Clinical performance of a new hepatitis B surface antigen quantitative assay with automatic dilution

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KEYWORDS
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Abstract Hepatitis B virus surface antigen (HBsAg) levels reflect disease status and can predict the clinical response to antiviral treatment; however, the emergence of HBsAg mutant strains has become a challenge. The Abbott HBsAg quantification assay provides enhanced detection of HBsAg and HBsAg mutants. We aimed to evaluate the performance of the Abbott HBsAg quantification assay with automatic sample dilutions (shortened as automatic Architect assay), compared with the Abbott HBsAg quantification assay with manual sample dilutions (shortened as manual Architect assay) and the Roche HBsAg quantification assay with automatic sample dilutions (shortened as Elecsys). A total of 130 sera samples obtained from 87 hepatitis B virus (HBV)-infected patients were collected to assess the correlation between the automatic and manual Architect assays. Among the 87 patients, 41 provided 42 sera
Introduction

Despite the availability of an efficient vaccine, hepatitis B virus (HBV) infection remains a serious health problem worldwide [1,2]. After decades of HBV infection, liver cirrhosis develops in 30–40% of infected people, and hepatoma develops in 1–5% of cirrhotic patients [3,4]. Several factors related to the disease progression of HBV infection have been identified, including age at infection, host immune status, and the level of HBV replication [5].

With regard to HBV replication, the HBV DNA level and hepatitis B virus surface antigen (HBsAg) level were found to be potent indicators, which promoted monitoring and evaluation of diseases [6–9]. Among the hepatitis B e antigen (HBeAg)-negative patients, a high HBsAg level, but not a high HBV DNA level, was shown to be the only viral risk factor associated with hepatocellular carcinoma [10–13]. The HBsAg level reflects the clinical stage of liver disease [12,14], and a cirrhotic patient with high HBsAg levels is at a higher risk of disease progression [8]. For patients undergoing therapy, a rapid decrease in HBsAg concentration during interferon therapy is associated with a higher chance of sustained virological response [15].

Several standardized commercial assays for hepatitis B surface antigen quantification are currently available. Abbott Architect HBsAg, a widely used assay introduced by Abbott Diagnostics (Lake Forest, IL, USA), is used for enhanced detection of HBsAg and HBsAg mutants compared with previous assays [16,17]. The Roche Elecsys HBsAg reagent kit (shortened as Elecsys) is another widely used commercial reagent kit developed by Roche Diagnostics (Basel, Switzerland), which has long provided HBsAg assay reliability compared with the Abbott Architect HBsAg assay.

In this study, the Abbott Architect HBsAg reagent kit was evaluated using an automatic dilution assay platform, Abbott Architect HBsAg i1000 (shortened as the automatic Architect assay). By contrast, the manual Architect assay refers to the Abbott Architect HBsAg reagent kit with a manual dilution assay platform, Abbott Architect HBsAg i2000. These new reagent kits demonstrate the enhanced power of the assay to detect HBsAg and HBsAg mutants, thereby providing enhanced specificity for the detection, diagnosis, and management of HBV infection [16]. Nevertheless, the manual dilution assay was reported to be inferior to the automatic dilution assay in terms of reproducibility.

This study aimed to further investigate the performance of the automatic and manual Architect assays in terms of their reproducibility and linearity, as well as their relative performance in patient subgroups. We also evaluated their performance and compared these results with those of the Roche Elecsys reagent kit. Our analyses enabled the determination of the power and accuracy of the Abbott Architect HBsAg and Roche Elecsys HBsAg quantitative assays. Investigation of the kinetics of the HBsAg level shows that these quantitative assays will help predict the viral activities, evaluate the response to antiviral therapy, estimate the prognosis, and ultimately reveal the clinical significance of HBsAg.

Materials and methods

Patients and sera

Initially, we collected 133 sera samples from 90 HBV-infected patients at different time points during their regular follow-up evaluations. The patients showed positive serum HBV DNA, and the serum HBsAg had been persistently positive for at least 6 months. In total, 130 samples were collected from 87 HBV-infected patients for the study, among which 42 sera samples were assayed using the Abbott and Roche reagent kits (automatic and manual Architect assays, plus Elecsys) and were designated as the Abbott & Roche group, and 88 sera samples were assayed using the automatic and manual Abbott Architect assays and were designated as the Abbott automatic and manual groups, respectively (Figure S1).
In the study, all patients were treated or evaluated at Chung-Ho Memorial Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan. Patients with human immunodeficiency virus, autoimmune hepatitis, alcohol abuse (≥ 40 g ethanol consumed per day), or evidence of cirrhosis or hepatocellular carcinoma were excluded.

