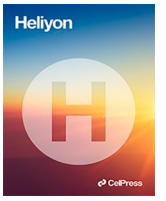
Heliyon 10 (2024) e32698

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon



Research article

Comparison of Autolumo A2000 Plus and Architect i2000 for detection of hepatitis B virus serological markers

Xue-Dong Zhang [a,d,1], Xue-Dong Song [b,c,1], Jian-Hua Lu [b,1], Yan Dai [d], Bin Li [d], Ping Zhu [e], Er-Hei Dai [b], Calvin Q. Pan [f,g,*], Wei Chen [a,**]

[a] *Department of Clinical Laboratory, the First Affiliated Hospital of Xi'an Jiao Tong University, Xi'an, Shaanxi, China*
[b] *Hebei Key Laboratory of Immune Mechanism of Major Infectious Diseases and New Technology of Diagnosis and Treatment, The Fifth Hospital of Shijiazhuang, Hebei Medical University, Shijiazhuang, China*
[c] *Department of Laboratory Medicine, Handan Central Hospital, Hebei Medical University, Handan, China*
[d] *Autobio Diagnostic Co.Ltd., Zhengzhou, China*
[e] *Department of Laboratory Medicine, the Sixth Hospital of Shijiazhuang, Hebei, China*
[f] *Center of Liver Diseases, Beijing Ditan Hospital, Capital Medical University, Beijing, China*
[g] *Division of Gastroenterology and Hepatology, Department of Medicine, NYU Langone Health, New York University Grossman School of Medicine, New York, USA*

ARTICLE INFO

Keywords:
Hepatitis B infection
Laboratory medicine
Diagnostic performance
Autolumo A2000Plus systems
Abbott Architect i2000 systems
Quantitative coherence

ABSTRACT

Serological detection of hepatitis B virus markers plays a vital role in the diagnosis, treatment, prognosis, and therapeutic surveillance of hepatitis B. To compare the diagnostic performance of Autolumo A2000Plus and Abbott Architect i2000 systems in the detection of hepatitis B infection markers. A total of 6 HBV seroconversion panels and 743 participants were enrolled in this study, including 383 HBV-infected patients and 360 healthy adults. Clinical diagnostic information, laboratory results, and HBV genotyping were collected to evaluate the diagnostic performance of the A2000Plus and i2000 systems in detecting HBV infection markers. The results showed that the total percent agreement of HBV markers was all >90 % in both detection systems among the six seroconversion panels and 743 serum samples from the population. The $\chi 2$ values of the Chi-square test among hepatitis B virus serological markers in both analyzers were between 550.7 and 743.0, $p < 0.0001$. HBV marker consistency test results show perfect consistency between the two analyzers, with Kappa values ranging from 0.854 to 1.000. For specific samples, including Hepatitis B patients with Genotype C, chronic hepatitis B, hepatitis B-related cirrhosis, and hepatocellular carcinoma, spearman correlation analysis showed HBsAg correlation coefficients ranging from 0.8532 to 0.9745, $p < 0.001$ in both analyzers. In conclusion, Autolumo A2000Plus diagnostic performance in consistency and correlation is comparable to Abbott Architect i2000 when detecting markers of hepatitis B infection. The Autolumo A2000Plus system can be used as a reliable instrument for HBV marker detection.

* Corresponding author. Center of Liver Diseases, Beijing Ditan Hospital, Capital Medical University. Or No. 8, Jingshun East Street, Chaoyang District, Beijing, 100015, China.

** Corresponding author. The First Affiliated Hospital of Xi'an Jiaotong University, Address: 277 West Yanta Road, Xi'an, Shaanxi, China.
E-mail addresses: Panc01@nyu.edu (C.Q. Pan), chenwei808@xjtu.edu.cn (W. Chen).

[1] **XZ, XS and JL share first authorship**.

https://doi.org/10.1016/j.heliyon.2024.e32698
Received 7 June 2023; Received in revised form 27 May 2024; Accepted 6 June 2024
Available online 8 June 2024

1. Introduction

Hepatitis B virus (HBV), with a high infection rate, could cause a lifelong chronic infection. Without treatment, individuals who were chronically infected with HBV had a high risk of liver fibrosis, cirrhosis, and hepatocellular carcinoma (HCC) [1]. Viral hepatitis is a major public health concern globally, and access to laboratory testing is one of the key control measures in their prevention [2]. It is estimated that 292 million persons worldwide have chronic infection with HBV and about one-third of these HBV-infected individuals reside in China [3,4]. The screening, diagnosis, and monitoring of treatment outcomes of chronic hepatitis B (CHB) infection require the measurement of serum HBV markers, including HBsAg, HBsAb, HBeAg, HBeAb and HBcAb [5–7]. The screening of these infections is based on serological testing in clinical laboratories, and high-throughput analyzers are typically used for this service [8]. Serological tests for viral hepatitis and HIV are not only used for the detection of suspected infection but also in the screening of blood products, antenatal screening, as well as in exposure incidents, such as sharps injuries [9], with the requirement of a very high standard of test performance. Thus, trustworthy diagnostic analyzers were essential for the safety of blood products and the management of patients with CHB.

