The Performance of the Abbott i2000 for Measuring Serum Markers of Infectious Diseases

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Background: To date, there is a trend that the chemiluminescent microparticle immunoassays (CMIA) and electrochemiluminescence immunoassays (ECIA) technology gradually replacing the enzyme-linked immunosorbent assay (ELISA). But the performance such as the limit of quantitation (LOQ), precision, linear range of CMIA, or ECIA for serum markers of infectious diseases has rarely been reported. **Methods:** Using proficiency testing samples and standard materials, we confirmed the LOQ of the ELISA and the precision, linear range, LOQ, and instrument biases of the Abbott i2000 for eight serum markers. We used the Abbott i2000 and ELISAs to assess five HIV samples; the researchers were blinded to the true status of the samples. **Results:** For the Abbott i2000, the coefficients of variation (CV) for the low, medium, and high concentration samples ranged from 1.06 to 12.74%, which were less than the

allowable error; the linear ranges of HBsAg and HBsAb were 0.66–304.11 IU/ml and 8.16–1205.9 mIU/ml, respectively. For the Abbott i2000, the LOQs of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV, anti-TP, and anti-HIV were 0.026 IU/ml, 4 mIU/ml, 0.14 NCU/ml, 0.56 NCU/ml, 0.99 NCU/ml, 0.5 NCU/ml, 8.8 mIU/ml, and 1.92 NCU/ml, respectively, and these values were 0.16 IU/ml, 6.97 mIU/ml, 1.16 NCU/ml, 1.63 NCU/ml, 1.79 NCU/ml, 1.03 NCU/ml, 8.33 mIU/ml, and 1.3 NCU/ml, respectively, for the ELISA. When five HIV samples were blindly assessed, two cases were missed by the Abbott i2000 and the ELISA results were consistent with the expected results. **Conclusions:** The Abbott i2000 performed significantly better than the ELISA on HBV and HCV screening; however, for anti-TP and anti-HIV, the ELISA remained the preferred method. *J. Clin. Lab. Anal.* 31:e22015, 2017. © 2016 Wiley Periodicals, Inc.

Key words: Abbott i2000; enzyme-linked immunosorbent assay; serum markers

BACKGROUND

Infectious agents, such as hepatitis B virus (HBV), hepatitis C virus (HCV), *Treponema Pallidum* (TP), and human immunodeficiency virus (HIV), cause global public health problems. According to World Health Organization (WHO) estimates, in 2015, approximately 240 million people worldwide were infected with HBV, and more than 780,000 people died of HBV (1). Regarding HCV, 130–150 million people were infected, and approximately 500,000 people died due to HCV-related liver diseases worldwide (2). Globally, the number of newly acquired sexually transmitted infections (STIs) (including chlamydia, gonorrhea, syphilis, and trichomoniasis) per year is approximately 357 million (3). At the end of 2014, approximately

36.9 million people were infected with HIV, and the global numbers of new HIV infections and deaths due to HIV infection in 2014 were 2 million and 1.2 million, respectively (4). Data from National Health and Family Planning Commission of the People Republic of China demonstrated that the incidences of HBV, HCV, syphilis, and HIV were 1,085,113, 232,400,

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458,682, and 51,556 individuals, respectively, in China in 2015 (5).

Serum marker detection has been the preferred method for diagnosing patients infected with HBV, HCV, TP, and HIV, and it is crucial for preventing their transmission, providing effective treatment, and ensuring the safety of clinical blood. The current primary assays include ELISAs, CMIA, and ECIA. Due to their low detection limit, wide linear range, high precision, and shortened turnaround times, CMIA and ECIA technology, including Abbott and Roche products, is now widely applied to detect serum markers of HBV, HCV, TP, and HIV. In this study, the precision, linear range, and detection limit of the Abbott i2000 were evaluated for five HBV serum markers, HCV antibodies (anti-HCV), TP antibodies (anti-TP), and HIV antibodies (anti-HIV), and a comparison between the Abbott i2000 instrument and ELISAs was performed.