Sera were removed from clots within 4 hours of collection and stored at −70°C until further use. Alanine aminotransferase (ALT) levels were measured using a standard autoanalyzer.

After informed consent was obtained, sera were collected from the patients or their guardians. The study was performed according to the ethical guidelines of the 1975 Declaration of Helsinki. The Institutional Review Board of Chung-Ho Memorial Hospital, Kaohsiung Medical University, approved the study prior to its start.

HBsAg quantification assays

Three methods were used to quantify the HBsAg levels. Two methods included the automatic and manual Architect assays, which used the Abbott Architect HBsAg i1000 and i2000 assay platforms (Abbott Diagnostics), respectively. The automatic and manual Architect assays functioned on the basis of the detection of chemiluminescent microparticles. Both the Abbott Architect HBsAg i1000 and i2000 assay platforms provided an onboard dilution function, which automatically prediluted the samples after they were loaded. The automatic Architect assay was used for automatic dilution using the i1000 analyzer, and the manual Architect assay was performed using the i2000 assay. The detection range recommended by the manufacturer was from 0 IU/mL to 250 IU/mL. If the sera samples were of HBsAg titers greater than 250 IU/mL dilution, then either the automatic or the manual assay was performed. Both the assaying times were 30 minutes, and an additional 30 minutes were required for the manual dilution. The time for automatic dilution was ignored.

In addition, another method used the Roche Elecsys HBsAg reagent kit with the Cobas e 411 analyzer (Roche Diagnostics), which was designated as the reference assay. The Elecsys assay was an electrochemiluminescence microparticle assay, which measured the concentration of the antibody—antigen complexes in a similar manner to the Architect assays. The Roche Cobas e 411 assay platform also provided an automatic dilution function. The duration of the assay was 18 minutes. The analytic measurement range proposed by the manufacturer was between 5 IU/mL and 13,000 IU/mL, in which the samples were diluted 100-fold using the automated dilution function.

Linearity of dynamic range

Three selected sera specimens with an HBsAg level > 10^8 IU/mL, as confirmed using the three HBsAg quantitative assays, underwent serial 1:10 dilution. Each dilution was prepared using 0.1 mL of the previous dilution and 0.9 mL of a standard lacquer thinner. All the dilutions were tested using the automatic Architect assay to evaluate the linearity of the dynamic range, which was assessed by calculating the R^2 value.

Reproducibility

An additional nine specimens from the 130 sera samples, containing low (< 500 IU/mL), medium (500–10,000 IU/mL), or high (> 10,000 IU/mL) levels of HBsAg, were measured using the automatic Architect assay. Each specimen was repeatedly tested once per day, for 3 consecutive days. Next, a coefficient of variation was derived for each specimen. The reproducibility was assessed on the basis of the coefficients of variation of the nine samples.

Quantification of HBV DNA

We used the Roche COBAS TaqMan HBV analyzer (Roche Diagnostics, Indianapolis, IN, USA); a nucleic acid amplification test, which correlates well with Abbott RealTime HBV (RealTime assay) [18], using the automated real-time polymerase chain reaction assay for the quantification of HBV DNA, for all 130 samples. The primer used for the quantification of HBV DNA was a fragment of the S gene of HBV DNA. The detection limit for quantification ranged from 20 IU/mL to 1.7 × 10^8 IU/mL.

Dilution of sera samples

Dilution, automatic or manual, was performed if, in the sera samples tested, the HBsAg titers were > 250 IU/mL. The automatic and manual Architect assays reported, respectively, 37 (80.4%) and 31 (67.4%) sera samples with HBsAg > 250 IU/mL in the Abbott auto group and manual group, and 21 (51.2%) and 30 (73.1%) samples with HBsAg > 250 IU/mL in the Abbott & Roche group. Among all the 130 samples, the rate of dilution was similar for the automatic and manual Architect assays (44.6% vs. 46.9%). For both the automatic and the manual Architect assay, the rate of dilution was higher in the HBeAg-positive group (65.7% and 62.9% vs. 35.8% and 38.2% in the HBeAg-negative group, for the automatic and manual assays, respectively). A significantly higher rate of dilution was also found in the high HBV DNA groups (80.9% and 74.5% vs. 22.9% and 30.1% in the HBeAg-negative group, for the automatic and manual assays, respectively).

