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RESEARCH ARTICLE

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Performance evaluation of the mindray anti-HCV assay for the detection of hepatitis C virus infection

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Background: Anti-hepatitis C virus (anti-HCV) antibody assays are recommended for HCV infection screening. The Mindray anti-HCV assay, based on a third-generation immunoassay, was recently launched in China. We aimed to evaluate its diagnostic performance compared with that of two other widely used assays.

Methods: Six HCV infection seroconversion panels were used to evaluate the sensitivity of the assay for early detection. A total of 1952 clinical samples were tested by the Mindray anti-HCV, Elecsys anti-HCV II, and Architect anti-HCV assays. Samples with reactive results using at least one anti-HCV assay were further tested with the recombinant immunoblot assay (RIBA). Inconsistent results were investigated by the HCV RNA assay and HCV core antigen assay. HCV infection diagnosis was made according to the results of laboratory tests and medical records.

Results: The Mindray anti-HCV assay and Elecsys anti-HCV II assay detected seroconversion in an average of 12.5 days and 10.5 days, respectively, and this difference was not significant (P = .818). Of the 1952 cases, 90 were categorized as "HCV infection" and 1862 were categorized as "no HCV infection." The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+), and negative likelihood ratio (LR-) of each assay were as follows: the Mindray anti-HCV assay, 95.6%, 99.2%, 85.1%, 99.8%, 118.6 and 0.045, respectively; the Architect anti-HCV assay, 98.9%, 95.2%, 50.0%, 99.9%, 20.69 and 0.012, respectively; and the Elecsys anti-HCV II assay, 96.7%, 99.9%, 98.9%, 99.8%, 1799.9 and 0.033, respectively. There were significant differences in the specificity, PPV and LR+ among the three assays (P < .001). There were no significant differences in the sensitivity, NPV or LR- among the three assays (P > .05).

Conclusions: The Mindray anti-HCV assay displays a similar sensitivity to the Elecsys anti-HCV II assay with respect to the early detection of HCV infection. The Mindray anti-HCV assay shows excellent diagnostic performance and is suitable for the screening of HCV infection.

KEYWORDS
anti-HCV, Architect anti-HCV assay, diagnostic performance, Elecsys anti-HCV II assay, hepatitis C virus, Mindray anti-HCV assay

Zhi-hong Yue and Chang-sheng Xia contributed equally to this work and should be considered as co-first authors.

1 | INTRODUCTION

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). According to the Global Hepatitis Report (WHO, 2017), approximately 71 million people worldwide have chronic HCV infection and 399 000 people die each year from hepatitis C, mostly from cirrhosis or hepatocellular carcinoma.[1]

Although direct-acting antiviral treatment for HCV is becoming simpler and more effective, HCV infection is asymptomatic in the majority of patients; thus, it remains difficult to diagnose clinically until more advanced stages of fibrosis are present.[2,3] HCV infection diagnosis relies heavily on clinical laboratory tests, including anti-HCV antibody detection, detection of HCV core antigen (HCVcAg), and nucleic acid testing (NAT) for HCV RNA.[4,5] In clinical practice, HCV infection diagnosis is a two-step process that starts with an anti-HCV assay, which is typically used to screen for virus exposure, followed by the more complex and expensive NAT to confirm viremia.

Chemiluminescent immunoassays (CLIAs) for anti-HCV antibody detection have been fully automated using high-throughput, random access instruments that are widely used as a screening tool for HCV infection, particularly in high-volume clinical laboratories. Recently, the new Mindray anti-HCV assay was developed for clinical laboratories. It is a third-generation immunoassay using antigens corresponding to the HCV core, NS3, and NS4 proteins for the qualitative detection of anti-HCV antibodies in human serum or plasma. The aim of this study was to evaluate its clinical diagnostic performance compared with that of the Architect anti-HCV assay and Elecsys anti-HCV II assay.