OBJECTIVES

To evaluate the performance of the Abbott i2000 for measuring serum markers of infectious diseases and to compare the results with ELISA.

STUDY DESIGN

Precision Evaluation

According to the requirements listed in the Clinical and Laboratory Standards Institute (CLSI) EP15-A2 document (6), low, medium, and high concentration samples from China National Center for Clinical Laboratory Proficiency Testing for HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV, anti-TP, and HIV-Ag/Ab were prepared; every sample was measured by the Abbott i2000 (Abbott Diagnostics, Abbott Park, IL, USA) three times daily for five consecutive days. Within-run precision and laboratory precision were calculated, and the imprecision was required to be less than the allowable error. The standard deviation was calculated using the following formula:

$$\text{Within-Run Precision : } Sr = \sqrt{\frac{\sum_{d=1}^D \sum_{i=1}^n (X_{di} - \bar{X}_d)^2}{D(n-1)}},$$

D = total number of days (five), n = total number of replicates per day (three), X_{di} = result for replicates per day (three replicates), $\bar{X}_d$ = average of all results for day d ,

$$\text{Laboratory Precision : } Sb^2 = \frac{\sum_{d=1}^D (\bar{X}_d - \bar{\bar{X}})^2}{D-1},$$

$\bar{\bar{X}}$ = average of all results,

$$SI = \sqrt{\frac{n-1}{n} \cdot Sr^2 + Sb^2}$$

Linearity Evaluation

According to the requirements of the CLSI EP6-A2 document (7), samples from China National Center for Clinical Laboratory proficiency testing of HBsAg and HBsAb with concentrations near the expected upper reportable limit were selected and diluted with the recommended diluent to prepare a series of sample concentrations. The ranges of concentrations were 0.66–304.11 IU/ml for HBsAg and 0.63–1205.9 mIU/ml for HBsAb. Each sample was assayed twice by the Abbott i2000, and the following procedures were conducted to determine whether the dataset was acceptable: measurement of the mean value (Y -axis) and assignment value (X -axis), visual evaluation of the point on the graph, and assessment of outliers; if more than one outlier was present, the data were considered invalid. If the dataset was acceptable, then polynomial regression analysis using first-, second-, and third-order polynomials was performed. If a nonlinear coefficient was found, then we determined whether the degree of nonlinearity was $\leq$ the allowable error.

Verification of the Limit of Quantitation (LOQ)

Quantitative tests

Standard material (Abbott GmbH & Co. KG, Wiesbaden, Germany) was diluted with saline to near the expected lower reportable limit; the prepared sample concentrations were 0.026–0.04 IU/ml for HBsAg and 4–4.8 mIU/ml for HBsAb. The prepared samples were measured with the Abbott i2000 once daily for 20 consecutive days, and the coefficient of variation (CV) and the bias were calculated. The lowest concentration at which the CV and the bias were less than or equal to the allowable error was considered the LOQ.

Qualitative tests

According to the requirements of the CLSI EP12-A document (8), standard material (Beijing Controls & Standards Biotechnology Co. Ltd, Beijing, China) was

