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ORIGINAL ARTICLE

Performance Evaluation of Mindray SAL 8000: a New Integrated Clinical Chemistry and Immunoassay Analyzer System

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SUMMARY

Background: **The Mindray SAL 8000 is an integrated serum analyzer for photometric, electrochemical, and immunological assays. The technical, analytical, and workflow performance of the system were evaluated in this study.**
Methods: **The technical evaluation was performed using protocols adopted from the guidelines of the China Food and Drug Administration (CFDA). The precision, linearity, interference, and method comparison were carried out according to the Clinical and Laboratory Standards Institute (CLSI) protocols. The verification of carryover and turnaround time were conducted using specimens containing different analytes.**
Results: **The technical performance was acceptable for all evaluated aspects. The repeatability and within-laboratory coefficients of variation (CVs) ranged between 0.22% and 4.23% for routine chemistry and between 1.05% and 6.89% for immunochemistry, respectively. All evaluated analytes exhibited linearity over the ranges claimed by the manufacturer. Significant interferences were observed during low concentration TBIL and P measurements due to the presence of lipemia. Method comparisons showed good agreement with the comparison systems and with the correlation coefficients ≥ 0.988 except for anti-HBs (r = 0.812). No significant intra-module and inter-module carryovers were detected. For all the 1,220 samples, 25%, 54%, 63%, 79%, 91%, and 100% samples completed analysis in 16.3 minutes, 30 minutes, 60 minutes, 120 minutes, 180 minutes, and 320 minutes, respectively.**
Conclusions: **The Mindray SAL 8000 integrated system achieved optimal technical performance and met most of the criteria regarding analytical performance. The workflow study of the system met the turnaround time (TAT) requirements of laboratories. Therefore, it is a good candidate to be used in medium and large-sized laboratories.**
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Mindray SAL 8000, integrated analyser, technical performance, analytical performance, turnaround time

INTRODUCTION

The performance of an analytical system is crucial for clinical assays to meet the specifications of clinical applications. High quality results and shorter turnaround times (TATs) achievable at lower costs are the expectation of many laboratories [1]. In general, laboratory automation and the consolidation of multiple serum test-

ing platforms into a single integrated system can be utilized to improve the performance of laboratory testing and to decrease its cost [2].

With this goal in mind, the design of Mindray SAL 8000 system consolidates clinical chemistry assays, ion-selective electrode (ISE) assays, and immunochemistry assays into a single analytical system. Mindray SAL 8000 is a random-access and fully automated analyzer for clinical chemistry laboratories.

The aim of the present study was to evaluate the technical and analytical performance and turnaround time workflow of the SAL 8000 system. In this study, 37 representative assays were evaluated under routine conditions. As a result, this study was the first to evaluate the performance of SAL 8000 in a routine laboratory environment.

MATERIALS AND METHODS

Instruments

The Mindray SAL 8000 system is an automated clinical analyzer that integrates clinical chemistry (BS-2000) and immunoassay (CL-2000i) processing modules through a sample handling manager (SPL 1000). Mindray SAL 8000 has been designed as a novel, scalable, and flexible automated system. It has the capability to determine the concentration or activity of various substances in body fluids, such as electrolytes, liver function, kidney function, blood lipid, cardiac markers, tumor markers, and hormones. The BS-2000 module is a multi-parametric, automated clinical chemistry system which can perform spectrophotometric, immunoturbidimetric, and ISE assays. BS-2000 is also one of a few automatic chemistry analyzers that can carry out measurements at a speed of 2000 tests/h. The CL-2000i module applies a heterogeneous microparticle-based chemiluminescent technology and is capable of carrying out 240 tests/hour.

Reagents, calibration, and quality control

All reagents, calibrators, and controls used in this study were provided by Mindray. Calibrations were carried out according to the manufacture's recommendations. For each parameter, two levels of lyophilized or liquid controls were measured daily.

Serum samples

Residual materials from routine work were submitted for testing. Serum/plasma samples were collected using Eppendorf tubes and stored at -20°C. Fresh (non-frozen) samples were also used in certain assays. Samples were selected to meet the requirements for the wide value ranges encountered in routine applications.

Evaluation protocol

Technical performance of BS-2000 module

The technical performance of BS-2000 module was evaluated according to the "Guideline for Automatic Chemistry Analyzer" issued by China Food and Drug Administration (CFDA) [3].

Stray light: The absorbance of 50 g/L sodium nitrite solution was measured five times at 340 nm. The minimum absorbance should be greater than 4.9 A.

Photometric linearity: 11 concentrations of potassium dichromate and orange G solutions were measured at 340 nm and 450 nm, respectively. Each of was assayed in 3 replicates. The relative bias between mean values and theoretical values should be no more than 5%. Theoretical values of all concentrations were calculated by least square method.

Photometric accuracy: Three consecutive measurements of 0.5 A and 1.0 A potassium dichromate solutions were carried out at 340 nm. The accuracy bias should be less than 0.025 A and 0.07 A for 0.5 A and 1.0 A potassium dichromate solutions, respectively.

Photometric stability: A 0.5 A potassium dichromate solution and a 0.5 A copper sulphate solution were continuously measured at 340 nm and 660 nm, respectively. Absorbances were recorded every 18 seconds during the maximum reaction time of the BS-2000 module. The difference between the maximum and minimum values of continuous measurements should be no more than 0.01 A.

Photometric imprecision: A 1.0 A potassium dichromate solution was measured at 340 nm using the minimum reaction volume of 80 µL. The desirable coefficient of variation (CV) of 20 successive measurements should be less than 1.0%.

Effectiveness of the thermostatic system: The temperature was recorded once every 30 seconds during the maximum reaction time of the BS-2000 module using a temperature measuring instrument with a precision of not less than 0.1°C. Temperature accuracy and temperature fluctuation should be less than ± 0.3°C and ± 0.1°C, respectively.