Statistical analysis

For the purpose of data analyses using suitable statistical methods, an HBV DNA titer below the lower detection limit of 108 IU/mL was deemed as 54 IU/mL. The clinical data were expressed as the mean ± standard deviation after logarithmic (log10) transformation of the original values. Pearson’s correlation coefficient (R) was used to analyze the correlations between the results of the automatic Architect, manual Architect, and Elecsys assays. Simple linear regression (R^2) was used to examine the linearity of the measurements of the automatic Architect assay, in which three selected sera samples underwent a serial 1:10 dilution from 10^−1 to 10,000×. The coefficient of variation was applied to test the reproducibility of the automatic Architect assay. Data processing and analyses were performed using the SPSS version 18.0 (SPSS Inc., Chicago, IL, USA).
Results

Basic demographic data

Among the 87 HBV-infected patients (Table 1), the average age was 42.7 years (range 23–67 years), and males were predominant. Among the 130 sera samples, alanine aminotransferase (ALT) levels were tested in 124 samples, and 66 samples were within the normal range (40 IU/L). Furthermore, of the 116 sera samples tested, 30.2% were HBeAg positive. The HBV DNA titer was determined in all the 130 sera samples, with 29 sera samples exhibiting a DNA level greater than the upper limit (1.7 × 10^5 IU/mL) and 56 showing a DNA level lower than the detection limit. The cutoff value of the HBV DNA titer was determined; the high DNA group consisted of a sera sample DNA titer of > 5000 IU/mL. In addition, the low DNA group, which consisted of 83 sera samples, had a DNA titer ≤ 5000 IU/mL.

Table 1  Baseline characteristics of 87 chronic hepatitis B patients with HBsAg levels as assayed using the Abbott and Roche assays.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Abbott all</th>
<th>Abbott and Roche</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>All patients</td>
<td>87 (41)</td>
<td></td>
</tr>
<tr>
<td>All samples</td>
<td>130</td>
<td>42</td>
</tr>
<tr>
<td>Age (y)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;40</td>
<td>37 (42.5)</td>
<td>15 (36.6)</td>
</tr>
<tr>
<td>40–60</td>
<td>45 (51.7)</td>
<td>23 (56.1)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>5 (5.8)</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>62 (71.3)</td>
<td>32 (78)</td>
</tr>
<tr>
<td>Female</td>
<td>25 (28.7)</td>
<td>9 (22)</td>
</tr>
<tr>
<td>ALT^a (IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤40</td>
<td>66 (53.2)</td>
<td>36 (85.7)</td>
</tr>
<tr>
<td>&gt;40</td>
<td>58 (46.8)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>HBeAg^b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>35 (30.2)</td>
<td>2 (6.1)</td>
</tr>
<tr>
<td>Negative</td>
<td>81 (69.8)</td>
<td>31 (93.9)</td>
</tr>
<tr>
<td>HBV DNA^c</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above detection limit^d</td>
<td>29 (22.3)</td>
<td>16 (38.1)</td>
</tr>
<tr>
<td>Below detection limit^e</td>
<td>56 (43.1)</td>
<td>26 (61.9)</td>
</tr>
<tr>
<td>HBV DNA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High DNA group^g</td>
<td>47 (36.2)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>Low DNA group</td>
<td>83 (63.8)</td>
<td>36 (85.7)</td>
</tr>
</tbody>
</table>

ALT = alanine aminotransferase; HBeAg = hepatitis B e antigen; HBV = hepatitis B virus.

^a Among the 130 sera samples studied, 124 samples were tested for the ALT levels.

^b HBeAg count was based on the sera sample instead of the patient number. HBeAg may be repeatedly checked if the sera sample was repeatedly collected. Two ambiguous values and 12 unchecked sera samples were excluded, and 116 sera samples were studied.

^c Among the 130 sera samples, 72 samples were tested for HBV DNA levels. The sera samples of the Abbott and Roche group were all tested for HBV DNA levels.