2 | MATERIALS AND METHODS

2.1 | Subjects

This study included a total of 1952 cases from Peking University People's Hospital. The median patient age was 58 years (range, 5 to 89 years), and 894 and 1058 patients were male and female, respectively. This study was approved by the ethics committee of Peking University People's Hospital.

2.2 | Serological assays for HCV antibody detection

This prospective study was conducted in two stages. In the first stage, 1860 consecutive unselected fresh serum samples, which were submitted daily to the Department of Clinical Laboratory of Peking University People's Hospital for routine clinical testing, were analyzed using the Architect anti-HCV assay on the Architect i2000 system (Abbott Diagnostics, Wiesbaden, Germany). These samples were collected from October 2016 to December 2016. In the second stage, 92 serum samples with reactive results from the Architect anti-HCV assay were collected from May 2017 to July 2017. The collected serum samples were stored at −80°C prior to other testing. All of the 1952 samples were tested by the Mindray anti-HCV assay on the CL-2000i analyzer (Mindray Diagnostics, Shenzhen, China) and by the Elecsys anti-HCV II assay on the Cobas 601 analyzer (Roche Diagnostics, Mannheim, Germany).

The results from all three anti-HCV assays are expressed as signal-to-cut-off (S/CO) ratios, with a S/CO ratio of < 1.0 indicating a nonreactive result and a S/CO ratio of ≥ 1.0 indicating a reactive result. The tested samples that were initially reactive were retested in duplicate. If one or both duplicates were reactive, the result was considered anti-HCV antibody CLIA-reactive, and S/CO levels corresponded to the antibody concentration.

All anti-HCV antibody CLIA-reactive samples according to at least one assay were further tested using the RecomLine HCV IgG strip immunoassay (Mikrogen GmbH, Neuried, Germany). The recombinant immunoblot assay (RIBA) results are expressed as negative, indeterminate or positive. Samples that yielded negative or indeterminate results in the RIBA were further investigated by NAT (COBAS CAP/CTM V2, Roche Diagnostics, Almere, the Netherlands) and the HCVcAg assay (Architect HCV Ag assay, Abbott, Hoofddorp, the Netherlands). Medical records, including previous and follow-up laboratory tests, were retrospectively reviewed to identify cases with or without HCV infection. The testing sequence for these samples is shown in Figure 1. The characteristics of the three automated anti-HCV assays are shown in Table 1.

2.3 | Seroconversion panels

Six HCV infection seroconversion panels were used to evaluate the sensitivity of the Mindray anti-HCV assay and Elecsys anti-HCV II assays for early detection. These panels included PHV913, PHV915, PHV917, PHV920, PHV922, and PHV925 (Sera-Care Life Sciences, Milford, MA, USA).

2.4 | Statistical analysis

Statistical analysis was carried out using SPSS statistical software version 16.0 (SPSS Inc., Chicago, IL, USA) and R package software. The sensitivity, specificity, positive and negative predictive values (PPV and NPV, respectively), and positive and negative likelihood ratios (LR+ and LR−, respectively) with 95% confidence intervals (CIs) were estimated by comparing the anti-HCV antibody results of each anti-HCV CLIA assay with the diagnosis, that is, the presence or absence of HCV infection. The "DTComPair" test was used to perform a qualitative data comparison between each anti-HCV CLIA assay. The correlation between each anti-HCV CLIA assay was evaluated using Pearson's correlation test. The percentages of samples with S/CO ratios < 1.0, between 1.0 and 10.0, and > 10.0 in each assay were evaluated using Kendall's tau-b statistic. A *P*-value <.05 was considered significantly different.

