การประเมินประสิทธิภาพของเครื่องวิเคราะห์ทางเคมีคลินิกอัตโนมัติ Mindray BS 430 analyzer

Analytical performance evaluation of the mindray BS 430 clinical chemistry analyzer

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บทคัดย่อ

เครื่อง BS 430 analyzer บริษัท Mindray จากประเทศจีน เป็นเครื่องวิเคราะห์ทางเคมีคลินิกอัตโนมัติที่ผลิตออกมาใหม่และมีราคาไม่สูงมากนัก ได้รับความสนใจและเริ่มมีการนำไปใช้งานมากขึ้นในห้องปฏิบัติการทั่วประเทศไทย แต่เนื่องจากผลิตโดยบริษัทแถบเอเชียอาจทำให้ไม่ได้รับความเชื่อมั่นในการใช้งานเท่ากับเครื่องจากผู้ผลิตเดิมจากแถบประเทศตะวันตก จึงมีความจำเป็นในการทดสอบและประเมินประสิทธิภาพเพื่อให้ได้ผลการตรวจวิเคราะห์ที่มีความถูกต้อง แม่นยำ และน่าเชื่อถือสำหรับห้องปฏิบัติการที่จะนำเครื่องไปใช้ วัตถุประสงค์ในงานวิจัยเพื่อประเมินประสิทธิภาพของเครื่องวิเคราะห์ทางเคมีคลินิกอัตโนมัติ Mindray BS 430 analyzer โดยประเมินความแม่นยำ ความถูกต้องและและช่วงของผลการทดสอบตามแนวทางของเกณฑ์มาตรฐาน Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) ผลการประเมินความแม่นยำ ค่า within-run precision (% CV) เท่ากับ 0.49-3.34 % และ day-to-day precision (% CV) เท่ากับ 2.40-6.81 % พบว่าอยู่ในเกณฑ์ที่กำหนดทุกรายการ พบ 3 รายการมีค่า intermediate precision สูงกว่าเกณฑ์ ด้านความถูกต้องจากการตรวจวัดเปรียบเทียบกับเครื่องมืออ้างอิง Cobas® pro Chemistry Analyzer มีค่าสัมประสิทธิ์สหสัมพันธ์อยู่ระหว่าง 0.935-1.000 ที่ระดับนัยสำคัญ $p<0.000$ พบ 3 รายการที่ค่าน้อยกว่า 0.975 และการประเมินช่วงของผลการทดสอบ ในทุกรายการมีค่า %bias ไม่เกิน Total Allowable error (TEa) สรุปผลการศึกษาเครื่องวิเคราะห์อัตโนมัติ Mindray BS 430 analyzer มีความแม่นยำและความถูกต้องเหมาะสมสามารถนำไปใช้ตรวจวัดสารชีวเคมีในเลือดในงานประจำวันของห้องปฏิบัติการได้ ในรายการที่ไม่ผ่านเกณฑ์ที่กำหนด ควรมีการทดสอบเพิ่มเติมก่อนที่นำไปใช้งานจริง จากข้อมูลในการศึกษานี้สามารถนำมาใช้เป็นแนวทางสำหรับผู้ใช้ในการเลือกเครื่องวิเคราะห์ทางเคมีคลินิกอัตโนมัติเพื่อให้เกิดประโยชน์สูงสุดสำหรับห้องปฏิบัติการ

คำสำคัญ: เครื่องวิเคราะห์ทางเคมีคลินิกอัตโนมัติ Mindray BS 430, การประเมินวิธีการทดสอบ, ความแม่นยำ, ความถูกต้อง, ช่วงของผลการทดสอบ

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Ab stract

The BS 430 analyzer from Mindray, China, is a newly released, low-cost automated clinical chemistry analyzer that is gaining popularity and is increasingly used in laboratories across Thailand. However, because it is manufactured by an Asian company, it may not be regarded with the same confidence as devices from traditional Western manufacturers. Therefore, it is important to evaluate its performance, since laboratory results must be accurate, precise, and reliable. The aim of this study was to evaluate the performance of the Mindray BS 430 automated clinical chemistry analyzer, including precision, accuracy, and evaluation of the reportable range of analysis, all in accordance with the guidelines of the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) standards. The precision assessment showed within-run precision (%CV) ranging from 0.49% to 3.34% and day-to-day precision (%CV) ranging from 2.40% to 6.81%. All tests met the specified criteria; however, three tests exhibited intermediate precision values higher than the allowed limits. With regard to accuracy, compared to the reference device (Cobas® pro Chemistry Analyzer), the correlation coefficient (r) ranged from 0.935 to 1.000 with significance level of $p<0.000$. Three tests having an r value of less than 0.975. The evaluation of the reportable range from the linearity experiment showed a %bias for all items that did not exceed the Total Allowable Error (TEa). The study concluded that the Mindray BS 430 analyzer has adequate precision and accuracy for blood biochemical measurements in routine laboratory use. Some analytes require further investigation and adjustment before routine implementation. The study provides guidance for users in selecting an automated clinical chemistry analyzer to optimize their laboratory's effectiveness.