Patients and healthcare professionals need to be able to trust medical devices that help them make reliable diagnoses, such as in vitro diagnostic medical devices [10]. Currently, several methods are available for the measurement of HBV serological markers either qualitatively or quantitatively, which include enzyme immunoassay (EIA), radioimmunoassay (RIA), and chemiluminescence (CLIA) [11]. To improve the efficiency of testing with short turnaround time and large sample volumes, the automated analyzer has been developed as an instrument designed to measure different chemicals and others in several biological samples with minimal human assistance. Among them, CLIA combined with an automatic immunoassay analyzer was a tool widely accepted in clinical practice because of the features of high sensitivity, wide linear range, prolonged luminous time, and stable results [12]. However, these analyzers are not manufactured the same, and comparisons have to be made to gain a better understanding of the difference in terms of performance and accuracy [8,13–16].

It is critical to provide comparison data for clinicians when they assess the patients' test results measured by different analyzers, particularly in patients who are transferred from other healthcare facilities using the analyzer differing from the one at the current institution. In 2022, China issued a regulation "Medical agency inspection and management method of mutual recognition of test results" [17]. For the mutual recognition of test results between different systems, emphasizing the correlation and consistency of test results were very important. With that in mind, we designed a study to compare the quantitative measurement of the aforementioned HBV serological markers between the two most commonly used and commercially available analyzers in China. Although the Abbott Diagnostic Architect i2000 (direct chemiluminescence test system) has been used for many years and the market shares have gradually been replaced by the Autobio Autolumo A2000 Plus (horseradish peroxidase-labelled system) in China, the comparison data between the two are lacking. We aimed to investigate the correlation of HBV marker quantitative measurements between the Abbott Diagnostic Architect i2000 analyzer and the Autobio Autolumo A2000 Plus analyzer. We also assessed the concordance rates between the two analyzers. Our findings were anticipated to provide important data and inform clinicians when interpreting reports on HBV serological makers generated from these analyzers.

2. Materials and methods

2.1. Participants, clinical diagnostic information and sample collection

This was a single-center and cross-sectional study that enrolled 743 individuals including participants with hepatitis B infection (n = 383) and healthy adults (n = 360) who had annual physical check-ups at the Fifth Hospital of Shijiazhuang in Hebei province, China. There is no gold standard in clinical diagnosis of CHB. The screening of patients with CHB and healthy persons is based on the clinical characteristics and laboratory tests by clinicians. Clinical diagnostic information and serum samples were collected between October 2018 and May 8, 2024. Sera were isolated by centrifugation at 4000 rpm for 10 min and cryopreserved at -80 °C until use. The demographic information of participants was presented in Table 1. The data presented in this paper are all obtained through immunological tests using different detection systems. Consecutive specimens were tested in parallel by the two aforementioned immunoassay systems.

The study protocol was approved by the Ethics Committee of the Fifth Hospital of Shijiazhuang (approval number: 2018-08-060). Appropriate informed consent was obtained from patients before participation in the study. The study was conducted according to the World Medical Association Declaration of Helsinki guidelines.

2.2. Instruments and reagents

AutoLumo A2000Plus analyzer (Autobio, Zhengzhou, China), and Abbott ARCHITECT i2000 analyzer (Abbott, Abbott Park, Illinois, USA). All measurements were performed following the standardized operating procedures provided by the manufacturer. All immunoassays were carried out in the central laboratory by experienced operators at the Fifth Hospital of Shijiazhuang in a blinded manner. Other instruments included an Automatic biochemical analyzer (TBA-FX8, Canon Medical Systems LTD, China) and an ABI 7500 real-time PCR system (Applied Biosystems, Inc. USA).

The current study assessed markers of hepatitis B infection in the serum quantitatively, which included HBsAg, HBsAb, HBeAg, HBeAb, and HBcAb. The detection systems were closed, and the original matching reagents (Autobio, Zhengzhou, China; and Abbott, Abbott Park, Illinois, USA) were used. Six commercially available HBV seroconversion panels PHM909, PHM910, PHM912, PHM921,

PHM934 and PHM941 (Boston Biomedica, Inc., Gaithersburg, USA). DNA of hepatitis B detection kit (DaAn Gene Co., Ltd, China). AST, ALT, TBIL, DBIL (Autobio, Zhengzhou, China). HA, LN, PCIIINP, CIV (Autobio, Zhengzhou, China). Hepatitis B Virus (HBV) genotyping detection kit (Xiamen Amply Bioteh. CO., LTD., China).

2.3. Cut-off values and interpretations between A2000Plus and i2000

For HBsAg and Anti-HBs measurements, we used the same test principle (Sandwich CMIA, quantitative determination) for both analyzers A2000Plus and i2000 to generate quantitative concentrations. For HBeAg, Anti-HBe, and Anti-HBc detection, we used A2000Plus to generate the quantitative concentration and used i2000 to produce the qualitative results. The test principle, cut-off values, and interpretations of HBV serological markers measured by the aforementioned two analyzers are shown in Supplementary Table S1.

2.4. Laboratory testing among participants with hepatitis B virus infection

An automatic biochemical analyzer (TBA-FX8, Canon Medical Systems LTD, China) was used to detect and compare the differences in markers of liver function (AST, ALT, TBIL and DBIL). and liver fibrosis (HA, LN, PCIIINP and CIV) in 383 patients with hepatitis B infection, including chronic hepatitis B, hepatitis B-related cirrhosis, and hepatocellular carcinoma. All measurements were performed following the standardized operating procedures provided by the manufacturer. All testing was carried out in the central laboratory by experienced operators at the Fifth Hospital of Shijiazhuang in a blinded manner.