3 | RESULTS

3.1 | Sensitivity of the assays for the early detection of HCV infection

Six HCV infection seroconversion panels were used, and the Mindray anti-HCV assay detected seroconversion in an average of 12.5 days (7, 12, 85, 13, 7, and 27 days), while the Elecsys anti-HCV II assay

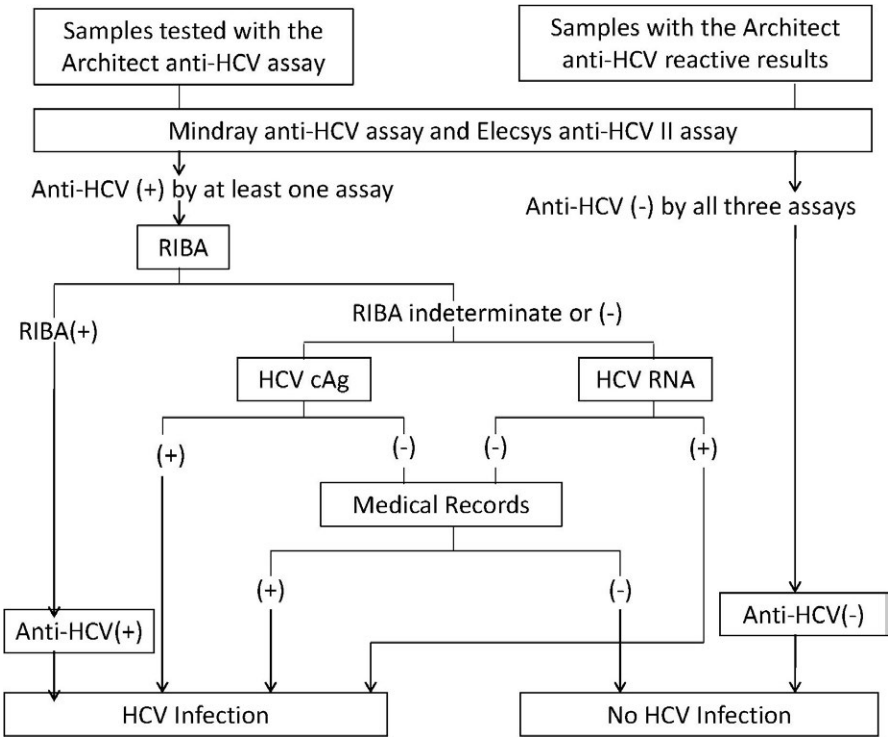

FIGURE 1 HCV testing sequence for clinical routine and preselected samples with the Architect anti-HCV assay reactive results. S/CO = signal/cut-off, RIBA = recombinant immunoblot assay

TABLE 1 Characteristics of the three automated anti-HCV assays

Reagent	Elecsys anti-HCV II	Architect anti-HCV	Mindray anti-HCV
Analyzer	Cobas 601	Architect i2000	CL-2000i
Manufacturer	Roche Diagnostics	Abbott Laboratories	Mindray Bio-Medical Electronics Co., Ltd.
HCV antigen-Core	Present	Present (HCr43)	Present
HCV antigen-NS3	Present	Present (HCr43)	Present
HCV antigen-NS4	Present	Present (c100-3)	Present
HCV antigen-NS5	Absent	Absent	Absent
Method	ECLIA	CLIA	CLIA
Solid phase	Magnetic particle	Paramagnetic particle	Paramagnetic particle
Labeled substance	Ruthenium complex	Acridinium ester	AMPPD
Sample vol (μL)	40	20	40
Time of reaction (min)	18	29	39

detected seroconversion in average of 10.5 days (7, 5, 85, 13, 14, and 8 days) (Figure 2). There was no significant difference between the two assays (P = .818).

3.2 | Serological assays for HCV antibody detection

Of the 1952 enrolled samples, 1771 samples subjected to CLIAs were nonreactive in all three assays. These cases indicated no HCV infection. The remaining 181 samples were reactive according to at least one anti-HCV CLIA assay and were further tested with RIBA. Among these samples, 47.5% (86/181) were RIBA-positive, 12.2% (22/181) were RIBA-indeterminate, and 40.3% (73/181) were RIBA-negative. Moreover, 86 cases with RIBA-positive results had HCV infection. In addition, 95 cases with indeterminate and negative RIBA results were further investigated by NAT for HCV RNA, the HCVcAg assay, and the patient's medical records. We observed one case with an HCV RNA-positive result, two cases with an HCVcAg-positive result, and one case with a medical record of HCV infection, and these four cases indicated HCV infection. The remaining 91 cases with HCV RNA- and HCVcAg-negative results indicated no HCV infection. In general, of the 1952 cases, 90 cases were categorized as HCV infection and 1862 cases were categorized as no HCV infection.