Keywords: Mindray BS 430 analyzer, method evaluation, precision, accuracy, reportable range

Introduction

Automated clinical chemistry analyzers of different models and manufacturers can differ in their performance and functions for biochemical analyses. The Medical Technology Clinic of Rangsit University has recently switched from the Cobas Integra 400 plus analyzer (Roche) to the Mindray BS 430 analyzer. This new automated clinical chemistry analyzer, manufactured by an Asian company, is attracting increasing interest and use in laboratories across Thailand. Therefore, it is crucial to test and evaluate the performance of this new analyzer for current use at the Medical Technology Clinic of Rangsit University. This assessment must include precision, accuracy, and reportable range to ensure compliance with the established standards. Therefore, an evaluation of the performance of the Mindray BS 430 analyzer is required for its implementation in the Medical Technology Clinic of Rangsit University. Before an automated analyzer can be routinely used in a laboratory, it must undergo a process known as method validation. This involves a series of steps and verifications to ensure the reliability and validity of the analytical method or instrument to guarantee the accuracy of the reported results. Method validation essentially proves that the chosen instrument or method fulfils the intended purpose and provides the expected results. When selecting a new analyzer, laboratories generally consider several factors: quality, technology and size of the device in relation to workload, budget and customer service (Boqué *et al*., 2002). In addition, the performance characteristics of the individual analytical methods are of crucial importance for the laboratory. To build confidence in the analytical methods, it is essential to evaluate whether the capabilities of the instrument match the manufacturer's quality guarantees and to assess the performance of the analytical methods to ensure that they meet the established standards. The aim of this study was therefore to evaluate the performance of the Mindray BS 430 analyzer. To this end, replication experiments to assess precision and method comparisons to determine accuracy were performed with the Cobas® pro Chemistry Analyzer (Roche). Moreover, linearity experiment was carried out to determine reportable range. These evaluations followed the guidelines of the Clinical Laboratory Improvement Amendments (CLIA) standards. The goal is to confirm that the Mindray BS 430 analyzer has adequate accuracy,

precision, and reportable range for further use in the Medical Technology Clinic of Rangsit University. Furthermore, other laboratories can use this information to guide the selection of automated clinical chemistry analyzers, and to ensure that test results are accurate, reliable, and beneficial future to medical service recipients.

Materials and Methods

The study was approved by the Ethics Review Board, Rangsit University with number RSUERB2022-113. The performance evaluation (method validation) of the Mindray BS 430 automated blood chemistry analyzer was performed in accordance with CLIA regulations. A total of 15 tests were evaluated, as shown in Table 1.

Precision was rigorously assessed through a series of replication experiments. Quality control materials, in particular two levels of ClinChem Multi Control from Mindray, were used as analytical samples. The evaluation of precision was divided into two different approaches. For within-run precision, both control levels were subjected to 20 replicate analyzes on a single day. In contrast, day-to-day precision, both control levels were analyzed once a day for 20 consecutive days. Furthermore, it is also possible to calculate additional intermediate precision values from all data of within-run and day-to-day precision. After data collection, we calculated the mean, standard deviation and coefficient of variation (%CV) for within-run, day-to-day and intermediate precision. Evaluation criteria: According to the CLIA guidelines (CLSI., 2014), the CV value for within-run precision must not exceed 0.25 times the total allowable error (TEa), and for day-to-day precision the %CV value must not exceed 0.33 times the TEa. Intermediate precision is evaluated according to guidelines provided by CLSI in document EP05-A3. These guidelines outline how to assess the precision of analytical methods, including the use of relative standard deviation (%RSD). However, they do not establish universal %RSD criteria. Instead, acceptable %RSD values for intermediate precision are specific to each method. Generally, an %RSD of less than 10% is considered acceptable, as noted in the ICH guidelines (ICH Q2R(1), Guidelines, 2005). The accuracy was determined by a comprehensive comparison of the methods. This included the analysis of at least 40 patient samples analyzed using the Cobas® pro Chemistry Analyzer (Roche) at Central laboratory, Department of Pathology, Phramongkutklao Hospital. Care was taken to select samples that included all analyte concentrations (low, normal and high) to ensure that the full reportable range of the instrument was represented. All samples were analyzed only once per patient. The results obtained from these analyses were then utilized to calculate a linear regression equation. Then, to identify the presence of an outlier, one criterion is that the data should fall within the range of aX + b +/- 3.5 Standard Error of Estimate (Sy.x). If any data points fall outside this range, they may be considered outliers, and it could be appropriate to remove them. After doing so, it is advisable to recalculate the slope, y-intercept, and Sy.x. Measurement data was checked for outlier values, and no outliers were found beyond the acceptable range. Therefore, all the data in this experiment could be used. So, this equation facilitated the calculation of bias by substituting the medical decision level (Xc) into the linear regression equation to derive Yc. The absolute difference between Yc and Xc represented the systematic error (SE). Evaluation criteria: according to the Westgard QC guideline (Westgard, OJ. 2020). For an analysis method to be considered acceptable, the evaluation of SE that show bias had to be smaller than the Ea and TEcal less than TEa. So, TEcal is usually estimated by combining the individual estimates of random and systematic errors, as shown in the following equation $TEcal = bias_{meas} + Zs_{meas}$, a z-value of 2 would include 95% of the distribution. In addition, the correlation coefficient (r) can be determined, which can be used to assess the relationship between comparative result (Cobas® pro Chemistry Analyzer) and test result (Mindray BS 430). The correlation coefficient (r) was calculated to evaluate the relationship between measurements. Statistical for analysis using SPSS Statistics version 29, after testing distribution of the data that show normal distribution use parametric method (person correlation coefficient). If the data is non- normal distribution use non-parametric, the Spearman ranks correlation