Sample carryover: Triplicate of a 200 A Orange G solution and distilled water (25 µL each) were measured successively at 340 nm with distilled water as the reagent, and repeated five groups. The carryover rate of each group was calculated. The sample carryover was acceptable if the mean results did not exceed 0.1%.

Accuracy and precision of sample/reagent dispensing: Degassed distilled water of a specific volume was added into an empty sample cup using sample or reagent probes, and the actual sample volume was calculated by weighing method using an electronic balance with a measuring precision of 0.01 mg. This procedure was repeated twenty times for each probe. The relative bias and CV should be no more than ± 5% and 2%, respectively.

Within-run imprecision: Twenty measurements of fresh serum samples of ALT (30 - 50 U/L), TP (50 - 70 g/L), and UREA (9 - 11 mmol/L) were carried out. The obtained CV values should be no more than 5%, 2.5%, and 2.5%, respectively.

Technical performance of CL-2000i

The technical evaluation of CL-2000i was carried out according to the "Guideline for Automatic Luminescence Immunoassay Analyzer" issued by CFDA [4]. Effectiveness of the thermostatic system: We monitored the temperature of the reaction fluid every 30 seconds during 10 minutes using a temperature measuring instrument with a precision of not less than 0.1°C. Temperature accuracy and temperature fluctuation should be less than ± 0.5°C and ± 1.0°C, respectively.

Stability: Two different concentrations of ALP were measured in triplicate at 0 hour, 4 hours, and 8 hours. The relative deviation from the base value (0 h) should be less than ± 10%.

Within-run imprecision: Imprecision was checked using 20 analyses of HCG in serum sample. The CV should be less than 8%.

Linearity: Patient serum samples at five concentrations were measured three times and the regression curve was obtained for measured and theoretical values. The correlation coefficient (r) should not be less than 0.99.

Sample carryover: Three low-concentration HCG serum samples were measured immediately after the measurement of three high-concentration samples. This procedure was repeated five times. The carryover rate was calculated. The maximum of carryover rate should be no more than 10 parts per million (ppm).

Evaluation of analytical performance

Precision

Using at least two levels of quality control materials, precision studies were performed according to the Clinical and Laboratory Standards Institute (CLSI) EP05-A3 protocol [5]. A minimum of 20 acceptable operating days was generally necessary.

Linearity

In compliance with CLSI guideline EP06-A, linearity was verified for all parameters except for qualitative items (HBeAg, Anti-HBe, and Anti-HBc), FT4, and FT3 [6]. Six levels of equally spaced sample concentrations were prepared to cover the lower and upper limits of the claimed linearity. In addition, high-concentration calibrators, concentrated quality controls, and serum samples containing pure analytes and proper diluents were also used if the concentration of clinical samples was not high or low enough. Samples were measured in duplicate to obtain the average values, which were then compared with theoretical values using linear regression analysis. A method could be considered linear if the differences between measured values and expected values were ≤ 10% (5% for electrolytes) or smaller than the absolute deviation specified by the manufacture. The R value should be > 0.99 for immunoassays.

Interference

According to CLSI protocol EP07-A2, the potential interference from hemolysis, icterus, and lipemia was investigated for the BS-2000 module [7]. In brief, pooled serum containing recommended low and high concentrations of analytes were spiked with different amount of interfering substances and an equivalent volume of basic solutions (deionized water or 0.1mol/L NaOH). As a result, two samples containing 100% and 0% interference were generated, respectively. Hemoglobin was obtained from Sysmex (ref. 79370), while Intralipid (20%) and bilirubin were obtained from Sigma Aldrich (St. Louis, MO, USA). For each tested substance, a series of five samples with increasing interferent concentrations were prepared by blending the above two samples. Each specimen was promptly assessed in triplicate and the relative deviation of the results from the baseline value was calculated. An observed deviation exceeding the allowed bias goals (relative deviation 10% for all assays) was defined as evidence of interference (SI, significant interference). Otherwise, it was defined as NSI (no significant interference).

Method comparison

The comparative study was conducted according to the CLSI EP09-A3 protocol [8]. For each analyte, a minimum of 40 clinical specimens were tested. Since different items were carried out on different systems in our laboratory, the results of clinical chemistry measurements were compared with those obtained by the Cobas 8000 (Roche). The results of HBV serological markers were compared with those obtained by the Architect $i2000_{SR}$ (Abbott), and the results of the remaining immunoassays were compared with those obtained by the ADVIA Centaur (Siemens). Collecting samples distributed over the entire analytical measurement range was difficult for certain items. Therefore, we used some samples supplemented with pure analytes or diluted by proper solutions.

Carryover

Carryover in the sample dispensing system (2 sample probes) was assessed by using the Glu and AST assay as an example: a specimen with a high Glu/AST concentration was analyzed three times (H_1, H_2, H_3) and followed by three determinations of a sample with a low concentration (L_1, L_2, L_3). The carryover rate was calculated from $(L_1 - L_3)/(H_3 - L_3)$ x 100%.

Carryover caused by reagent probes and mixers (assay A influenced assay B) was tested between UA (assay A) and P (assay B) and between LDL-C (assay A) and TG (assay B). Assay B was carried out 6 times alone, then, assay B was required 9 times after 6 consecutive determinations of assay A. The mean of the first six measurements of B was compared with the first result of B obtained in the second sequence.

Carryover caused by cuvettes was also evaluated between the above two couples. Test B was first measured 20 times. In light of 206 cuvettes on the inner and outer carousel of BS-2000 module respectively, the following sequence was performed: 20 tests of A, then 186 tests of water (sample and regent were both deionized water), finally 20 tests of B. The carryover was the difference

between the mean of 20 times measurements of B in both series.