^d The detection limit of the HBV DNA was 108 IU/mL. For analysis, a HBV DNA below the detection limit was designated as 54 IU/mL.

^e The high-DNA group consisted of a sera sample DNA level that is greater than the cutoff value of 5000 IU/mL.

Among the 130 sera samples studied by Abbott assays, 42 samples from 41 HBV-infected patients comprised the Abbott & Roche group, which provided the tested values from the Roche and Abbott automatic assays, i.e., Elecsys and automatic Architect assays (Table 2, fourth column). All 42 sera sample exhibited ALT, 36 of which were within the normal range (40 IU/L). In addition 33 sera samples exhibited HBeAg and were mostly e antigen negative (HBeAg positive vs. HBeAg negative: 2 vs. 31). Six patients were in the high HBV DNA group, and 36 patients belonged to the low HBV DNA group.

Linearity

To examine the linearity of the automatic Architect assay, we tested three selected sera samples with an HBsAg level of > 10^5 IU/mL, in which each underwent a serial 1:10 dilution from 10^x to 10,000x. The calculated R^2 values ranged from 0.996 to 1 (Figs. 1A–C).

Reproducibility

Reproducibility of the automatic Architect assay was tested in terms of the coefficient of variation. In total, nine sera samples generated a coefficient of variation ranging from 0.44% to 9.53%, with a median of 3.75%. The samples were sorted into three groups according to the mean value of HBsAg. The median values of the lower, medium, and high HBsAg groups were 110.4 IU/mL, 719.3 IU/mL, and 19373.4 IU/mL, respectively, and the coefficients of variation were 5.13%, 5.61%, and 3.1%, respectively.

Correlations between assays

Forty-two sera samples comprised the Abbott & Roche group, which were measured using all the three assays. The Abbott & Roche group showed a positive correlation; their HBsAg levels were assayed using the automatic Architect and Elecsys assay (R = 0.938; Fig. 2A). Similarly, a positive correlation was found in the Abbott & Roche group, as measured using the manual Architect and Elecsys assays (R = 0.985; Fig. 2B). For all 130 samples assayed using the automatic and manual Architect assays, there was a positive correlation between the results (R = 0.898; Fig. 3A).

All 130 sera samples were divided into the following subgroups: HBeAg-positive and -negative groups, and high- and low-DNA groups. Interestingly, there was a correlation between the two Architect assays. After the values were transformed to log_{10}, the correlation was better in the HBeAg-negative group than in the HBeAg-positive group (HBeAg-negative vs. HBeAg-positive groups: R = 0.885 vs. R = 0.865, both p < 0.01; Figs. 3B and 3C, respectively). The correlation between the two Architect assays for the results of the high HBV DNA (> 5000 IU/mL) group (R = 0.844, p < 0.01) and low HBV DNA (≤ 5000 IU/mL) group (R = 0.886, p < 0.01) are illustrated in Figs. 3D and 3E, respectively. A better correlation was found in the low HBV DNA group (compared with the high DNA level group) and in the HBeAg-negative group (compared with the HBeAg-positive group).
Implication for health policy/practice/research/medical education

The Abbott Architect HBsAg assays, which demonstrate enhanced detection of HBsAg mutants, yielded reliable results and showed a significant correlation with the Roche Elecsys assay. The correlation between the automatic and manual Architect assays was better in the HBeAg-negative and low DNA groups. The Abbott Architect HBsAg assays should enable optimal monitoring of disease and timely adaptation of an antiviral therapy for HBV infection.

Discussion

As an endemic viral infection in Taiwan, HBV remains a major public health issue. To adequately diagnose, treat, and evaluate a patient’s treatment responses with the aid of a reliable diagnostic tool are crucial. Thus, the fluctuating HBsAg level discloses the interaction between HBV and host immune control. Among HBV-infected patients with a low viral load, serum HBsAg levels help predict disease progression [8]. The level of HBsAg has been proposed as a marker of infected liver mass or the amount of covalently closed circular DNA (cccDNA), particularly for treatment-naive patients [11]. HBsAg levels have been shown to be a steady, reliable marker of chronic HBV carriage, which can also be used to evaluate the clinical stage of liver disease [12, 14] and to predict clinical outcomes [8, 19].

