	B	C	D	E	F	G
Sensitivity (%) (95% CI)	100 (91.5–100)	100 (91.5–100)	100 (91.5–100)	94 (83.2–98.6)	100 (91.5–100)	96 (85.8–99.7)	100 (91.5–100)
Specificity (%) (95% CI)	98 (88.5–100)	96 (85.8–99.7)	100 (91.5–100)	100 (91.5–100)	98 (88.5–100)	98 (88.5–100)	96 (85.8–99.7)
PPV (Prevalence)							
PPV (0.5%)	20.08%	11.16%	100.00%	100.00%	20.08%	19.43%	11.16%
PPV (1.0%)	33.56%	20.16%	100.00%	100.00%	33.56%	32.65%	20.16%
PPV (10.0%)	84.75%	73.53%	100.00%	100.00%	84.75%	84.21%	73.53%
NPV (Prevalence)							
NPV (0.5%)	100.00%	100.00%	100.00%	99.97%	100.00%	99.98%	100.00%
NPV (1.0%)	100.00%	100.00%	100.00%	99.94%	100.00%	99.96%	100.00%
NPV (10.0%)	100.00%	100.00%	100.00%	99.34%	100.00%	99.55%	100.00%

Abbreviations: HCV, hepatitis C virus; RDT, rapid diagnostic test; CI, confidence interval; PPV, positive predicative value; NPV, negative predicative value.

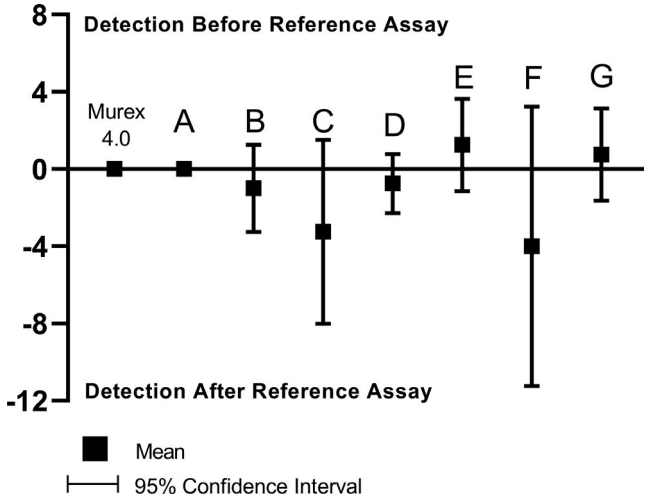

FIGURE 1 Relative Performance of HCV RDT reagents in Seroconversion Panels compared to Reference Assay (Murex 4.0 HCV)

these HCV RDT kits had no cross-reactivity with haemoglobin, triglycerides, and other viral infections, such as HIV, HBV and syphilis (see Table 2).

3.4 | Results of HCV mixed titre performance panel

The set of mixed titre performance panel was used to evaluate the detection ability of HCV RDT kits with different antibody titres. The reference results with different antibody titres were tested by anti-HCV ELISA (Beijing WANTAI Biological Pharmacy Enterprise Co.Ltd). As shown in Table 3. The M7 specimen in HCV mixed titre performance panel was confirmed to be negative, and the results of six HCV RDT kits exhibited negative, except for weak-positive result of E reagent. In addition, the M4, M5, and M6 specimens were tested by reference assay with low S/CO, and it could not be fully detected by C, D, and F kits. Moreover, the results of A, B, and G kits were consistent with the reference results (see Table 3).

3.5 | Results of HCV genotype qualification panel

The set of HCV genotype qualification panel was used to evaluate the detection ability of HCV RDT kits with different HCV genotypes. As shown in Table 4. It can be observed that all of the seven HCV RDT reagents can detect the HCV genotype 1b, 2a, 3a, 4a, 5a and 6. But the specimens of HCV subtypes 1a and/or 2b were not detected by all HCV RDT kits, except that the specimen of subtype 2b was detected by C kit (see Table 4).

3.6 | Results of HCV characteristic panel

The set of HCV characteristic panel was used to evaluate the detection ability of HCV RDT kits to different bands. The results exhibited that the 20 specimens with different bands in HCV characteristic panel were detected by B kit. However, the P4 and/or P5 specimens in this panel were not detected by other six kits. The RIBA results showed that the P4 and P5 specimens had single bands with only NS4-1 bands (see Table 5).