TABLE 1. Precision Evaluate for Low, Medium, and High Concentration Samples

	Day 1				Day 2				Day 3				Day 4				Day 5				Within-Run Imprecision	Laboratory Imprecision	
	X1	X2	X3	X _d	X1	X2	X3	X _d	X1	X2	X3	X _d	X1	X2	X3	X _d	X1	X2	X3	X _d			
Low concentration																							
HBsAg	0.14	0.13	0.12	0.13	0.13	0.13	0.14	0.13	0.14	0.14	0.14	0.14	0.13	0.13	0.14	0.13	0.14	0.14	0.14	0.14	0.14	4.27%	4.80%
HBsAb	35.03	34.03	34.98	34.68	36.57	35.04	36.40	36.00	34.65	34.54	33.83	34.34	34.80	33.59	33.37	33.92	34.09	35.34	34.40	34.61	34.09	1.90%	2.73%
HBsAg	0.77	0.80	0.78	0.79	0.76	0.76	0.80	0.77	0.87	0.86	0.86	0.86	0.86	0.83	0.81	0.82	0.82	0.85	0.86	0.84	0.82	1.78%	4.84%
HBsAb	1.61	1.61	1.57	1.60	1.66	1.74	1.69	1.70	1.72	1.80	1.72	1.75	1.60	1.73	1.72	1.68	1.76	1.65	1.88	1.76	1.76	3.97%	5.04%
HBsAb	0.54	0.57	0.54	0.55	0.56	0.53	0.52	0.54	0.61	0.56	0.60	0.59	0.59	0.62	0.61	0.61	0.61	0.62	0.58	0.60	0.61	3.55%	6.26%
Anti-HCV	0.72	0.75	0.71	0.73	0.72	0.73	0.69	0.71	0.69	0.72	0.69	0.70	0.77	0.74	0.72	0.74	0.79	0.82	0.77	0.79	0.79	3.02%	5.50%
Anti-TP	0.67	0.67	0.67	0.67	0.69	0.68	0.64	0.67	0.69	0.67	0.69	0.68	0.73	0.72	0.71	0.72	0.73	0.70	0.70	0.71	0.71	2.32%	3.85%
Anti-HIV-Ag/Ab	0.75	0.69	0.71	0.72	0.71	0.74	0.68	0.71	0.86	0.69	0.69	0.75	0.74	0.74	0.74	0.78	0.81	0.84	0.76	0.80	0.81	6.87%	7.49%
Medium concentration																							
HBsAg	25.32	25.69	26.15	25.72	26.12	25.48	25.32	25.64	24.78	25.22	26.18	25.39	25.05	26.81	25.62	25.83	23.48	24.59	25.69	24.59	23.48	2.95%	3.11%
HBsAb	78.26	77.82	78.03	78.04	81.14	83.55	81.39	82.03	79.97	80.34	79.02	79.78	78.34	79.81	75.14	77.59	83.12	81.17	81.33	81.87	83.12	1.60%	2.91%
HBsAg	2.73	2.76	2.86	2.78	2.93	2.88	2.86	2.89	2.89	2.88	2.80	2.86	2.81	2.83	2.84	2.83	2.96	2.98	2.80	2.91	2.96	2.05%	2.43%
HBsAb	0.73	0.73	0.70	0.72	0.74	0.69	0.70	0.71	0.65	0.67	0.71	0.68	0.66	0.64	0.65	0.65	0.70	0.64	0.68	0.67	0.70	3.55%	5.08%
HBsAb	2.80	2.75	2.75	2.77	2.83	2.83	2.73	2.80	2.76	2.81	2.81	2.79	2.96	2.99	2.89	2.95	2.92	2.97	2.99	2.96	2.92	1.44%	3.46%
Anti-HCV	2.76	2.43	2.69	2.63	2.67	2.64	2.55	2.62	2.69	2.76	2.82	2.76	2.90	2.78	2.44	2.71	2.56	2.79	2.51	2.62	2.56	5.53%	5.09%
Anti-TP	2.89	2.91	2.92	2.91	2.87	2.96	2.91	2.91	3.00	3.07	3.03	3.07	2.89	2.97	2.97	2.94	2.90	2.86	2.94	2.90	2.90	1.29%	2.15%
Anti-HIV-Ag/Ab	2.76	2.62	2.67	2.68	2.64	2.85	2.85	2.78	2.66	2.73	2.72	2.73	2.91	2.89	2.79	2.86	2.76	2.78	2.80	2.78	2.76	2.43%	3.26%
High concentration																							
HBsAg	174.35	181.64	174.44	176.81	172.77	171.30	171.14	171.73	174.38	180.20	179.72	178.10	159.96	170.74	192.70	174.47	201.61	186.85	193.20	193.89	201.61	4.75%	6.21%
HBsAb	421.39	428.77	425.17	425.11	432.01	424.67	419.39	425.46	422.46	429.09	418.96	423.50	432.06	422.69	429.38	428.04	423.25	429.17	418.25	423.56	423.25	1.06%	1.18%
HBsAg	21.45	23.17	22.69	22.44	26.24	22.38	20.46	23.03	24.33	25.29	25.01	24.88	23.49	26.31	24.17	24.66	25.19	24.32	22.63	24.05	25.19	6.79%	7.08%
HBsAb	0.17	0.14	0.16	0.16	0.2	0.16	0.19	0.18	0.16	0.21	0.18	0.18	0.21	0.2	0.16	0.19	0.17	0.2	0.21	0.19	0.17	12.74%	12.74%
HBsAb	18.94	16.48	18.31	17.91	16.99	18.74	21.06	18.93	18.65	19.34	16.88	18.29	19.67	20.32	18.15	19.38	16.49	17.53	19.26	17.76	16.49	7.69%	7.30%
Anti-HCV	25.39	23.44	22.96	23.93	25.19	21.64	23.99	23.61	24.37	25.92	23.49	24.59	23.42	21.99	22.87	22.76	25.01	22.63	23.17	23.06	25.01	5.15%	5.05%
Anti-TP	13.26	13.63	13.44	13.44	13.09	12.88	13.93	13.30	14.32	13.29	14.01	13.87	15.06	13.95	14.19	14.40	14.36	14.87	13.02	14.08	14.36	4.43%	4.88%
Anti-HIV-Ag/Ab	79.69	72.45	76.32	76.15	74.01	75.36	72.99	74.12	78.16	75.02	74.18	75.79	72.39	72.19	73.65	72.74	73.95	71.89	74.33	73.39	73.95	2.33%	2.76%