2.5. Genotyping of hepatitis B virus

According to the principle of in vitro gene amplification, the specificity of HBV genotypes (B, C and D) in 383 patients with hepatitis B virus infection (Chronic hepatitis B, Hepatitis B cirrhosis, Hepatocellular carcinoma) was qualitatively analyzed by using real-time fluorescence resonance energy transfer tracking fluorescence quantitative detection method. Amplification and extraction reagents were prepared according to the instructions (Xiamen Amply Bioteh. CO., LTD., China). The total system was 50 μl and the cycling conditions were 38 °C for 5 min and 95 °C for 2 min. The following cycle was entered: 95 °C for 15 s, 58 °C for 50 s (fluorescence was read after 30 s), and 40 cycles. If the Ct value of the sample was within the range of $35.0 \leq Ct < 40.0$, the sample was retested. If the sample $Ct < 40.0$, it was judged as positive and reported as positive. If the Ct value of the retest sample was 0.0, it was judged as negative and reported as negative.

2.6. Detection of hepatitis B seroconversion panel between A2000Plus and i2000

Hepatitis B seroconversion panel (Boston Biomedica, Inc., USA), is a group of serial bleeds from an individual plasma donor during seroconversion for markers of Hepatitis B. This panel is intended for use by our laboratory in evaluating their HBV marker assays with well-characterized specimens, to evaluate and compare the consistency and compliance of the two systems in HBsAg detection, and to provide comprehensive data for comparative analysis. Six commercially available seroconversion panels (PHM909, PHM910, PHM912, PHM921, PHM934 and PHM941) were used in this study. PHM909 is a 7-member seroconversion panel, and collected over 22 days in 1991 from a single donor. PHM910 is 6-member seroconversion panel and collected over 50 days from a single donor in 1990. PHM912 is 9-member seroconversion panel and collected over 48 days from a single donor in 1990. PHM921 is 6-member seroconversion panel and collected over 20 days from a single donor in 1990. PHM934 is 6-member seroconversion panel and collected over 85 days in 1998 from a 58 years old male. PHM941 is a 9-member seroconversion panel and collected over 142 days in 2008 from a 43 years old female and characterized as genotype A. These seroconversion panels have tested negative by U.S. FDA-licensed tests for anti-HIV, anti-HTLV, and anti-HCV. As shown in Fig. S2.

2.7. Inter-instrument coherence and correlation assessment between A2000Plus and i2000

We tested 743 serum samples with two automatic immunoassay analyzers. The positive rates of each HBV marker were detected between the two analyzers, and positive percent agreement (PPA), negative percent agreement (NPA) and total percent agreement (TPA) were calculated. The coherence and correlation between the two instruments were evaluated according to the Chi-square test and Kappa consistency test. We also carried out the Spearman correlation analysis to evaluate correlations of quantitative results for HBsAg and anti-HBs between A2000Plus and i2000.

2.8. Statistical analysis

Statistical analyses were performed by using GraphPad Prism (version 9.0.0, La Jolla, California, USA). The coherence and correlation between the two instruments were evaluated by the Chi-square test and Kappa consistency test. Spearman correlation analysis was used to evaluate the relationship between the quantitative results of HBsAg and Anti-HBs generated from A2000Plus and i2000. Data were calculated with SPSS Base 25.0 (SPSS INC., Chicago, IL). $p < 0.05$ was considered statistically significant.

3. Results

3.1. Clinical diagnostic information

To compare the diagnostic performance of Autolumo A2000Plus and Abbott Architect i2000 systems in the detection of markers of hepatitis B infection. In this study, we recruited 383 patients with hepatitis B infection, including chronic hepatitis B (n = 188), hepatitis B-related cirrhosis (n = 144), and hepatocellular carcinoma (n = 51). The median age of the individuals in this hepatitis B infection cohort was 51.0 (IQR: 40.0–59.0) years old, and there were 253 males and 130 females. Laboratory test results showed that HBV DNA detection was positive in all participants, and the median of specific value was 3E+06 (IQR: 2E+05-5E+07). The demographic information of participants is presented in Table 1.

3.2. Laboratory-testing markers of liver function and liver fibrosis for hepatitis B infection

The results of liver function and liver fibrosis were measured among 383 participants with hepatitis B infection, including chronic hepatitis B (n = 188), hepatitis B-related cirrhosis (n = 144), and hepatocellular carcinoma (n = 51). As shown in Supplementary Table S2, the median of liver function items was 78.1U/L (ALT), 77.5U/L (AST), 23.4 μmol/L (TBIL) and 9.1 μmol/L (DBIL), and the median of liver fibrosis items were 25.9 ng/mL (HA), 124.4 ng/mL (LN), 250.2 ng/mL (PCIIINP), and 170.3 ng/mL (CIV), respectively. We found that the secretion of ALT was significantly lower compared to the chronic hepatitis B cohort with 1.5-, and 1.8-fold reductions in median, respectively. TBIL and DBIL were significantly higher compared to chronic hepatitis B cohort ranging from 1.9-fold to 2.5-fold. Meanwhile, the secretion of LN, HA, and CIV among patients with hepatitis B-related cirrhosis and hepatocellular carcinoma was significantly higher compared to chronic hepatitis B cohort with range from 1.2-fold to 5.4-fold increase. As shown in Fig. S1 and Supplementary Table S2.