We used a sample carryover protocol that directed the BS-2000 chemistry module to process samples with very high immunoassay analyte concentrations followed by samples with very low concentrations for the same analyte. Then low concentration samples were tested by the CL-2000i immunoassay module to determine if the presence or absence of detectable sample carryover from chemistry module to immunoassy module could be documented. HBsAg was chosen as an example because of its low limit of detection (LoD). The high concentration samples (within ± 20% of 1,000,000 IU/mL) were obtained by spiking purified HBsAg in the negative serum pool (negative for five HBV markers, HCV-Ab, HIV-Ag/Ab and TP-Ab) that comprised the low concentration samples. The low concentration sample (L) and the high concentration sample (H) were measured in 10 replicates to calculate the reference values. After enough three high concentration samples ($H_{1\text{-}3}$) and nine low concentration samples ($L_{1\text{-}9}$) were prepared, a single X test (an open item, 25 µL sample volume, and reagent was deionized water) was performed per sample in sequence (H_1, L_1, L_2, L_3, H_2, L_4, L_5, L_6, H_3, L_7, L_8, L_9) on the BS-2000 system. Then all nine low concentration samples were tested on the CL-2000i system for HBsAg successively. If the observed results for the potentially contaminated samples were higher than those of the low reference value, the carryover rate was calculated. The carryover rate should be less than 0.1 ppm, or the results of potentially contaminated samples were less than LoD of HBsAg (0.05 IU/mL).

Turnaround time

For turnaround time, fresh serum samples collected from patients were measured on the SAL 8000 for 5 consecutive days. TAT evaluation was carried out for items such as liver function, kidney function, blood lipid, myocardial markers, electrolytes, inorganic ions, blood glucose, and amylase, which were measured using the BS-2000, as well as items such as thyroid function, tumor markers and hepatitis B virus makers, which were measured by the CL-2000i. The entire length of testing as well as the maximum, minimum, mean, and quartile TAT were calculated.

Statistical analysis

Statistical analysis included the calculation of mean, standard deviation (SD), CV (%), bias, and R value. All measured data were calculated and analyzed using Analyse-It for Microsoft Excel Version 3.60 (Analyse-It Software, Ltd).

RESULTS

Technical performance of BS-2000

The BS-2000 module consists of an internal and external reaction system, so most of the technical performances were verified on the inner and outer carousels. All goals were from the manufacturer, which were not lower than those from the CFDA guideline.

The minimum absorbance of stray light at 340 nm was 5.77 A on the inner reaction carousel, and 5.51 A on the outer reaction carousel. The relative bias of linearity at 340 nm was from -1.48% to 1.01% on the inner reaction carousel and from -1.78% to 0.78% on the outer reaction carousel. At 450 nm, the relative bias of linearity was from -0.96% to 0.55% on the inner reaction carousel and from -1.98% to 0.02% on the outer reaction carousel. On the inner reaction carousel, the accuracy deviations (340 nm) at 0.5 A and 1.0 A were 0.00095 A and -0.00577 A, respectively. On the outer reaction carousel, the accuracy deviations at 0.5 A and 1.0 A were 0.00010 A and 0.00089 A, respectively. On the inner reaction carousel, the stability deviations at 340 nm and 660 nm were 0.00188 A and 0.00158 A, respectively. On the outer reaction carousel, the stability deviations at 340 nm and 660 nm were 0.00084 A and 0.00076 A, respectively. At 340 nm, the imprecision CV was 0.36% and 0.28% on the inner and outer reaction carousels, respectively. The temperature accuracy and fluctuation bias were -0.04°C and 0.05°C, respectively. The sample carryover was 0.01% and 0.04% on the inner and outer carousels, respectively. The sample/reagent dispensing accuracy bias was from -4.08% to 1.13%, while the precision CV was from 0.05% to 1.61%. On the inner carousel, the within-run imprecision CV was 0.8% for ALT, 1.0% for TP, and 1.2% for UREA. On the outer carousel, the within-run imprecision CV was 3.4%, 1.7%, and 0.7%, respectively, for above measurements. All results indicated that the technical performance of the BS-2000 met all desirable criteria.

Technical performance of CL-2000i

The temperature accuracy and fluctuation bias were 0.03°C and 0.08°C, respectively. For 0.3 ng/mL ALP enzyme, the stability deviation was 0.50% at 4 hours and 0.79% at 8 hours. For 2 ng/mL ALP enzyme, the stability deviation was 0.33% at 4 hours and 1.23% at 8 hours. The within-run precision CV was 2.34% for HCG. The correlation coefficient of linearity was 1.000. The maximum sample carryover was 2.66 ppm among the five groups. All results were acceptable.

Evaluation of analytical performance

Precision

Repeatability and within-laboratory precision were shown through the replicate assay of control pools over twenty days as described in the CLSI document EP05-A3. The results are summarized in Table 1. The repeatability CVs were below 1/4 CLIA'88 allowable total error (TEa), while the within-laboratory CVs were less

Table 1. Precision performance of SAL 8000 in chemistry assays and immunoassays expressed as coefficient of variation (CV%).