For a chronic HBV carrier, the spontaneous clearance of serum HBsAg is rare, which occurs at a rate of approximately 0.5–2.3% per year [2, 20]. With regard to antiviral treatment, HBsAg clearance characterizes a sustained remission of HBV infection [21], and the annual incidence of hepatocellular carcinoma is reduced by over 80% as HBsAg clearance is achieved [7]. Among patients with liver cirrhosis, high HBsAg levels are consistently associated with a higher risk of development of HBeAg-negative hepatitis and cirrhosis [8]. In the subgroup of HBeAg-negative carriers, serum HBsAg levels help stratify the risk of hepatocellular carcinoma [22]. A decrease in HBsAg level was also associated with both sustained virological response and clearance of HBsAg [23, 24]. For patients undergoing

Table 2 Hepatitis B virus surface antigen levels$^a$ of the Abbott & Roche group, using 42 sera samples, as tested using the automatic Architect assay, manual Architect assay, and Elecsys assay.

<table>
<thead>
<tr>
<th>HBsAg assay (platform)</th>
<th>Automatic Architect assay (Abbott Architect HBsAg i1000)</th>
<th>Manual Architect assay (Abbott Architect HBsAg i2000)</th>
<th>Elecsys (Roche Cobas e 411)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st quartile (KIU/mL)</td>
<td>119.3$^b$ (43.1)$^c$</td>
<td>240.7$^b$ (40.5)</td>
<td>151.3$^b$</td>
</tr>
<tr>
<td>2nd quartile (KIU/mL)</td>
<td>256.1 (216.0)</td>
<td>392.1 (224.8)</td>
<td>300.1</td>
</tr>
<tr>
<td>3rd quartile (KIU/mL)</td>
<td>1221.8 (1455.9)</td>
<td>1949.7 (1826.2)</td>
<td>1006</td>
</tr>
<tr>
<td>IQR</td>
<td>1102.5 (1412.8)</td>
<td>1709 (1785.7)</td>
<td>854.7</td>
</tr>
</tbody>
</table>

HBeAg = hepatitis B e antigen; HBV = hepatitis B virus; IQR = interquartile range.

$^a$ The detection limit of the HBV DNA was 0.108 KIU/mL. For analysis, an HBV DNA below the detection limit was designated as 0.054 KIU/mL.

$^b$ Values outside of the bracket symbols were generated from 42 sera samples.

$^c$ Values inside the bracket symbols were generated from all 130 sera samples, which were assayed using both Abbott analyzers.

Figure 1. Linearity of the Abbott Architect HBsAg (automatic dilution) based on randomly chosen serum samples (A) F27412 (diluted in series from $10 \times$ to $10,000 \times$; $R^2 = 1$, $p < 0.01$), (B) R41990 (diluted in series from $10 \times$ to $10000 \times$; $R^2 = 1$, $p < 0.01$), and (C) F28262 (diluted in series from $10 \times$ to $10,000 \times$; $R^2 = 0.996$, $p < 0.01$).
therapy, lower baseline HBsAg levels were superior to HBV cccDNA or serum HBV DNA in predicting virological responses to peginterferon alfa-2a and/or lamivudine treatment, and a rapid decrease in HBsAg concentration during interferon therapy is associated with a higher chance of sustained virological response [15,25]. The serum HBsAg profile was also shown to be valuable in clinical follow-up evaluations for hepatitis B- and C-coinfected patients treated with interferon [26,27].

The Abbott Architect HBsAg provides enhanced detection of HBsAg and HBsAg mutants compared with previous assays [16,17], and this study was the first to assess the reliability of the newly developed Abbott Architect HBsAg reagent kits, which involved automatic and manual dilutions, compared with the conventional Roche Elecsys HBsAg. Three serially diluted samples (from $10^2$ to $10,000^2$) were analyzed using the same assay, which showed good linearity. The reproducibility of the Abbott Architect HBsAg assay with automatic dilution (automatic Architect assay) was assessed on the basis of the coefficients of variation, which yielded feasible results ranging from 0.44% to 9.53%.