diluted with saline to prepare the samples. Each sample was tested twice with the Abbott i2000 and an ELISA (Beijing Modern Gaoda Biotechnology Co., Ltd, Beijing, China). Linear regression was performed using the mean of the measured values as the dependent variable and the assignment value as the independent variable. In the linear regression formula, the limit of detection (LOD) was used as a cut-off value. Samples with concentrations 20% above the LOD were prepared to assess the LOQ. Then, the LOD and LOQ samples were measured once per day for 20 consecutive days. The lowest concentration that yielded positive results in $\geq 95\%$ of all measurements was recorded as the LOQ.

Evaluation of Consistency

Five HIV samples were provided by the Xi'an City CDC, and ELISAs (Beijing Modern Gaoda Biotechnology Co., Ltd) and the Abbott i2000 were used to assess the samples. The researchers were blinded to the status of the samples.

Twenty samples from China's National Center for Clinical Laboratory Proficiency Testing that covered the detection range of the Abbott i2000 for HBsAg

and HBsAb were selected and assessed using five Abbott i2000 machines (serial numbers: 52691, 52693, 52694, 50143, and 54290). The median value was used as the target, allowable and observed error were determined, and the observed error was required to be less than or equal to the allowable error.

Statistical Analysis

EP Evaluator 11 (Data Innovations LLC, Suite South Burlington, VT) was used to evaluate the precision and linearity and for multiple instrument comparisons. The allowable error was $\leq 15\%$.

RESULTS

Precision Evaluation

For low, medium, and high concentration samples of eight serum markers assessed by the i2000, the imprecision (based on the within-run and laboratory precision) was less than the allowable error. The range of imprecision was as follows: low concentrations, 1.9–7.49%; medium concentrations, 1.29–5.09%; and high concentrations, 1.06–12.74%. The results are shown in Table 1.

Fig. 1. Linear analysis of HBsAg and HBsAb. (a) Scatter Plot and Residual Plot for HBsAg. (b) Scatter Plot and Residual Plot for HBsAb.