4 | DISCUSSION

To detect HCV infection, accurate and reliable diagnostic for HCV infection is indispensable. Currently, HCV RDT kits are widely used for screening tests of HCV infection, and it could reduce the risk of HCV transmission. Because HCV RDT kits are easy to perform without the need for expensive equipment or experienced personnel, and it has also high sensitivity and specificity.[5,11] In this study, we constructed HCV antibody basic panel, analytical specificity panel, mixed titre performance panel, characteristic panel, and commercially seroconversion panel, commercially genotype qualification panel to evaluate the performance of the HCV RDT kits. The basic panel results showed that the clinical sensitivity and clinical specificity of the seven HCV RDT kits ranged from 94% (95% CI: 83.2–98.6) to 100% (95% CI: 91.5–100), which was consistent with previous studies that the sensitivities of RDTs have varied from 90.8% to 99.9% and the specificities have varied from 92.1% to 99.9%.[12,13] The data suggest that HCV RDT kits evaluated in this study have high clinical sensitivity and clinical specificity to detect HCV infection.

In addition, the prevalence of HCV infection is different in different populations. For example, the prevalence of HCV infection in premarital screening population was 0.3%,[14] while that of intravenous drug user population was ranging from 22% to 95%.[15] Therefore, this study set the different prevalence of HCV infection in the population (0.5%, 1% and 10%, respectively), and

TABLE 2 Results of HCV analytical specificity panel with different HCV RDT kits

	A	B	C	D	E	F	G
Number of negative	45	45	44[a]	45	45	45	45
Analytical specificity %(95%CI)	100 (90.6–100)	100 (90.6–100)	97.8 (87.4–100)	100 (90.6–100)	100 (90.6–100)	100 (90.6–100)	100 (90.6–100)

Abbreviations: HCV, hepatitis C virus; RDT, rapid diagnostic test.

[a]This misjudged specimen was haemolytic.

TABLE 3 Results of HCV mixed titre performance panel with different HCV RDT kits

Panel number	Reference results(S/CO)	A	B	C	D	E	F	G
M1	8.96	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M2	6.76	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M3	4.51	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M4	3.26	Pos	Pos	Pos	**Neg**	Pos	Pos	Pos
M5	2.65	Pos	Pos	**Weak Pos**	Pos	Pos	**Neg**	Pos
M6	1.38	Pos	Pos	**Neg**	Pos	Pos	**Neg**	Pos
M7	0.11	Neg	Neg	Neg	Neg	**Weak Pos**	Neg	Neg
M8	10.29	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M9	12.87	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M10	14.67	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M11	7.98	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M12	9.62	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M13	18.52	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M14	20.62	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M15	15.53	Pos	Pos	Pos	Pos	Pos	Pos	Pos
M16	13.06	Pos	Pos	Pos	Pos	Pos	Pos	Pos

Bold indicates that the test results of these kits do not match the reference results.

Abbreviations: HCV, hepatitis C virus; RDT, rapid diagnostic test; S/CO, sample/cut off; Weak Pos, weak positive, the results refer to very light of the test line; Pos, positive; Neg, negative.

combined with clinical sensitivity and specificity to calculate PPV and NPV. It was found that the NPVs of all HCV RDT kits in different HCV prevalence were more than 99.9%, indicating that the negative test results of RDT kits were truly uninfected. While the PPVs of most RDT kits were less than 50% when the prevalence of HCV infection was 0.5% and 1%, and the PPVs of all kits in HCV prevalence of 10% were ranging from 73.53% to 100%, suggesting that with increasing HCV prevalence, the proportion of HCV false-positive decreases, and when most HCV RDT kits were used in the population with low prevalence of HCV infection (such as voluntary blood donation),[16] this results may by false positive. Therefore, the results of the screening test that are reactive need to be further verified by supplementary tests.