3.3. Genotyping of hepatitis B virus for specific samples

Genotyping of hepatitis B virus among 383 patients with hepatitis B infection was qualitatively analyzed by using real-time fluorescence resonance energy transfer tracking (RERI). The results showed that genotype C accounted for 86.4 %, genotype B was 4.2 %, mixed B and C accounted for 3.1 %, and other types accounted for 6.3 %. The proportion of C in patients with hepatocellular carcinoma (98 %) was higher than that of chronic hepatitis B cohort (83 %) and hepatitis B-related cirrhosis (86.8 %). Genotyping of hepatitis B results of participants with viral hepatitis B infection were shown in Fig. 1 and Supplementary Table S2.

3.4. Evaluation of HBsAg sensitivity in commercially available seroconversion panels between the A2000Plus and i2000 analyzers

This panel is intended for use by our laboratory in evaluating their HBV marker assays with well-characterized specimens, to evaluate and compare the consistency and compliance of the two systems in HBsAg detection, and to provide comprehensive data for comparative analysis. To determine the sensitivity of each analyzer, 6 seroconversion panels containing 43 samples of HBsAg were tested in the A2000Plus analyzer and the i2000 analyzer in parallel. These panels convert from negative to positive for hepatitis B surface antigen (HBsAg), and all panel members are positive for HBV DNA. There were 3 blood samples from the PHM909, 2 blood samples from PHM912, 6 blood samples from the PHM921, 6 blood samples from the PHM934 panel and 7 blood samples from PHM941 tested positive by both A2000Plus and i2000 analyzers. In addition, blood samples from PHM910 tested positive by the

Table 1
The demographic information of participants with viral hepatitis B infection.

Characteristics	Total (n = 383)	Chronic hepatitis B (CHB)	Hepatitis B cirrhosis	Hepatocellular carcinoma (HCC)
No. of participants	383	188 (49.1 %)	144 (37.6 %)	51 (13.3 %)
Gender (n, %)				
Male	253 (66.1 %)	124 (66.0 %)	93 (64.6 %)	36 (70.6 %)
Female	130 (33.9 %)	64 (34.0 %)	51 (35.4 %)	15 (29.4 %)
Age (median, IQR)	51.0 (40.0, 59.0)	44.00 (35.0, 54.8)	54.00 (44.0, 61.0)	58.00 (53.0, 66.0)
Age (n, %)				
≤18	3 (0.8 %)	3 (1.6 %)	NA	NA
19–29	14 (3.7 %)	13 (6.9 %)	1 (0.7 %)	NA
30–39	76 (19.8 %)	58 (30.9 %)	16 (11.1 %)	2 (3.9 %)
40–49	74 (19.3 %)	37 (19.7 %)	32 (22.2 %)	5 (9.8 %)
50–59	123 (32.1 %)	50 (26.6 %)	52 (36.1 %)	21 (41.2 %)
60–69	59 (15.4 %)	17 (9.0 %)	26 (18.1 %)	16 (31.4 %)
≥70	34 (8.9 %)	10 (5.3 %)	17 (11.8 %)	7 (13.7 %)
HBV DNA				
Positive (n, %)	383 (100.0 %)	188 (100.0 %)	144 (100.0 %)	51 (100.0 %)
Specific value (median, IQR)	3E+06 (2E+05, 5E+07)	3E+06 (2E+05, 1E+08)	2E+06 (1E+05, 2E+07)	3E+06 (2E+05, 2E+07)
Anti-HCV				
Positive (n, %)	2 (0.5 %)	NA	1 (0.7 %)	1 (2.0 %)

IQR, interquartile range.