Test item	Repeatability		1/4 TEa (%)	Within-laboratory precision		1/3 TEa (%)
	Level 1	Level 2		Level 1	Level 2	
Clinical chemistry						
ALT (U/L)	0.99	0.62	5.00	1.16	0.90	6.67
AST (U/L)	1.09	0.55	5.00	1.26	0.80	6.67
ALP (U/L)	0.77	0.64	7.50	3.88	4.23	10.00
γ-GT [a] (U/L)	0.51	0.45	5.53	1.41	1.17	7.37
TBIL (μmol/L)	0.43	0.26	5.00	1.72	0.48	6.67
DBIL [a] (μmol/L)	1.01	0.79	11.13	2.25	1.39	14.83
TP (g/L)	0.54	0.67	2.50	1.56	1.76	3.33
ALB (g/L)	0.57	0.40	2.50	0.91	0.84	3.33
CREA (μmol/L)	0.45	0.48	3.75	1.01	0.85	5.00
UA (μmol/L)	0.34	0.34	4.25	0.55	0.51	5.67
UREA (mmol/L)	1.08	0.53	2.25	1.87	1.90	3.00
Glu (mmol/L)	0.56	0.51	2.50	0.87	0.94	3.33
TC (mmol/L)	0.83	0.76	2.50	0.94	1.15	3.33
TG (mmol/L)	0.47	0.42	6.25	1.14	1.74	8.33
LDL-C [a] (mmol/L)	1.05	0.88	2.98	1.89	1.62	3.97
HDL-C (mmol/L)	0.62	0.87	7.50	1.31	2.05	10.00
Ca [c] (mmol/L)	0.02	0.02	0.06 mM	0.03	0.03	0.08 mM
P [a] (mmol/L)	0.55	0.39	2.53	0.70	0.69	3.37
α-AMY (U/L)	0.71	0.51	7.50	1.09	0.75	10.00
C3 [b] (g/L)	0.76	0.86	3.15	3.75	3.90	4.20
IgG (g/L)	0.69	1.01	6.25	1.07	1.29	8.33
FR-CRP[a] (mg/L)	0.76	2.29	14.15	0.90	2.63	18.87
K [c] (mmol/L)	0.03	0.02	0.13 mM	0.03	0.05	0.17 mM
Na [c] (mmol/L)	0.63	0.30	1.00 mM	0.94	0.47	1.33 mM
Cl (mmol/L)	0.57	0.22	1.25	0.68	0.36	1.67
Immunoassays						
HBsAg (IU/mL)	/	4.85	/	/	6.89	/
Anti-HBs (mIU/mL)	/	2.40	/	/	4.22	/
HBeAg (COI)	1.58	1.83	/	3.92	2.65	/
Anti-HBe (COI)	2.55	2.08	/	3.30	3.77	/
Anti-HBc (COI)	2.28	2.22	/	3.66	4.16	/
AFP (ng/mL)	1.32	1.30	/	2.20	2.32	/
CEA (ng/mL)	2.76	2.77	/	2.96	3.34	/
CA125 (U/mL)	2.50	1.05	/	2.99	2.24	/
CA19-9 (U/mL)	1.80	1.30	/	2.62	2.36	/
TSH (μIU/mL)	2.43	2.38	/	3.54	3.19	/
FT4 (ng/dL)	1.88	1.52	/	2.77	1.93	/
FT3 (ng/dL)	1.36	1.33	/	2.21	2.12	/

[a] - TEa was from the desirable specification in biologic variation, and FR-CRP followed CRP, [b] - TEa was from the minimum specification in biologic variation, [c] - The results were expressed as SDs, / - not applicable, mM - mmol/L. The mean value and SD for HBsAg and Anti-HBs (level 1) were 0, so we did not calculate the CVs.

Table 2. Linearity performance of various SAL 8000 assays.

Test item	Manufacturer's claim	Tested range	Linear regression analysis		
			r	Slope	Intercept
Chemistry assays					
ALT (U/L)	4 - 1,000	3.4 - 1,167.8	1.000	1.01	5.47
AST (U/L)	4 - 800	3.9 - 822.4	1.000	1.01	-5.16
ALP (U/L)	5 - 800	4.6 - 1,000.8	1.000	1.00	-3.60
γ-GT (U/L)	4 - 650	3.2 - 741.2	0.999	1.00	11.11
TBIL (μmol/L)	2 - 684	1.9 - 692.7	1.000	1.00	-2.76
DBIL (μmol/L)	1 - 430	0.9 - 477.2	0.997	1.02	9.16
TP (g/L)	2 - 120	1.3 - 122.6	1.000	1.00	-1.02
ALB (g/L)	3 - 60	2.7 - 61.3	0.999	1.01	0.51
CREA (μmol/L)	10 - 7,000	7.8 - 8,107.9	1.000	1.00	9.35
UA (μmol/L)	20.8 - 1500	19.2 - 1,753.2	1.000	1.00	-12.65
UREA (mmol/L)	1 - 40	0.8 - 49.8	1.000	1.00	0.38
Glu (mmol/L)	0.3 - 28	0.3 - 28.6	1.000	0.99	0.23
TC (mmol/L)	0.1 - 20	0.1 - 21.0	0.998	1.02	0.37
TG (mmol/L)	0.1 - 12.5	0.02 - 13.6	0.999	1.00	0.25
LDL-C [a] (mmol/L)	0.05 - 20	0.02 - 23.4	1.000	1.00	0.20
HDL-C [a] (mmol/L)	0.05 - 6	0.03 - 6.1	1.000	1.00	0.07
Ca (mmol/L)	0.1 - 3.75	0.1 - 3.9	1.000	1.01	0.01
P (mmol/L)	0.3 - 4	0.1 - 5.5	1.000	1.00	-0.02
α-AMY (U/L)	5 - 1,500	4.9 - 1,794.3	1.000	1.00	-0.51
C3 [a] (g/L)	0.04 - 3.3	0.02 - 3.5	0.996	1.02	0.11
IgG (g/L)	0.3 - 35	0.2 - 39.7	1.000	0.99	-0.19
FR-CRP (mg/L)	0.2 - 320	0.2 - 323.6	1.000	0.99	0.01
K (mmol/L)	1 - 10	0.9 - 11.7	1.000	1.00	-0.01
Na (mmol/L)	100 - 200	79.9 - 240.8	1.000	1.00	-0.84
Cl (mmol/L)	50 - 200	45.9 - 206.9	1.000	1.01	-0.67
Immunoassays					
HBsAg (IU/mL)	5 - 200	3.1 - 269.2	0.999	0.98	1.05
Anti-HBs (mIU/mL)	5 - 200	2.4 - 239.6	1.000	0.99	2.63
AFP (ng/mL)	1 - 400	0.8 - 454.3	1.000	1.01	-1.01
CEA (ng/mL)	0.4 - 1,000	0.4 - 1109.3	0.999	1.00	19.14
CA125 (U/mL)	2 - 3,000	1.7 - 3924.2	0.998	0.97	108.58
CA19-9 (U/mL)	2 - 2,000	0 - 2,424.6	0.997	0.99	93.63
TSH (μIU/mL)	0.01 - 100	0.01 - 103.3	0.995	1.02	3.14

[a] - Increased volume mode.

than 1/3 CLIA'88 TEa. Furthermore, the results of γ-GT, DBIL, LDL-C, P, C3, and FR-CRP were compared with allowable total errors derived from biological variation [9]. For immunoassays, the repeatability CVs were less than 5%, while within-laboratory CVs were less than 7%, consistent with the statements of Mindray.