3.3 | Diagnostic performance of the three anti-HCV assays

The sensitivity, specificity, PPV, NPV, LR+ and LR- of each assay for the detection of HCV infection are listed in Table 2 as follows: the

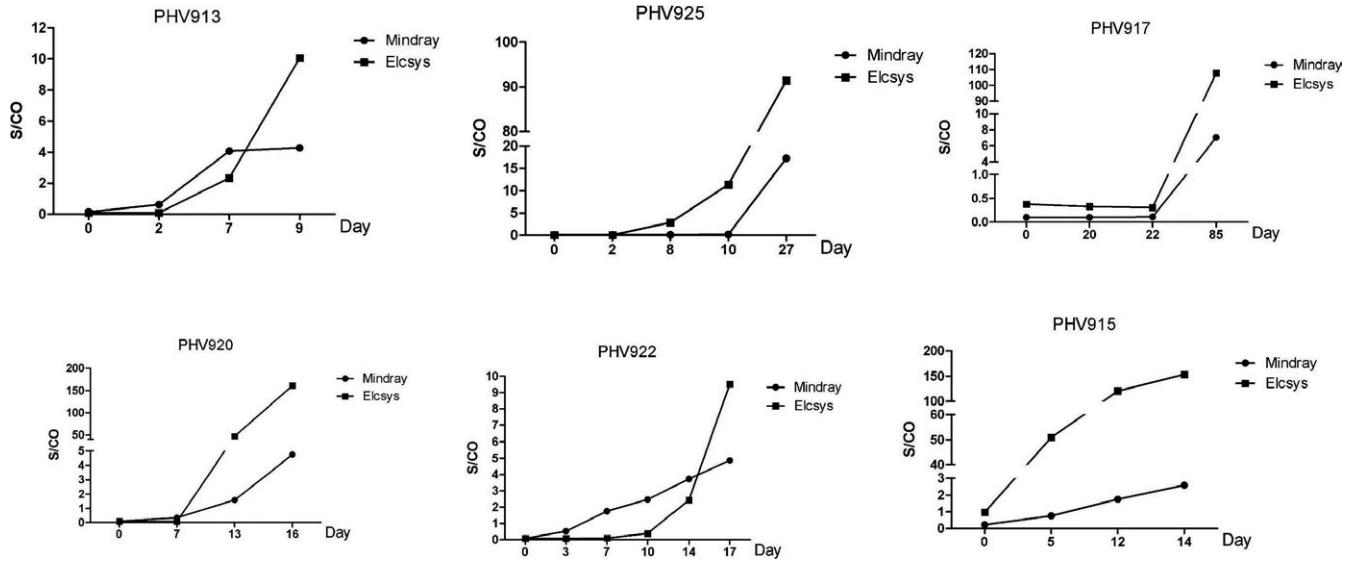

FIGURE 2 Results of the six HCV seroconversion panels using two different anti-HCV assays

Mindray anti-HCV assay, 95.6%, 99.2%, 85.1%, 99.8%, 118.6 and 0.045, respectively; the Architect anti-HCV assay, 98.9%, 95.2%, 50.0%, 99.9%, 20.69 and 0.012, respectively; and the Elecsys anti-HCV II assay, 96.7%, 99.9%, 98.9%, 99.8%, 1799.9 and 0.033, respectively. The "DTComPair" test results are listed in Table 3 and Table 4. There were no significant differences in the sensitivity, NPV and LR- among the three assays ($P > .05$). There were significant differences in the specificity, PPV, and LR+ between the two assays ($P < .001$).