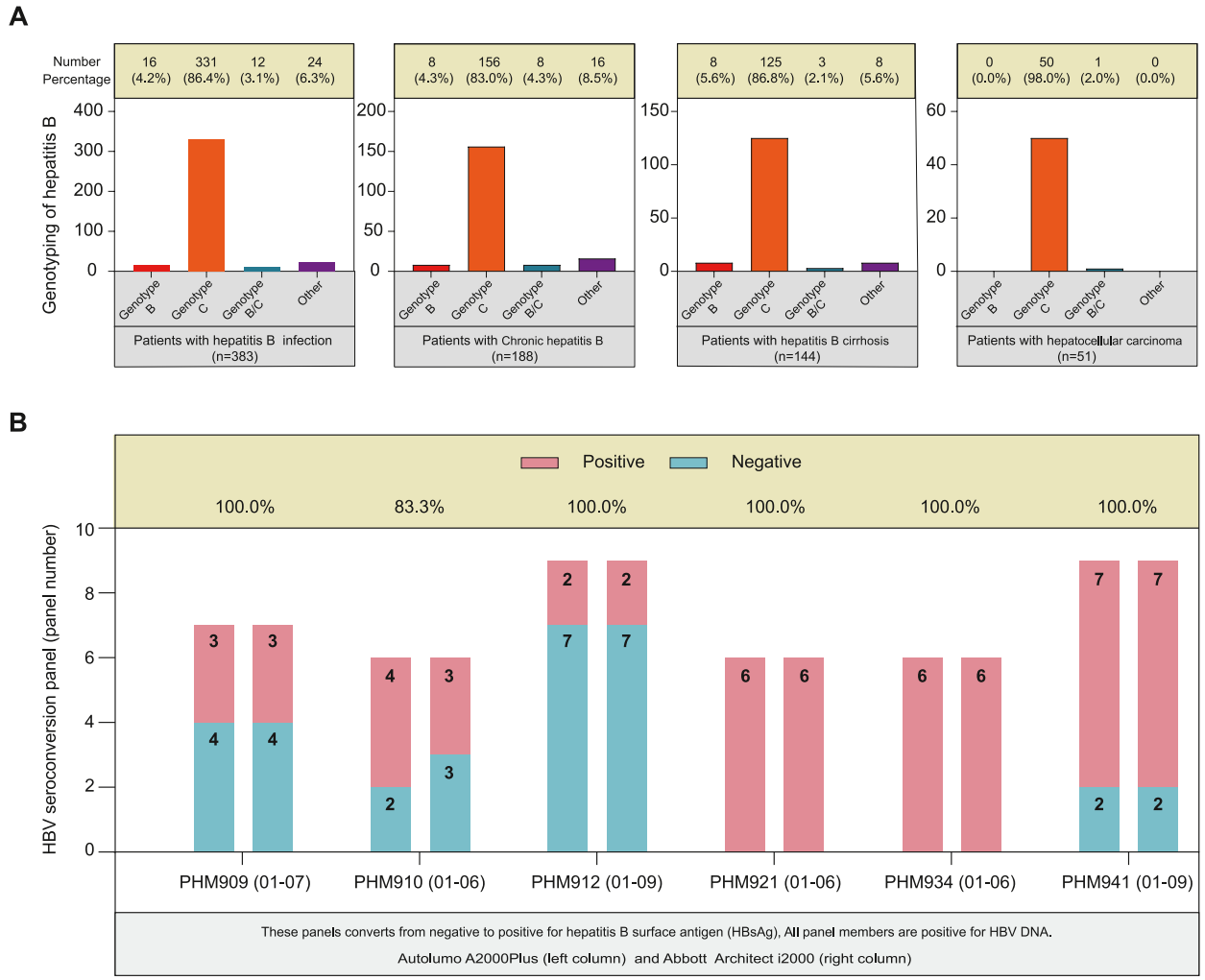


Fig. 1. Genotyping of hepatitis B virus and detection of HBV seroconversion panels in A2000Plus and the i2000 analyzer.
(A) Distribution of hepatitis B virus genotypes. Genotyping of hepatitis B virus among 383 patients with hepatitis B infection were qualitatively analyzed by using real-time fluorescence resonance energy transfer tracking. **(B)** Evaluation of HBsAg sensitivity in commercially available seroconversion panels between the A2000Plus and i2000 analyzers. 6 seroconversion panels containing 43 samples of HBsAg were tested in the A2000Plus analyzer and the i2000 analyzer in parallel, and to evaluate and compare the consistency and compliance of the two systems in HBsAg detection.

A2000Plus and i2000 analyzers were 4 and 3, respectively. The HBsAg of total percent agreement (TPA) was 97.7 % between the A2000Plus and i2000 analyzers systems. The $\chi 2$ value and Z value of Chi-square test among HBsAg between the A2000Plus and i2000 analyzers was 38.87 and 6.235, $P < 0.0001$. According to Kappa consistency test showed that the Kappa value was 0.95, $p < 0.001$, the coherence between the two analyzers was almost perfect in the detection of seroconversion panels. As shown in Fig. 1, Fig. S2, and Supplementary Table S3.

3.5. The coherence and correlation assessment of HBV makers in crowd serum samples between the A2000Plus and i2000 analyzers

Hepatitis B virus serological markers were detected among 743 serum samples including chronic hepatitis B (n = 188), hepatitis B-related cirrhosis (n = 144), hepatocellular carcinoma (n = 51), and healthy adults (n = 360), between the A2000Plus and i2000 analyzers. We observed high agreement between the two analyzers on measuring HBV markers. The HBsAg of positive percent agreement (PPA), negative percent agreement (NPA), and total percent agreement (TPA) were all 100.0 % between the A2000Plus and i2000 analyzers systems. The true positive rate of HBV markers ranged from 91.4 % to 100 %, true negative rate was 93.6 %–100 %, and total agreements ranged from 94.6 % to 100 %. We conducted the Chi-square test and Kappa consistency test among the results of hepatitis B virus serological markers between the A2000Plus and i2000 analyzers. The $\chi 2$ values of the Chi-square test among hepatitis B virus serological markers between the A2000Plus and i2000 analyzers ranged from 550.7 to 743.0, $P < 0.0001$. According to Kappa values of Kappa consistency test among HBV markers, ranged from 0.854 to 1.000, the coherence between the two analyzers was

almost perfect, and $P < 0.0001$. As shown in Table 2.