Furthermore, early detection ability of RDT kit was also analysed by using HCV seroconversion panels.[5,12,17] It was found that the early detection time of A, E and G reagent was earlier than that of the reference assay, which indicated that the early detection ability of HCV RDT kit was roughly the same as that of ELISA. It was possible that the antigenic composition of RDT reagent coated was similar to that of ELISA, and even some antigen components of HCV RDT kits were superior to that of ELISA, resulting in more sensitive in early detection of antibodies compared to ELISA. However, the early detection ability of the other four HCV RDT reagents was lower than that of ELISA. Therefore, some HCV RDT kits should be further improved in kinds and composition of coated antigens in order to detect infected population as soon as possible.

TABLE 4 Results of HCV genotype qualification panel with different HCV RDT kits

Panel number	Genotypes	A	B	C	D	E	F	G
2400–1	1a	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
2400–2	1b	Pos	Pos	Pos	Pos	Pos	Pos	Pos
2400–3	2a	Pos	Pos	Pos	Pos	Pos	Pos	Pos
2400–4	2b	**Neg**	**Neg**	Pos	**Neg**	**Neg**	**Neg**	**Neg**
2400–5	3a	Pos	Pos	Pos	Pos	Pos	Pos	Pos
2400–6	4a	Pos	Pos	Pos	Pos	Pos	Pos	Pos
2400–7	5a	Pos	Pos	Pos	Pos	Pos	Pos	Pos
2400–8	6	Pos	Pos	Pos	Pos	Pos	Pos	Pos
n2400–9	N/A	Neg	Neg	**Pos**	Neg	Neg	Neg	Neg

Bold indicates that the test results of these kits do not match the reference results.

Abbreviations: HCV, hepatitis C virus; RDT, rapid diagnostic test; Pos, positive; Neg, negative; N/A, not available.

TABLE 5 Results of HCV characteristic panel with different HCV RDT kits

	A	B	C	D	E	F	G
Number of positive	18	20	18	18	19	19	19
Percentage % (95%CI)	90 (68.7–98.4)	100 (80.0–100)	90 (68.7–98.4)	90 (68.7–98.4)	95 (74.6–100)	95 (74.6–100)	95 (74.6–100)

And the genome of HCV has strong variability, HCV can be divided into 7 genotypes and 67 gene subtypes according to the variation sites.[18] In this study, HCV genotypes qualification panel containing HCV genotypes 1–6 were purchased to evaluate the detection ability of seven HCV RDT reagents for different genotypes. The results showed that the specimens with HCV genotypes 1b, 2a, 3a, 4a, 5a, 6 in genotype qualification panel could be detected, but specimens with genotypes 1a and 2b could not be detected. Moreover, previous data exhibited that the most common HCV genotype in China was genotype 1b, accounting for 56.8% of the total HCV infection, HCV genotype 1a was rare, accounting for only 1.4%, and HCV genotypes 4, 5, and 2b hadn't been found in mainland China.[1,19] Therefore, HCV RDT reagent can detect common HCV genotypes in China, but samples of domestically rare genotypes such as 1a and 2b may be missed.

Additionally, specimens with different S/CO in HCV mixed titre performance panel values and specimens with different bands in HCV characteristic panel were also tested by RDT kits. The results showed most HCV RDT kits had great performance in samples with different titres and different bands. But some low S/CO value specimens may be not fully detected by C, D, and F kit, and the single-band specimens with only NS4-1 bands could be missed by few HCV RDT kits, indicating that some HCV RDT kits had low sensitivity for diagnosing low-titre and/or single-band samples. This phenomenon may be due to the variability gene sequence of HCV NS4-1 region, resulting in weak antigen antibody reaction.[20] Therefore, specimens with low-titre and/or single-band may be not detected.

Our study has a few limitations in the study findings. Firstly, this study had low number of HCV-positive and -negative specimens in different serum panel. A larger specimen size from different populations would have given the study results more reliable and comprehensive. Secondly, some rare HCV genotypes could not be detected by HCV RDT reagents, but the number of samples with rare HCV genotypes was low, and these results were not verified.

In conclusion, all of seven HCV RDT kits evaluated had high clinical sensitivity, clinical specificity and analytical specificity, good anti-interference ability and good detection ability of early infection, which proved that they could meet the requirements of clinical HCV antibody screening. But some special samples (such as HCV subtype 1a and/or 2b, low titre, single band) may be missed by using certain HCV RDT kits.

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CONFLICTS OF INTEREST

The author declared no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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