3.4 | S/CO ratio analysis of the three anti-HCV assays

For the 181 samples with at least one anti-HCV CLIA-reactive result, the scatter diagrams of the S/CO ratios for each anti-HCV assay are shown in Figure 3. There was a good correlation between the Mindray anti-HCV assay and Architect anti-HCV assay ($r = .916$, $P < .001$; Figure 3A). However, we found a significant but weak positive correlation between the Mindray anti-HCV assay and the Elecsys anti-HCV II assay ($r = .364$, $P < .001$; Figure 3B) and between the Elecsys anti-HCV II assay and the Architect assay ($r = .430$, $P < .001$; Figure 3C). The distribution of the S/CO ratios for the 181 samples associated with each anti-HCV assay is shown in Figure 4. The percentages of samples with an S/CO ratio<1.0, between 1.0 and 10.0, and >10.0 in each assay were as follows: the Mindray anti-HCV assay, 44.2% (80/181), 14.9% (27/181) and 40.9% (74/181), respectively; the Architect anti-HCV assay, 1.7% (3/181), 60.7% (110/181) and 37.6% (68/181), respectively; and the Elecsys anti-HCV II assay, 51.4% (93/181), 1.1% (2/181) and 47.5% (86/181), respectively. There were significant differences in the distribution of the S/CO ratios between each pair of assays ($P < .001$).

TABLE 2 Diagnostic performance of anti-HCV assays for the detection of HCV infection (n = 1952)

Assay and results	HCV infection NO. of patients Yes	No	%Sensitivity (95%CI)	%Specificity (95%CI)	PPV (95%CI)	NPV (95%CI)	LR+ (95%CI)	LR− (95%CI)
Mindray								
Reactive	86	15	95.6% (91.3%-99.8%)	99.2% (98.8%-99.6%)	85.1% (78.2%-92.1%)	99.8% (99.6%-100.0%)	118.6 (71.5-196.7)	0.045 (0.02-0.12)
Nonreactive	4	1847						
Architect								
Reactive	89	89	98.9% (96.7%-100.0%)	95.2% (94.3%-96.2%)	50.0% (42.7%-57.3%)	99.9% (99.8%-100.0%)	20.69 (16.87-25.37)	0.012 (0.002-0.082)
Nonreactive	1	1773						
Elecsys								
Reactive	87	1	96.7% (93.0%-100.0%)	99.9% (99.8%-100.0%)	98.9% (96.6%-100.0%)	99.8% (99.7%-100.0%)	1799.9 (253.6-12775.9)	0.033 (0.011-0.101)
Nonreactive	3	1861						

CI, confidence interval; LR−, negative likelihood ratio; LR+, positive likelihood ratio; NPV, negative predictive value; PPV, positive predictive value.

TABLE 3 Sensitivity comparisons of the three anti-HCV CLIA assays in patients with HCV infection (n = 90)

	NO. of patients						
	Architect		Elecsys		Mindray		DTCompair test
Assay and results	Reactive	Nonreactive	Nonreactive	Negative	Reactive	Nonreactive	*P* value
Mindray							
Reactive	85	4					.179
Nonreactive	1	0					
Architect							
Reactive			86	3			.317
Nonreactive			1	0			
Elecsys							
Reactive					86	1	.317
Nonreactive					0	3	

TABLE 4 Specificity comparisons of the three anti-HCV antibody assays in patients with no evidence of HCV infection (n = 1862)

	NO. of patients						
	Architect		Elecsys		Mindray		DTComPair test
Assay and results	Reactive	Nonreactive	Reactive	Nonreactive	Reactive	Nonreactive	*P* value
Mindray							
Reactive	13	76					<.001
Nonreactive	2	1771					
Architect							
Reactive			1	88			<.001
Nonreactive			0	1773			
Elecsys							
Reactive					1	0	<.001
Nonreactive					14	1847	

4 | DISCUSSION

Early detection of HCV antibody is important for the effective screening and fast diagnosis of HCV infection, enabling infected patients to be diagnosed and treated to prevent disease progression and viral spread. Previous studies have revealed that the Elecsys anti-HCV II assay is more sensitive for early detection than the Architect anti-HCV assay and other comparative assays.[6,7] According to our study, the Mindray anti-HCV assay displayed a similar sensitivity to the Elecsys anti-HCV II assay with respect to the early detection of HCV infection.