We also performed a Spearman correlation analysis of quantitative results for HBsAg and anti-HBs in specific samples between the A2000Plus and i2000 analyzers. Spearman correlation analysis showed that the results of the two systems were positively correlated. Specific samples (n = 331) from patients with hepatitis B infection (Genotype C), spearman correlation analysis of quantitative results for HBsAg showed that the correlation coefficient was r = 0.9251, $p < 0.001$ (Fig. 2A). Participants including hepatitis B infection (n = 383) and healthy adults (n = 360), spearman correlation analysis of quantitative results for anti-HBs showed that the correlation coefficient was r = 0.8532, p < 0.001, both the two systems (Fig. 2B). Specific samples from patients with chronic hepatitis B (n = 188), hepatitis B-related cirrhosis (n = 144), hepatocellular carcinoma (n = 51), spearman correlation analysis showed that the correlation coefficients of HBsAg were 0.9195, 0.9745 and 0.8972 ($p < 0.001$), between the A2000Plus and i2000 analyzers, respectively. (Fig. 2D, E and 2F).

4. Discussion

For decades, laboratory technicians worldwide have been dedicated to achieving consistency, comparability, and mutual recognition of test results [18–22]. In China, the earliest official document proposing the concept of mutual recognition of test results can dates back to 2006 [23]. In 2021, the Medical Administration Bureau of the National Health Commission issued the “Administrative Measures for Mutual Recognition of Inspection and Inspection Results of Medical Institutions (Draft)", which provided detailed methods for mutual recognition of results. In 2022, the National Health Commission, the National Health Security Administration, the National Administration of Traditional Chinese Medicine, and the Health Bureau of the Logistic Support Department of the Central Military Commission jointly issued the “Administrative Measures for Mutual Recognition of Inspection Results of Medical Institutions” [17]. Mutual recognition of results has received increasing attention, from the earliest and simplest purpose of reducing the burden on patients to the present purpose of efficient use of resources and saving money. Our study aims to compare the diagnostic performance of Autolumo A2000Plus and Abbott Architect i2000 systems in the detection of markers of hepatitis B infection and achieve mutual recognition of results between different detection systems.

Clinical laboratories perform over 7 billion tests per year, the results of which influence clinical decisions, so the results of these tests must be as accurate as possible [24]. As chronic hepatitis B infection has a high prevalence in China with approximately 90 million patients, challenges remain in the areas of screening and linkage to care [25]. In this study, we recruited 360 healthy adults and 383 patients with hepatitis B infection, including chronic hepatitis B (n = 188), hepatitis B-related cirrhosis (n = 144), and hepatocellular carcinoma (n = 51). We compared the results of HBsAg, anti-HBs, HBeAg, anti-HBe, and anti-HBc between Autobio A2000Plus and Architect i2000 as both are commercially available in China and found that the Abbott i2000 analyzer and Autobio A2000Plus analyzer were comparable although the latter one was developed locally in China.

Screening for viral hepatitis is very important, including liver function markers and hepatitis virus markers, which have been included in the mutual recognition of clinical laboratory results in China. It is worth noting that anti-HBV test samples were collected from healthy individuals who had been vaccinated with HBV vaccine and anti-HBc IgG test samples were collected from patients infected with HBV [26]. A previous study conducted by D. Huzly et al., in 2008 assessed anti-HBs results on nine different analyzers, they found the results obtained for each analyzer were not interchangeable [27]. Anti-HBc was an essential epidemic parameter of HBV infection and positive rates were typically seen among the population at high risk of HBV [28,29]. Furthermore, baseline anti-HBc titers act as a useful predictor of Peg-IFN and NUC therapy efficacy in HBeAg-positive CHB patients [30]. Immunoassays are bioanalytical methods to measure the concentration of an analyte through the reaction of an antigen and an antibody [31]. Among these methods, the chemiluminescence detection method is a versatile and ultrasensitive tool that can simultaneously detect a broad range of molecules in clinical diagnosis and has been widely used with complete automation and the development of technology and related materials [32–35]. Moreover, equipment using the chemiluminescence detection method and related materials differs from laboratory to laboratory, and most laboratories issue test reports after only one test, so it is very important to compare Autobio Autolumo A2000 Plus and Abbott Architect i2000 for measuring serologic markers of hepatitis B virus.

Table 2
Concordance rate of hepatitis B markers between AutoLumo A2000 Plus and Abbott i2000.

	A2000 Plus	Abbott i2000		PPA (%)	NPA (%)	TPA (%)	Chi-square test			Kappa consistency test	
		+	–				$\chi 2$	*Z*	*P*-value	Kappa (95%CI)	*P*-value
HBsAg	+	383	0	100.0 %	100.0 %	100.0 %	743.0	27.3	<0.001	1.000 (1.000, 1.000)	<0.001
	-	0	360								
Anti-HBs	+	210	4	99.1 %	99.2 %	99.2 %	714.0	26.7	<0.001	0.980 (0.964, 0.996)	<0.001
	-	2	527								
HBeAg	+	224	5	91.4 %	99.0 %	96.5 %	629.7	25.1	<0.001	0.919 (0.890, 0.948)	<0.001
	-	21	493								
Anti-HBe	+	161	37	98.2 %	93.6 %	94.6 %	550.7	23.5	<0.001	0.854 (0.811, 0.897)	<0.001
	-	3	542								
Anti-HBc	+	382	1	100.0 %	99.7 %	99.9 %	739.0	27.2	<0.001	0.997 (0.991, 1.003)	<0.001
	-	0	360								

PPA, positive percent agreement; NPA, negative percent agreement; TPA, total percent agreement; CI, confidence interval.