Table 3. The interference effect of hemolysis, icterus, and lipemia.

Test item	Hemolysis			Icterus			Lipemia		
	Interfering concentration (mg/dL)	Effect on analyte		Interfering concentration (mg/dL)	Effect on analyte		Interfering concentration (mg/dL)	Effect on analyte	
		L	H		L	H		L	H
ALT (U/L)	500	NSI	NSI	40	NSI	NSI	500	NSI	NSI
AST (U/L)	/	/	/	40	NSI	NSI	500	NSI	NSI
ALP (U/L)	500	NSI	NSI	40	NSI	NSI	500	NSI	NSI
γ-GT (U/L)	500	NSI	NSI	40	NSI	NSI	500	NSI	NSI
TBIL (μmol/L)	300	NSI	NSI	/	/	/	250	SI↓ (168.3)	NSI
DBIL (μmol/L)	/	/	/	/	/	/	100	NSI	NSI
TP (g/L)	250	NSI	NSI	30	NSI	NSI	2,000	NSI	NSI
ALB (g/L)	500	NSI	NSI	20	NSI	NSI	500	NSI	NSI
CREA (μmol/L)	100	NSI	NSI	20	NSI	NSI	250	NSI	NSI
UA (μmol/L)	250	NSI	NSI	20	NSI	NSI	500	NSI	NSI
UREA (mmol/L)	500	NSI	NSI	40	NSI	NSI	500	NSI	NSI
Glu (mmol/L)	500	NSI	NSI	40	NSI	NSI	500	NSI	NSI
TC (mmol/L)	500	NSI	NSI	/	/	/	500	NSI	NSI
TG (mmol/L)	500	NSI	NSI	/	/	/	/	/	/
LDL-C (mmol/L)	300	NSI	NSI	/	/	/	300	NSI	NSI
HDL-C (mmol/L)	300	NSI	NSI	40	NSI	NSI	1,000	NSI	NSI
Ca (mmol/L)	500	NSI	NSI	40	NSI	NSI	/	/	/
P (mmol/L)	/	/	/	/	/	/	1,000	SI↑ (917.5)	NSI
α-AMY (U/L)	250	NSI	NSI	40	NSI	NSI	500	NSI	NSI
C3 (g/L)	500	NSI	NSI	40	NSI	NSI	/	/	/
IgG (g/L)	500	NSI	NSI	40	NSI	NSI	/	/	/
FR-CRP (mg/L)	500	NSI	NSI	40	NSI	NSI	500	NSI	NSI

L - low concentration analyte, H - high concentration analyte, ↑ - false increase, ↓ - false decrease. The value listed in brackets indicated that significant interference was observed at this level. Underlined, the interferent was red cell lysate. / - not applicable.

Linearity

The manufacturer's claims for linearity range were verified using CLSI document EP6-A. Summary results of the study are presented in Table 2. For the 32 analytes measured in this study, all correlation coefficients were more than 0.99. In addition, the regression slope ranged from 0.97 to 1.03. The measured values of all concentrations showed no significant deviation from their expected values. All corresponding results were linear and supported the claims.

Interference

The effects of routine interferences, i.e., hemolysis, icterus, and lipemia, on the measurements of 22 analytes were studied. Except for the lipemia interference of TBIL and P at the low concentrations, all assays were consistent with the statements of the manufacturer. But when the lipemia interfering concentrations of TBIL and P at the low concentrations were more than 168.3 mg/dL and 917.5 mg/dL, respectively, a significant interference was observed (Table 3).

Method comparison

Using linear regression and Pearson's correlation analyses, the slope, intercept, and correlation coefficient were obtained, and the relative and absolute biases at the medical decision levels (MDLs) were calculated. Statistical results are shown in Table 4. With the exception of anti-HBs ($r = 0.812$), good correlation and slope (r of all analytes were ≥ 0.988, and slope of 24 chemistry assays were between 0.93 and 1.06) were observed for most of tested parameters. Positive deviations were found in the regression analysis of ALT (23.92%) and γ-GT (15.06%) at the first MDL, while negative deviations were found in the regression analysis of CREA (-12.21%) at the first MDL and LDL-C

Table 4. Comparisons between SAL 8000 (Y) assays and various assays used on conventional analyzers (X).