Screening tests for the diagnosis of infectious diseases need to have high sensitivities to detect all or nearly all affected individuals. Consequently, screening tests generally produce more false-positive results and require good available supplemental tests. RIBA is labor-intensive and time-consuming and is no longer recommended as a supplemental test for anti-HCV confirmation in the 2013 CDC guidelines, and only NAT is required.[8] RIBA is still commonly used due to its high specificity in other countries, including China.[9] In the present study, we used RIBA to analyze 181 samples with at least one anti-HCV CLIA-reactive result. Among these samples, 47.5% (86/181), 12.2% (22/181), and 40.3% (73/181) cases were positive, indeterminate, and negative by RIBA, respectively. These results were consistent with those obtained in several previous studies.[10,11] It can be difficult to interpret the significance of RIBA-indeterminate results, as HCV RNA is usually not detectable. The possibility that the cases were CIA reactive but RIBA-indeterminate or RIBA-negative may be due to one of the following: (i) resolved HCV infection when the antibodies to some HCV antigens are no longer detectable; (ii) early seroconversion when fluctuating RNA levels may become temporarily undetectable; (iii) occult HCV infection; or (iv) nonspecific reactivity. In our study, the NAT for HCV RNA, the HCVcAg assay, and medical records were used to analyze the results for these cases to ensure the diagnostic accuracy and avoid false-positive and false-negative results.

Several studies have evaluated the currently available anti-HCV assays, with the sensitivity of each assay demonstrating variability

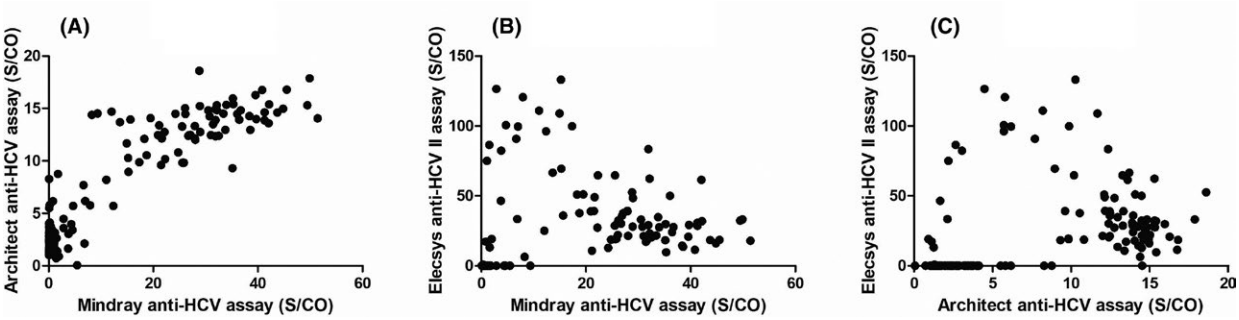

FIGURE 3 Correlation of the S/CO ratios among the Mindray anti-HCV, Architect anti-HCV, and Elecsys anti-HCV II assays (n = 181). S/CO = signal/cut-off

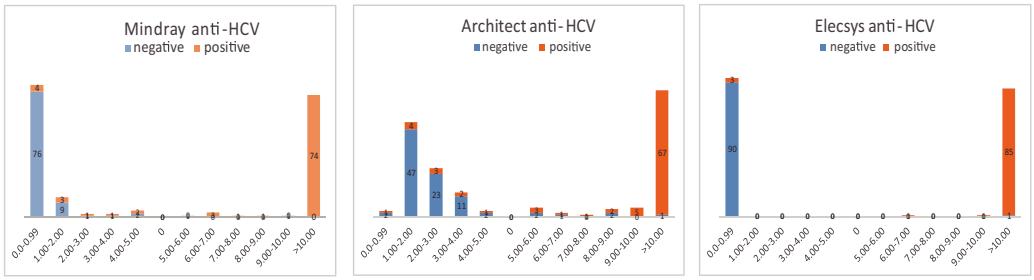

FIGURE 4 Distribution of S/CO ratios in 181 samples assayed using the Elecsys anti-HCV II assay, Architect anti-HCV assay and Mindray anti-HCV assay