Linearity Evaluation

In an outlier analysis of the dataset consisting of the two quantitative tests (HBsAg and HBsAb), no outliers were observed; therefore, the data were accepted. A nonlinear coefficient was found in a polynomial regression analysis; the best fit regression equation for HBsAg was $y = 0.001314 + 1.034x - 0.0001122x^2$, and the linear range was 0.66–304.11 IU/ml. For the HBsAb sample with a concentration of 0.63 mIU/ml, the degree of nonlinearity exceeded the allowable error; therefore, we discarded that point. Then, the best fit regression equation for HBsAb was $y = 0.003523 + 0.9792x + (1.722 \times 10^{-5})x^2$, and the linear range was 8.16–1205.9 mIU/ml. The results are shown in Figure 1.

Verification of the Limit of Quantitation (LOQ)

Quantitative tests

Twenty assays were conducted using the i2000 on samples with varying concentrations of HBsAg and HBsAb. The CVs for HBsAg (concentrations: 0.026 and 0.03 IU/ml) were 8.46% and 8.13%, respectively, and the biases were 12.76% and 10.49%, respectively. For HBsAb (concentrations: 4 and 4.8 mIU/ml), the CVs were 1.96% and 1.85%, respectively, and the biases were 13.63% and 8.74%, respectively. The CVs and biases were less than the allowable error; therefore, the LOQ of HBsAg and HBsAb using the i2000 was 0.026 IU/ml and 4 mIU/ml, respectively.

Qualitative tests (ELISA)

In 20 assessments of the LOQ samples of eight serum markers, the positive rate was 95–100%. However, in 20 assessments of the LOD samples for all serum markers except anti-HIV and anti-TP, the positive rate was lower than 95%; therefore, the LOQs of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV, anti-TP, and anti-HIV based on the ELISA were 0.16 IU/ml, 6.97 mIU/ml, 1.16 NCU/ml, 1.63 NCU/ml, 1.79 NCU/ml, 1.03 NCU/ml, 8.33 mIU/ml, and 1.3 NCU/ml, respectively.

Qualitative tests (i2000)

In 20 assessments of the LOQ samples of six serum markers, the positive rates were 95–100%. In 20 assessments of the LOD samples, except anti-TP and anti-HIV, the positive rates were $\geq 95\%$. The LOQ of HBeAg, HBeAb, HBcAb, anti-HCV, anti-TP, and anti-HIV was 0.14 NCU/ml, 0.56 NCU/ml,

TABLE 2. The Results of 20 Times Measuring for LOD and LOQ Sample

	LOD				LOQ				20 times determination (LOD)		20 times determination (LOQ)		Positive rate of 20 times (LOD)		Positive rate of 20 times (LOQ)	
	12000		ELISA		12000		ELISA		CV (%)	Bias (%)	CV (%)	Bias (%)	I2000 (%)	ELISA (%)	I2000 (%)	ELISA (%)
HBsAg	0.026 IU/ml		0.13 IU/ml		0.03 IU/ml		0.16 IU/ml		8.46	12.76	8.13	10.49	—	80	—	100
HBsAb	4 mIU/ml		5.81 mIU/ml		4.8 mIU/ml		6.97 mIU/ml		1.96	13.63	1.85	8.74	—	80	—	100
HBeAg	0.14 NCU/ml		0.97 NCU/ml		0.17 NCU/ml		1.16 NCU/ml		—	—	—	—	95	80	100	100
HBeAb	0.56 NCU/ml		1.36 NCU/ml		0.67 NCU/ml		1.63 NCU/ml		—	—	—	—	100	80	100	100
HBcAb	0.99 NCU/ml		1.49 NCU/ml		1.19 NCU/ml		1.79 NCU/ml		—	—	—	—	95	80	100	95
Anti-TP	7.33 mIU/ml		8.33 NCU/ml		8.8 mIU/ml		10 NCU/ml		—	—	—	—	80	100	100	100
Anti-HCV	0.5 NCU/ml		0.86 NCU/ml		0.6 NCU/ml		1.03 NCU/ml		—	—	—	—	100	80	100	100
Anti-HIV	1.6 NCU/ml		1.3 NCU/ml		1.92 NCU/ml		1.56 NCU/ml		—	—	—	—	80	95	100	100

NCU was National Clinical Unit (China National Center For Clinical Laboratories standard), IU and mIU were International Unit (WHO International Standard). LOD was Limits of Detection, LOQ was Limits of Quantitation.