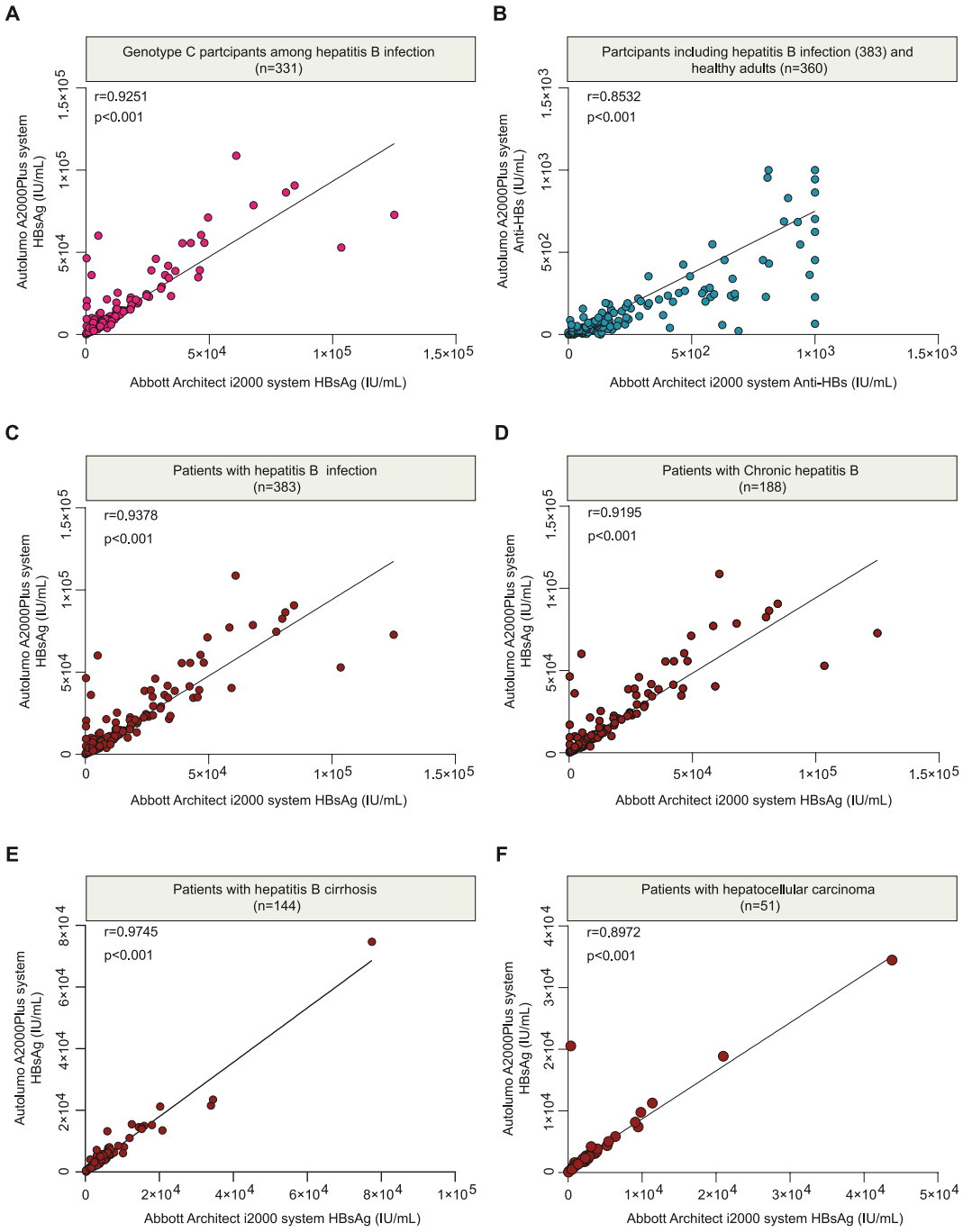


Fig. 2. Spearman correlation analysis of quantitative results for HBsAg and anti-HBs between the A2000Plus and i2000 analyzer.
(A) Specific samples (n = 331) from patients among hepatitis B infection (Genotype C), spearman correlation analysis of quantitative results for HBsAg. **(B)** 743 serum samples from 383 hepatitis B infection and 360 healthy adults, spearman correlation analysis of quantitative results for anti-HBs. **(C)** 383 serum samples from hepatitis B infection, spearman correlation analysis of quantitative results for HBsAg. **(D)** Specific samples (n = 188) from patients among Chronic hepatitis B, spearman correlation analysis of quantitative results for HBsAg. **(E)** Specific samples (n = 144) from patients among Hepatitis B cirrhosis, spearman correlation analysis of quantitative results for HBsAg. **(F)** Specific samples (n = 51) from patients among Hepatocellular carcinoma, spearman correlation analysis of quantitative results for HBsAg.
Spearman correlation analysis was performed by using GraphPad Prism (version 9.0.0, La Jolla, California, USA). i2000 analyzer (x-axis) and A2000Plus system (y-axis) were showed in graph.