On the basis of the 130 sera samples, the results of the two Architect immunoassays demonstrated a feasible correlation ($R = 0.898$). Correlation of results between these assays was also assessed in the four subgroups. A better correlation was found in the HBeAg-negative group ($R = 0.885$, $p < 0.01$; Fig. 3C) and low HBV DNA group ($R = 0.886$, $p < 0.01$; Fig. 3E), compared with the HBeAg-positive group ($R = 0.865$, $p < 0.01$; Fig. 3B) and high DNA group ($R = 0.844$, $p < 0.01$; Fig. 3D). To the best of our knowledge, the positive e antigen and high HBV DNA levels indicated a higher HBsAg titer [11,14]. A higher HBsAg titer, particularly when the value was $> 250$ IU/mL, required a dilution. However, the dilution itself might alter the correlation to some extent. HBeAg-negative and low HBV DNA groups required fewer dilution counts. The rate of samples requiring dilution, i.e., HBsAg titer $> 250$ IU/mL, in the HBeAg-negative group was 38.2%, compared with 62.9% in the HBeAg-positive group. The rate of samples requiring dilution in the low HBV DNA group was 30.1%, which was also lower than that in the high HBV DNA group (74.5%). The percentage of manual dilution in all 130 sera samples was 46.9%. Reduced necessity for manual dilution might provide a better correlation when assaying, in terms of the automatic and manual dilutions.

Significant correlations in HBsAg values were also found between the Roche Elecsys HBsAg and Abbott Architect HBsAg assays (automatic Architect vs. Elecsys, $R = 0.938$; manual Architect vs. Elecsys, $R = 0.985$; automatic Architect vs. manual Architect, $R = 0.898$).

The severity of HBV-related liver disease differs according to the HBV genotype/subgenotypes [28]. Thus, further research may help establish the reliability of the Architect assays in different groups of HBV genotypes, thereby revealing the natural course or treatment response of the HBsAg levels for each HBV genotype.

In conclusion, the results of the Abbott Architect HBsAg assays (automatic and manual Architect assays) correlated well with the results of the conventional Roche Elecsys HBsAg (Elecsys assay) and the Architect HBsAg reagent kit, which was demonstrated to be reliable in terms of linearity and reproducibility. The results of the two Architect assays also correlated well with each other, particularly in the HBeAg-negative and low HBV DNA groups. A lower demand for dilution due to lower HBsAg levels in the HBeAg-negative and low HBV DNA groups might enhance the correlation between the two Architect assays. Among the HBeAg-negative groups, as previously mentioned, a high HBsAg level, rather than a high HBV DNA level, was the only...
Figure 3. (A) Correlation between the Abbott Architect HBsAg (automatic dilution) and Abbott Architect HBsAg (manual dilution) assays. The HBsAg titer in 130 sera samples was quantified using both methods. The correlation was studied after the HBsAg values were transformed by log10. Pearson’s correlation coefficient $R = 0.898$, $p < 0.01$. (B) Correlation between the Abbott Architect HBsAg (automatic dilution) and Abbott Architect HBsAg (manual dilution) assay in terms of 35 HBeAg-positive sera samples. The correlation was studied after the HBsAg values were transformed by log10. Pearson’s correlation coefficient $R = 0.865$, $p < 0.01$. (C) Correlation between the Abbott Architect HBsAg (automatic dilution) and Abbott Architect HBsAg (manual dilution) assay in terms of 81 HBeAg-negative sera samples. The correlation was studied after the HBsAg values were transformed by log10. Pearson’s correlation coefficient $R = 0.885$, $p < 0.01$. (D) Correlation between the Abbott Architect HBsAg (automatic dilution) and Abbott Architect HBsAg (manual dilution) assays in terms of 48 high-HBV-DNA-level sera samples. The correlation was studied after the HBsAg values were transformed by log10. Pearson’s correlation coefficient $R = 0.844$, $p < 0.01$. (E) Correlation between the Abbott Architect HBsAg (automatic dilution) and Abbott Architect HBsAg (manual dilution) assays in terms of 82 low-HBV-DNA-level sera samples. The correlation was studied after the HBsAg values were transformed by log10. Pearson’s correlation coefficient $R = 0.886$, $p < 0.01$. HBeAg = hepatitis B e antigen; HBsAg = hepatitis B virus surface antigen.
viral risk factor associated with hepatocellular carcinoma [13,29]. The Abbott automatic dilution Architect HBsAg assay demonstrated enhanced HBsAg mutant detection power [16,17], and lower labor costs and human error compared with the manual dilution version, which enabled optimal disease monitoring and a timely adaptation of antiviral therapy for HBV infection.

Acknowledgments

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References


Appendix A. Supplementary data

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.kjms.2014.10.007.