TABLE 3. Evaluation of Consistency for HBsAg and HBsAb

Specimen	HBsAg						HBsAb											
	i2000-52693			i2000-52691			i2000-54290			i2000-50143			i2000-52694			i2000-54290		
	Target	Allow Error	Result	Obs. Error	Result	Obs. Error	Target	Allow Error	Result	Obs. Error	Result	Obs. Error	Result	Obs. Error	Result	Obs. Error		
1	22.53	±3.379	22.40	-0.12	22.53	0.00	15.33	±2.3	14.68	-0.65	15.33	0.00	17.46	2.13				
2	25.99	±3.899	28.08	2.08	25.99	0.00	17.41	±2.612	16.25	-1.16	17.41	0.00	18.82	1.41				
3	44.99	±6.749	42.49	-2.50	44.99	0.00	26.89	±4.034	26.31	-0.58	26.89	0.00	30.29	3.40				
4	48.47	±7.27	45.73	-2.74	52.36	3.89	35.46	±5.319	31.66	-3.80	35.46	0.00	36.37	0.91				
5	64.74	±9.711	61.35	-3.39	65.64	0.90	60.78	±9.117	54.42	-6.36	60.78	0.00	61.51	0.73				
6	69.79	±10.468	68.94	-0.85	75.82	6.03	62.81	±9.422	62.80	-0.01	62.81	0.00	69.16	6.35				
7	85.71	±12.856	85.71	0.00	88.65	2.95	85.47	±12.821	79.10	-6.37	85.47	0.00	95.93	10.46				
8	91.69	±13.753	91.69	0.00	97.00	5.31	177.09	±26.821	167.96	-9.13	177.09	0.00	182.25	5.16				
9	112.89	±16.933	121.25	8.37	112.89	0.00	201.74	±30.261	187.13	-14.61	201.74	0.00	204.28	2.54				
10	133.34	±20	125.31	-8.03	133.34	0.00	214.99	±32.249	199.12	-15.87	214.99	0.00	219.97	4.98				
11	134.58	±20.187	126.63	-7.94	135.18	0.60	247.62	±37.143	244.68	-2.94	247.62	0.00	259.00	11.38				
12	143.19	±21.478	143.19	0.00	140.28	-2.91	309.48	±46.422	287.77	-21.71	309.48	0.00	312.33	2.85				
13	163.18	±24.476	146.90	-16.27	154.14	-9.04	388.95	±58.343	362.07	-26.88	388.95	0.00	440.24	51.29				
14	169.61	±25.441	163.18	-6.43	180.04	10.43	410.75	±61.613	405.62	-5.13	410.75	0.00	465.89	55.14				
15	192.06	±28.809	196.94	4.88	187.60	-4.45	419.69	±62.954	406.19	-13.50	443.40	23.71	419.69	0.00				
16	198.59	±29.789	208.65	10.05	192.00	-6.59	459.9	±68.985	433.47	-26.43	459.90	0.00	497.92	38.02				
17	209.57	±31.436	238.97	29.39	192.06	-17.52	623.08	±93.462	605.97	-17.11	623.08	0.00	669.65	46.57				
18	243.17	±36.476	245.78	2.61	217.54	-25.63	693.91	±104.087	693.91	0.00	668.79	-25.12	777.48	83.57				
19	272.17	±40.825	289.58	17.41	272.17	0.00	701.93	±105.29	701.93	0.00	679.84	-22.09	750.22	48.29				
20	293.26	±43.989	321.67	28.42	283.11	-10.14	973.41	±146.012	973.41	0.00	998.96	25.55	930.83	-42.58				

0.99 NCU/ml, 0.5 NCU/ml, 8.8 mIU/ml, and 1.92 NCU/ml, respectively. The results are shown in Table 2.

Evaluation of Consistency

Of the five HIV samples, one was identified as positive and four were negative according to the Abbott i2000, whereas three were positive and two were negative based on an ELISA. Two positive cases were missed with the i2000, but in the ELISA, the results were consistent with expectations. When multiple i2000 instruments were used to evaluate consistency for 20 different samples with varying concentrations of HBsAg and HBsAb, the observed error was less than the allowable error. The results are shown in Table 3 and Figure 2.