from 61.0% to 100% and the specificity being high, ranging from 97.5% to 100%.[6,7,12-14] In the present study, we evaluated the diagnostic performance of the Mindray anti-HCV assay for the detection of HCV infection and showed a high sensitivity of 95.6% and excellent specificity of 99.2%. The sensitivity, NPV and LR– were similar to those of the Elecsys anti-HCV II assay and Architect anti-HCV assay ($P > .05$). The specificity, PPV and LR+ of the Elecsys anti-HCV II assay were superior to those of the Mindray anti-HCV assay ($P < .001$). The corresponding data from the Mindray anti-HCV assay were superior to those from the Architect anti-HCV assay ($P < .001$). These results are consistent with those of several previous studies in which the diagnostic performance of the Elecsys anti-HCV II assay was compared with that of the Architect anti-HCV assay.[7,15]

The prevalence of HCV infection was reported to be 0.43% in China. However, it was 4.6% in our study.[16] The reason for discrepancy may be due to the case selection bias in the present study. First, the presence of anti-HCV antibody was determined by a doctor. Second, some samples that yielded reactive results in the Architect Anti-HCV assay were selected. Thus, the prevalence of HCV infection should be considered in the evaluation of PPV and NPV according to our study.

The S/CO ratios of the Mindray anti-HCV assay correlated well with those of the Architect anti-HCV assay, showing a correlation coefficient of .916, but they correlated weakly with those of the Elecsys anti-HCV II assay. The Mindray and Architect anti-HCV assays were based on the indirect principle. However, the Elecsys anti-HCV II assay, an electrochemiluminescence assay, was based on the double-antigen sandwich principle. This finding may potentially explain why the best correlation was found between the results of the Mindray and Architect assays. Such discrepant results between immunoassays have been reported elsewhere.[6] The reasons for this discrepancy may be attributed to the methods and molecules used to generate and detect the signals, as well as the differences in the epitopes and specificities of the antigens and antibodies in the reagents between the assays.

CDC guidelines have recommended that the anti-HCV threshold S/CO ratio can be used to reduce the necessity for supplemental testing and may provide additional insight into a subject's true anti-HCV antibody status.[17] Several previous studies have reported the threshold S/CO ratio, which predicts positive results in ≥ 95% of supplemental tests for a variety of anti-HCV assays.[6,8,9,18] Among the 181 samples with anti-HCV CLIA-positive results according to at least one assay, the percentages of samples with an S/CO ratio between 1.0 and 10.0 according to the Mindray anti-HCV, Architect anti-HCV and Elecsys anti-HCV II assays were 14.9% (27/181), 60.7% (110/181), and 1.1% (2/181), respectively. Thus, the Elecsys anti-HCV II assay and Mindray anti-HCV assay have better signal-to-noise ratios for weakly reactive samples than the Architect anti-HCV assay. Thus, these assays could reduce the necessity for supplemental testing, and savings in cost and time could be achieved.

This study has several limitations. First, NAT and HCVcAg on the anti-HCV CLIA nonreactive samples were not performed. Anti-HCV results could be persistently negative while HCV RNA is positive in patients with chronic HCV infection, including those who have a compromised immune system. Second, this study included only 90 cases with HCV infection. Further studies with larger sample sizes are needed to confirm our findings.

In summary, the Mindray anti-HCV assay shows a high diagnostic performance, particularly in terms of high sensitivity, excellent specificity, and NPV, in the screening of routine clinical samples. However, our data suggest that each anti-HCV assay has limitations, including the potential for false-positive and false-negative results. Therefore, serum samples that are reactive based on a screening anti-HCV assay should be analyzed with a second test (e.g., HCVcAg, NAT).