Test item	n	r	Slope	Intercept	Bias at MDLs (%)			1/2 TEa (%)
					Level 1	Level 2	Level 3	
Chemistry assays								
ALT (U/L)	41	0.999	1.02	4.43	23.92	9.14	3.23	10.00
AST (U/L)	40	1.000	1.00	-1.13	-5.18	-1.40	0.11	10.00
ALP (U/L)	42	0.999	1.03	-1.53	-0.46	1.57	2.21	15.00
γ-GT [a] (U/L)	40	1.000	1.04	2.25	15.06	8.31	5.31	11.06
TBIL (μmol/L)	40	0.999	1.03	1.58	9.22	6.36	3.14	10.00
DBIL [a] (μmol/L)	40	0.995	0.97	0.93	/	/	/	22.25
TP (g/L)	43	0.995	0.97	-0.36	-3.66	-3.46	-3.31	5.00
ALB (g/L)	41	0.999	0.96	0.67	-0.53	-1.96	-2.58	5.00
CREA (μmol/L)	41	1.000	1.06	-9.90	-12.21	-0.50	4.61	7.50
UA (μmol/L)	41	1.000	0.94	1.60	-4.73	-5.74	-5.83	8.50
UREA (mmol/L)	40	1.000	1.03	0.00	2.84	2.64	2.62	4.50
Glu (mmol/L)	40	1.000	0.96	-0.02	-4.67	-4.04	-3.92	5.00
TC (mmol/L)	41	0.999	0.97	0.11	1.43	-1.55	-1.68	5.00
TG (mmol/L)	47	0.999	0.93	-0.01	-9.17	-7.85	-7.55	12.50
LDL-C [a] (mmol/L)	40	0.995	0.93	-0.04	-8.12	-7.58	-7.43	5.95
Ca [c] (mmol/L)	41	0.995	0.95	0.10	0.02	-0.02	-0.05	0.13 mM
P [a] (mmol/L)	40	0.996	0.98	0.00	-3.18	-2.83	-2.57	5.06
α-AMY (U/L)	40	1.000	1.06	-3.29	-0.33	3.51	4.61	15.00
C3 [b] (g/L)	42	0.994	0.93	0.02	-4.48	-6.26	/	6.30
IgG (g/L)	40	0.991	0.95	0.09	-3.09	-4.10	-4.46	12.50
FR-CRP [a] (mg/L)	42	0.999	1.05	0.14	7.66	5.54	/	28.30
K [c] (mmol/L)	44	1.000	0.98	0.08	0.02	-0.04	-0.07	0.25 mM
Na [c] (mmol/L)	40	0.999	0.95	6.55	0.33	-0.75	-1.56	2.00 mM
Cl (mmol/L)	47	0.998	0.99	3.09	2.34	1.67	/	2.50
Immunoassays								
HBsAg (IU/mL)	41	0.988	0.77	-0.28	/	/	/	/
Anti-HBs (mIU/mL)	46	0.812	1.20	7.59	/	/	/	/
AFP (ng/mL)	42	0.999	1.02	-4.34	/	/	/	/
CEA (ng/mL)	40	0.995	1.18	-1.94	/	/	/	/
CA125 (U/mL)	40	0.991	0.82	85.13	/	/	/	/
CA19-9 (U/mL)	40	0.997	0.58	11.70	/	/	/	/
TSH (μIU/mL)	40	0.988	1.00	2.68	/	/	/	/
FT4 (ng/dL)	40	0.991	0.74	0.05	/	/	/	/
FT3 (pg/mL)	40	0.989	0.88	0.05	/	/	/	/

[a] - TEa was from the desirable specification in biologic variation, and FR-CRP followed CRP Tea, [b] - TEa was from the minimum specification in biologic variation, [c] - The biases were expressed as absolute deviations, mM - mmol/L, Underlined - the results did not meet the specifications, / - not applicable, The bias was -2.10% for TC at the fourth MDL (data not shown in the table).

(-8.12% - -7.43%) at the three MDLs. They were all more than the 1/2 TEa from CLIA'88 or biological variation.

Carryover

No sample carryover (< 0.5%) in the dispensing system was observed for Glu and AST. Reagent-related carryover was not detected between UA and P nor between

Table 5. Sample-related and reagent-related carryover study.

Sample-related carryover							
Test item	**H_1**	**H_2**	**H_3**	**L_1**	**L_2**	**L_3**	**Carryover rate**
Glu	**55.84**	**53.44**	**55.61**	**4.71**	**4.74**	**4.72**	**-0.02%**
AST	**807.00**	**798.40**	**803.20**	**2.40**	**2.20**	**2.50**	**-0.01%**
Carryover caused by reagent probes and mixers							
A - B	**Mean B (n = 6)**	**The value of B_1 in sequence of $A_{1\cdots6}$-$B_{1\cdots9}$**					**Comparison bias**
UA - P	**1.15**	**1.14**					**0.01**
LDL-C-TG	**1.33**	**1.33**					**0**
Carryover caused by cuvettes							
A - B	**Mean B (n = 20)**	**The mean value of $B_{1\cdots20}$ in sequence of $A_{1\cdots20}$ - $Water_{1\cdots186}$-$B_{1\cdots20}$**					**Comparison bias**
UA - P	**1.12**	**1.11**					**0.01**
LDL-C-TG	**1.22**	**1.22**					**0**

Table 6. Carryover evaluation between the BS-2000 and CL-2000i modules.

Group	**First**			**Second**			**Third**		
Number	**L_1**	**L_4**	**L_7**	**L_2**	**L_5**	**L_8**	**L_3**	**L_6**	**L_9**
HBsAg (IU/mL)	**0.11**	**0.05**	**0.10**	**< 0.05**	**< 0.05**	**0.05**	**< 0.05**	**< 0.05**	**< 0.05**
Carryover rate (ppm)	**0.09**			/			/		

/ - not applicable.

Table 7. Trueness verification of four chemistries using reference samples.

Test item		**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**1/2 TEa (%)**
ALT (U/L)	**Target value**	**20.57**	**93.23**	**168.73**	**193.10**	**252.26**	**10.00**
	Relative bias (%)	**2.09**	**-1.10**	**2.53**	**2.95**	**3.11**	
γ-GT (U/L)	**Target value**	**30.40**	**96.40**	**134.30**	**175.80**	**251.40**	**11.06**
	Relative bias (%)	**-2.30**	**2.07**	**1.27**	**0.68**	**-0.84**	
CREA (μmol/L)	**Target value**	**66.41**	**703.38**	/	/	/	**7.50**
	Relative bias (%)	**-1.07**	**2.45**	/	/	/	
LDL-C (mmol/L)	**Target value**	**3.32**	**2.07**	/	/	/	**5.95**
	Relative bias (%)	**1.41**	**0.77**	/	/	/	

TEa was from CLIA'88 or desirable specification in biologic variation, / - not applicable.