DISCUSSION

The lack of a need for special equipment and its ease of operation and low cost make the ELISA the

preferred screening and diagnostic tool for HBV, HCV, TP, and HIV. In recent years, with the development of CMIA and ECIA technology, the advantages of high precision, low detection limits, and short turn-around times have led to a trend toward these methods gradually replacing the ELISA. To date, many studies have reported the performance of CMIA or ECIA (9–15); however, most have focused on only HBsAg (12, 15), anti-HCV (13), HIV-Ag/Ab (14), or methods comparisons between CMIA and ECIA (9–12, 14, 15). The performance of other serum markers, such as HBsAb, HBeAg, HBeAb, HBcAb, and anti-TP, used in CMIA or ECIA has rarely been reported.

In this study, using the i2000, the within-run and laboratory-level precision of measurements of low, medium, and high concentration samples met the requirements of the laboratory; the CV range was 1.06–12.74%. Only the high concentration sample of HBeAb was at the high end of the CV range (for the within-run precision, the CV was 12.17%, and for the within-laboratory precision, the CV was 12.74%). For

Fig. 2. Multiple instrument comparison for HBsAg and HBsAb. (a) Scatter Plot and Error Index by concentration for HBsAg. (b) Scatter Plot and Error Index by concentration for HBsAb.

all other markers and low concentration HBeAb samples, the CV was <7.5%. The linear ranges of HBsAg and HBsAb using the Abbott i2000 were 0.66–304.11 IU/ml and 8.16–1205.9 mIU/ml, respectively.

A comparison of the LOQs of the Abbott i2000 and the ELISA was performed in this study. The LOQs of the Abbott i2000 were approximately two to eight times lower than those of the ELISA for HBV serum markers (i.e., HBsAg, HBsAb, HBeAg, HBeAb, and HBcAb) and anti-HCV. For anti-TP, the LOQ of the ELISA was similar to that of the i2000, but for anti-HIV, the LOQ of the i2000 was higher than that of the ELISA. The LOQs of HBsAg found here are similar to those reported by Lou et al. (12). In a comparison of multiple i2000 instruments using HBsAg and HBsAb, the observed error was less than the allowable error. Many studies have confirmed that fourth-generation HIV assays, which combine the p24 antigen and HIV antibody, detect HIV earlier than third-generation HIV antibody assays (16–19). However, fourth-generation assays have a reduced antibody detection capacity compared with third-generation assays, which may contribute to their reduced sensitivity to HIV antibodies; this study supports this finding. During blind testing of five potentially HIV-positive samples using the Abbott i2000, two positive cases were missed. In contrast, when an ELISA was used, the results were consistent with the expectations. This finding may indicate that the detection limit for anti-HIV using the Abbott i2000 is higher than that for the ELISA; this is consistent with the comparison of anti-HIV LOQs between the i2000 and ELISA in this study.

We found that the Abbott i2000 performed significantly better than the ELISA on HBV and HCV screening; however, for anti-TP and anti-HIV, the ELISA remained the preferred method. The presence of a second diagnostic window for fourth-generation HIV assays has been reported (20–23). During this period, the reduction in the p24 antigen and antigen/antibody complexes may affect the sensitivity of these assays, and many acute HIV infections have been missed using fourth-generation assays. For high-risk populations, even if the fourth-generation HIV assay results are negative, supplemental assays such as tests on new blood samples obtained several days later, assays for HIV antibodies or the p24 antigen alone, or the use of an HIV RNA assay are essential.

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ETHICAL APPROVAL

The Ethics Committee of the First Affiliated Hospital of Xi'an Jiaotong University gave its approval to not require informed consent because the study did not use patient information or samples.

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