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REFERENCES

1. World Health Organization. Global hepatitis report 2017. World Health Organization. 2017. http://www.who.int/iris/handle/10665/255016. License: CC BY-NC-SA 3.0 IGO. Accessed May 8, 2017.
2. Cooke GS, Hill AM. Diagnostics for resource-limited settings in the era of interferon-free HCV therapy. *J Viral Hepat*. 2015;22:459-460.
3. Ward JW, Mermin JH. Simple, effective, but out of reach? Public health implications of HCV drugs. *N Engl J Med*. 2015;373:2678-2680.
4. Kamili S, Drobeniuc J, Araujo AC, Hayden TM. Laboratory diagnostics for hepatitis C virus infection. *Clin Infect Dis*. 2012;55(Suppl 1):S43-S48.
5. World Health Organization. Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection, Updated version, April 2016. World Health Organization. 2016. http://www.who.int/iris/handle/10665/205035. Accessed May 8, 2017.
6. Yang R, Guan W, Wang Q, Liu Y, Wei L. Performance evaluation and comparison of the newly developed Elecsys anti-HCV II assay with other widely used assays. *Clin Chim Acta*. 2013;426:95-101.
7. Alborino F, Burighel A, Tiller F-W, et al. Multicenter evaluation of a fully automated third-generation anti-HCV antibody screening test with excellent sensitivity and specificity. *Med Microbiol Immunol*. 2011;200:77-83.
8. Centers for Disease Control and Prevention (CDC). Testing for HCV infection: an update of guidance for clinicians and laboratorians. *MMWR Morb Mortal Wkly Rep*. 2013;62:362-365.
9. Pan J, Li X, He G, et al. Reflex threshold of signal-to-cut-off ratios of the Elecsys anti-HCV II assay for hepatitis C virus infection. *J Infect Dev Ctries*. 2016;10:1031-1034.
10. Kiely P, Styles C. Anti-HCV immunoblot indeterminate results in blood donors: non-specific reactivity or past exposure to HCV? *Vox Sang*. 2017;112:542-548.
11. Oh EJ, Chang J, Yang JY, Kim Y, Park YJ, Han K. Different signal-to-cut-off ratios from three automated anti-hepatitis C virus chemiluminescence immunoassays in relation to results of recombinant immunoblot assays and nucleic acid testing. *Blood Transfus*. 2013;11:471-473.
12. Kim S, Kim JH, Yoon S, Park YH, Kim HS. Clinical performance evaluation of four automated chemiluminescence immunoassays for hepatitis C virus antibody detection. *J Clin Microbiol*. 2008;46:3919-3923.
13. Tang W, Chen W, Amini A, et al. Diagnostic accuracy of tests to detect Hepatitis C antibody: a meta-analysis and review of the literature. *BMC Infect Dis*. 2017;17(Suppl 1):695.
14. Cadieux G, Campbell J, Dendukuri N. Systematic review of the accuracy of antibody tests used to screen asymptomatic adults for hepatitis C infection. *CMAJ Open*. 2016;4:E737-E745.
15. Esteban JI, van Helden J, Alborino F, et al. Multicenter evaluation of the Elecsys(R) anti-HCV II assay for the diagnosis of hepatitis C virus infection. *J Med Virol*. 2013;85:1362-1368.
16. Chen YS, Li L, Cui FQ, et al. A sero-epidemiological study on hepatitis C in China. *Chin J Epidemonol*. 2011;33:888-891.
17. Alter MJ, Kuhnert WL, Finelli L. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. Centers for Disease Control and Prevention. *MMWR Recomm Rep*. 2003;52(RR-3):1-13, 15; quiz CE1-4.
18. Kim B, Ahn HJ, Choi MH, Park Y. Retrospective analysis on the diagnostic performances and signal-to-cut-off ratios of the Elecsys Anti-HCV II assay. *J Clin Lab Anal*. 2017;32:e22165.

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