Therefore, we conducted an evaluation experiment of HBsAg sensitivity between the A2000Plus and i2000 analyzers. Six seroconversion panels containing 43 HBsAg samples were tested. Commercially available seroconversion panels PHM909, PHM910, PHM912, PHM921, PHM934 and PHM941 as the standard serum panels, and they can objectively reflect the analytical performance of both instruments. This panel is intended for use by our laboratory in evaluating their HBV marker assays with well-characterized specimens, to evaluate and compare the consistency and compliance of the two systems in HBsAg detection, and to provide comprehensive data for comparative analysis. Our study showed that total percent agreement of HBsAg was 97.7 % between A2000Plus and i2000 analyzer systems. The $\chi 2$ value and Z value of Chi-square test among HBsAg between the A2000Plus and i2000 analyzers was 38.87 and 6.235, $P < 0.0001$. According to Kappa consistency test showed that the Kappa value was 0.95, $p < 0.001$, the coherence between the two analyzers was almost perfect in the detection of seroconversion panels.

Different detection systems have good consistency and correlation, which is a prerequisite for mutual recognition of results in different medical institutions. We evaluated HBV coherence and correlation between A2000Plus and i2000 analyzers The positive rates of each HBV marker detected were similar between the two analyzers. We tested 743 serum samples including 383 participants with hepatitis B infection and 360 healthy adults between A2000Plus and i2000 analyzers. We performed Chi-square test and Kappa consistency test among hepatitis B virus serological markers between the two analyzers. The $\chi 2$ values of Chi-square test among hepatitis B virus serological markers between the A2000Plus and i2000 analyzers ranged from 550.7 to 743.0, $P < 0.0001$. According to Kappa values of Kappa consistency test among HBV markers, ranging from 0.854 to 1.000, the coherence between the two analyzers was almost perfect. We observed high agreement between the two analyzers on the measurement of HBV markers. Total agreements ranged from 94.6 % (anti-HBe) to 100.0 % (HBsAg). Comparison results suggested a similar and high agreement of HBV markers measured by the two analyzers**.** We also performed a Spearman correlation analysis of quantitative results for HBsAg and anti-HBs in specific samples between the A2000Plus and i2000 analyzers. Specific samples, including Hepatitis B patients with Genotype C, chronic hepatitis B, hepatitis B-related cirrhosis, and hepatocellular carcinoma, spearman correlation analysis showed that HBsAg correlation coefficients ranged from 0.8532 to 0.9745, $p < 0.001$ between A2000Plus and i2000 analysers. The coherence and correlation between the two analyzers were almost perfect in the detection of specific samples.

My study also has certain limitations. Firstly, this was a single-center study, and the sample was regionally specific. Secondly, 86.4 % of the participants with hepatitis B were genotype C, and the sample size was lower for other genotypes. Thirdly, although a specific sample such as chronic hepatitis B (n = 188), hepatitis B-related cirrhosis (n = 144), hepatocellular carcinoma (n = 51), and genotype C (n = 331) were added to this study, there was still a shortage of sample size. In this study, the differences between the two analyzers may be partly explained by these facts. Antigens were produced in different ways, and equipment using the chemiluminescence detection method and related materials differs from laboratory to laboratory [35–37]. Compared to the natural antigen source in reagents from the A2000Plus analyzer, the antigen used in the reagent coupled with the Abbott i2000 analyzer was constructed by expression of the recombinant vector in vitro. Distinctiveness in the individual immune response and interference by endogenous proteins or other substances in the individual samples might be other explanations.

In conclusion, this study demonstrates that Autolumo A2000Plus system diagnostic performance in consistency and correlation is comparable to Abbott Architect i2000 when detecting markers of hepatitis B infection. The Autolumo A2000Plus system can be used as a reliable instrument for HBV marker detection.

Funding

None.

Ethics declarations

This study was reviewed and approved by the Ethics Committee of the Fifth Hospital of Shijiazhuang, with the approval number: 2018-08-060.

Data availability statement

Data has not been shared in a publicly available repository and will be made available upon request. Data is available on request to the corresponding author (Wei Chen, M.D., E-mail: chenwei808@xjtu.edu.cn.)

CRediT authorship contribution statement

Xue-Dong Zhang: Writing – original draft, Investigation, Formal analysis, Data curation. **Xue-Dong Song:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Data curation. **Jian-Hua Lu:** Methodology, Investigation, Funding acquisition, Formal analysis, Data curation. **Yan Dai:** Methodology, Investigation, Formal analysis, Data curation. **Bin Li:** Resources, Methodology, Investigation, Data curation. **Ping Zhu:** Resources, Investigation, Formal analysis, Data curation. **Er-Hei Dai:** Visualization, Validation, Supervision, Project administration, Conceptualization. **Calvin Q. Pan:** Visualization, Validation, Supervision, Project administration, Funding acquisition, Conceptualization. **Wei Chen:** Visualization, Validation, Supervision, Resources, Project administration, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We thank all participants for providing blood samples.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e32698.

Abbreviations

CHB	chronic hepatitis B infection
CLIA	chemiluminescence
EIA	enzyme immunoassay
HBcAb	Hepatitis B core antibody
HBeAb	Hepatitis B e antibody
HBeAg	Hepatitis B e antigen
HBsAb	Hepatitis B s antibody
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
RIA	radioimmunoassay
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
TBIL	Total bilirubin
DBIL	Direct Bilirubin
LN	Laminin
HA	Hyaluronidase
PCIIINP	NP-terminal peptide of type III procollagen
CIV	Collagen type IV

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