LDL-C and TG (Table 5). For a high HBsAg sample of 963,020 IU/mL and a low HBsAg sample of < 0.05 IU/mL, the mean value of the first potentially contaminated samples (L_1, L_4, L_7) in the three groups was 0.09 IU/mL, so that the carryover rate was 0.09 ppm. The mean values of the second (L_2, L_5, L_8) and third (L_3, L_6,

L_9) samples in the three groups were both < 0.05 IU/mL (Table 6). In summary, no significant carryover was observed in this study.

Turnaround time

A total of 1,220 fresh serum samples were measured. The number of samples received from Monday to Friday was 224, 283, 272, 196, and 245, respectively. The total operation time on these five days was 5 hours: 22 minutes, 6 hours: 52 minutes, 7 hours: 25 minutes, 3 hours: 22 minutes, and 5 hours: 29 minutes, respectively. For the 1,220 samples, the minimum TAT was 1.7 minutes and the maximum TAT was 309.4 minutes, while the mean TAT was 65.9 minutes. In addition, the quartile 1, median, and quartile 3 TAT were 16.3 minutes, 25.9 minutes, and 98.9 minutes, respectively. These TAT values represented good performance and were deemed acceptable for various clinical conditions. Overall, the mean TAT was 65.9 minutes, while 305 samples (25%), 657 samples (54%), 772 samples (63%), 960 samples (79%), and 1,114 samples (91%) completed analysis in 16.3 minutes, 30 minutes, 60 minutes, 120 minutes, and 180 minutes, respectively. The analysis of the remaining 106 samples was finished in 180 - 320 minutes.

DISCUSSION

Considering the technical and analytical evaluation of SAL 8000 described above, it could be concluded that the system exhibited robust chemistry and immunoassay performance, and hence showed good potential to be used in clinical applications.

The core of the basic performance evaluation is to verify the technical performance of the photometer, sample adding system, and temperature control system. Understanding the technical performance of the instrument is critical. Good technical performance of the product is the prerequisite for good clinical results. According to the regulations of the CFDA guidelines, technical performance verification is necessary for each instrument in the factory and the results should meet the requirements from the manufacturer and professional standard before it can be put into application in clinical hospital [3,4]. The technical performance verification is equivalent to the process of instrument calibration and can provide valuable reference data for laboratory quality management. In addition, when the instrument fails, it can also help troubleshoot the cause of the trouble and locate the source of the fault. Therefore, we carried out technical performance evaluation before conducting clinical performance assessment. Based on the above assessment results, the overall technical performances for the BS-2000 and CL-2000i module met the criteria described in CFDA guidelines and the declaration of manufacturer. The technical performance evaluation is the part of the quality management of the laboratory, and is also a favorable way to monitor daily quality control. It is suggested that conditional the laboratory should conduct technical performance evaluation annually.

For precision study of chemistry assays, repeatability CVs ranged between 0.22% and 2.29%. Within-laboratory precision CVs ranging between 0.36% and 4.23% were obtained, and all results fulfilled the desired specification. During the 20 days of testing and apart from ALP and electrolytes, which only used a 7-day and 24-hours expiration date, respectively, all other tests were performed using the same calibration curve. Moreover, except for HBsAg, which used two different lots of reagents for two levels of precision, all other tests used an identical lot of reagents. It should also be remembered that lot variation affected precision but did not affect systematic and analytical errors [10].

Linearity is a quantitative parameter referring to the recovery of an analyte based on the measurement of serial sample dilutions of a linear proportion [6]. All evaluated assays in this study achieved their proposed goals of linearity. The wide linearity range for numerous test items allowed most low concentration samples to be measured, while most high concentration tests could be carried out without any dilution, thus saving time in routine clinical applications. In addition, when the concentration was beyond the linearity range, the analyzer performed automatic rerun (when the automatic mode was activated) using decreased or increased sample volumes.

In general, the tolerated level of three “visible” interferences, i.e., hemolysis, icterus and lipemia, by the system was acceptable for the 22 chemistry assays tested in this study. We also observed negative interference on TBIL and positive interference on P by lipemia, similar to the results published by Li et al. [11]. Since true lipemic sample was unavailable, we used intralipid as the interferent. However, Bornhorst et al. confirmed that the concentrations of triglyceride did not correlate well with Intralipid-supplemented serum pools. Samples with added Intralipid did not perfectly mimic lipemic samples. According to the relationship between L-index values and triglyceride concentrations for 16 pooled serum samples after supplementation with Intralipid reported in the research, we might estimate L-index values of 168.3 and 917.5 corresponded to a triglyceride concentrations of 6,000 mg/L and > 20,000 mg/L, respectively. Such high-concentration triglyceride samples were not common in clinical work, especially for > 20,000 mg/L [12]. In summary, the serum indices on the BS-2000 module enabled automated semi-quantitative assessments of hemolysis, icterus, and lipemia, thereby significantly improving the performance for assessing specimen integrity.

Method comparison is a necessary procedure when a new analytical system is introduced to routine laboratory applications. In this study, the comparison with Cobas 8000 yielded high correlation coefficients and a quite limited bias for most test items. However, some relatively significant bias values were found for ALT, γ-

GT, CREA, and LDL-C. Higher deviations at the first MDL for ALT, γ-GT, and CREA might be acceptable since the expected values obtained from the regression curve were close to the reference values (the absolute deviations were 4.78 U/L, 3.01 U/L, and -6.47 μmol/L, respectively). For LDL-C measurements, the biases were more than 1/2 of the desirable specification for TEa, a more stringent criterium. If we followed the 1/2 of the minimum specification for TEa (17.8%), the biases were acceptable. In addition, we further verified the trueness on ALT, γ-GT, CREA, and LDL-C and found that the deviations from the target values on the Mindray system were acceptable (Table 7). In addition, a poor slope of 0.89 was obtained for the HDL-C comparison and could be explained by the lack of samples covering the entire concentration range of the analyte (36 out of 40 measurements were clustered in the range of 0.6 - 2.0 mmol/L). During the study, it was difficult to collect high concentration HDL samples. In fact, an inadequate sample range was implicated in the poor values of slope, intercept and correlation coefficient in several studies [10,11,13,14]. A poor correlation was demonstrated for anti-HB ($r = 0.812$) measurements done on the CL-2000i and Architect $i2000_{SR}$, even though an international standard was used for the calibration of both systems. Such results were consistent with previous findings, which displayed an r value ranging from 0.83 to 0.94 [15-18]. The reasons for such poor correlation were complex and several hypotheses were proposed. For example, heterogeneity could be introduced by the reagents used in the assays, as Architect $i2000_{SR}$ used recombinant (E.coli) ad and ay antigens, while CL-2000i used recombinant ay. Furthermore, different sources of HBV vaccinations might also cause non-negligible variation [15-17,19,20]. Additionally, the quality of individual immune responses might also vary depending on actual clinical situations, such as the application of antivirus therapy and treatment strategies inhibiting HBV flare following liver transplant [19]. Moreover, the World Health Organization (WHO) standard, which was based on immunoglobulin preparations rather than serum preparations, could generate a matrix effect [17]. Although Huzly et al. found that the antigens used in the assay systems did not seem to affect incongruent anti-HB results, while the possibility of antigen production and preparation differences could not be completely excluded. Moreover, interference by endogenous proteins or other substances in individual samples might also explain the above discrepancies [21, 22].

It is generally true that a chemistry analyzer operates with reusable probes, mixers, and cuvettes, so this may result in carryover due to insufficient and inefficient washing. Following the principles from former carryover studies [23-25], we used two analytes and two potentially interfering pairs to assess sample and reagent related cross-contamination, and no significant carryover was observed in sample probes, reagent probes, mixers, and cuvettes. Thus, the cleaning procedure designed by the manufacturer satisfied the clinical requirement. Since each reagent disk had an inner and an outer carousel corresponding to their specific probes, the user could place potentially interfering assays into different carousels. Furthermore, the system could enhance the cleaning of reagent needle and cuvette using specific anti-cross-contamination parameters programmed into the software. We evaluated CL-2000i for sample carryover in the HCG assay and the carryover was insignificant (the mean carryover rate was 2.33 ppm), which was consistent with the results published by Forest et al. [26]. In addition, the use of disposable cups could better avoid cuvette carryover.

Immunoassays require even more rigorous reduction of sample carryover than biochemical testing. Therefore, when several samples are measured on the chemistry module in sequence, with one sample containing a high concentration of an analyte followed by other samples containing low concentrations of the analyte, carryover to the immunoassay module may lead to falsely high immunoassay results, thus may lead to misdiagnosis and eventually jeopardize the wellbeing of patients. In our study, no significant carryover was detected when a high concentration sample of HBsAg at 963,020 IU/mL was tested. Other studies also reported insignificant carryover on integrated clinical chemistry/immunoassay systems when HBsAg, HCG, AFP, and PSA were measured [27]. A drawback of this study was that the high concentration samples used in the measurements might not reflect the actual physiological concentrations of the analyte seen in the patients; nevertheless, these data still provided useful information. In general, the SAL 8000 system achieved its advantage in minimizing carryover through the following measures: a) samples (including chemistry and immunoassay tests) were run first on Cl-2000i; b) vigorous cleaning of BS-2000 was performed before the tests; c) sensitive immunoassay parameters were marked and retested. Due to the sufficient and efficient cross-contamination control technology, SAL 8000 may allow samples to be transferred and tested for multiple analytes between the two analyzer components.

What laboratories really need to consider is to ensure shorter TAT that satisfies the clinical demand [25]. The sample TAT in the laboratory has a close relationship with the tests ordered on samples, the number of samples loaded on an analyzer, and the STAT-vs-routine ratio [28]. In actual work, one must also consider the time it takes to do reruns and to resume testing when reagents or other consumptive material need to be replenished unexpectedly [25]. We chose samples received during 5 consecutive days in a week as an example. The samples' testing information represented the typical characteristics of sample flow in the laboratory, and a total of 1,220 clinical serum samples were simulated. The minimum TAT of all samples was 1.7 minutes, and the test items were Na, K, and Cl. The BS-2000 ISE module applied the indirect ion selective electrode method. It took only 18 seconds from the initiation to

the completion of the detection, and the rest TAT time was spent on sample scheduling. However, for 11 samples TAT exceeded 300 minutes, and the maximum TAT was 309.4 minutes. The main reason might be that the samples were loaded simultaneously, leading to the limited scheduling and test waiting. We analyzed the testing situation of all samples on the same day of the sample with maximum TAT and found that 168 samples were started during 8:00 - 9:00 am and 22 samples at 9:20 am. Forty-nine samples were put into the instrument at 9:42 am. The sample of maximum TAT was arranged in this run and followed by 37 samples, about 480 tests. Too many items, long reaction time of these items, and rerun of certain items might also influence the sample TATs in our experiment. Generally, sample handling capacity and scheduling efficiency of SAL 8000 analyzer system met the needs of medium and large-sized laboratories.

CONCLUSION

In summary, the Mindray SAL 8000 analyzer system is a useful tool for the concurrent analysis of different serum and plasma samples. It demonstrated excellent technical performance and good analytical performance for most analytes. Workflow studies documented satisfactory TATs. It could be concluded that the Mindray SAL 8000 presented robust capability for chemistry and immunochemistry assays, and hence showed good potential for workstation consolidation in medium and large-sized laboratories.

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Declaration of Interest:
The authors have no conflicts of interest to disclose.

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