coefficient. An r value of 0.975 or greater with statistically significant ($p < 0.05$) was considered indicative of a very high correlation, signifying that the obtained data comprehensively covered the instrument's reportable range. This strong correlation also provided confidence in the reliability of both the slope and the Y-intercept derived from the linear equation. To determine the reportable range (also known as the analytical range), we carried out a linearity experiment. Samples with different concentrations were prepared for this purpose. We started with a highly concentrated sample and serially diluted it to generate five different concentration levels that covered the expected linearity of the assay. Specifically, we have prepared two initial pools: Pool 1 (P1), a low concentration sample with values close to zero, and Pool 5 (P5), a high concentration sample intended to cover the upper limit of linearity of the assay. To generate the intermediate concentrations, P1 and P5 were mixed in specific ratios: pool 2 (P2) was a 3:1 mixture of P1 and P5, pool 3 (P3) was a 2:2 mixture and pool 4 (P4) was a 1:3 mixture. Each of these five concentration levels was then analyzed in triplicate.

Table 1 Assays and principles of measurement were analyzed by Mindray BS 430 analyzer.

Analyte	Unit	Method
Glucose (GLU)	mg/dL[a]	Hexokinase
Blood urea nitrogen (BUN)	mg/dL	Urease
Creatinine (Cr)	mg/dL	Creatininase
Aspartate aminotransferase (AST)	U/L[b]	Kinetic without Pyridoxol-5-Phosphat; IFCC*
Alanine aminotransferase (ALT)	U/L	Kinetic without Pyridoxol-5-Phosphat; IFCC*
Alkaline phosphatase (ALP)	U/L	Adenosine monophosphate-p-nitrophenol; IFCC[d]
Total protein (TP)	g/dL[c]	Biuret
Albumin (ALB)	g/dL	Dye-binding method, bromocresol green
Total bilirubin (TB)	mg/dL	Diazo (Modified Jendrassik and Grof)
Direct bilirubin (DB)	mg/dL	Diazo (Modified Jendrassik and Grof)
Total cholesterol (TC)	mg/dL	Oxidase/Peroxidase
Triglyceride (TG)	mg/dL	Glycerol phosphate oxidase
High density lipoprotein cholesterol (HDL-c)	mg/dL	Direct
Low density lipoprotein cholesterol (LDL-c)	mg/dL	Direct
Uric acid (UA)	mg/dL	Uricase

[a] mg/d; milligrams per deciliter, [b]U/L; units per liter, [c]g/dL; grams per deciliter
[d] IFCC; International Federation of Clinical Chemistry and Laboratory Medicine

We calculated the average of the triplicate measurements for each level and then determined the % bias by comparing these observed averages with the calculated theoretical values. For the test to be considered acceptable, the calculated %bias had to be less TEa (CLSI., 2020).

Results

Evaluation of the precision of the Mindray BS 430 automated clinical chemistry analyzer, which includes both within-run precision and day-to-day precision, showed acceptable performance for all 15 assays. Specifically, the %CV of within-run precision for level 1 control material ranged from 0.49% to 3.34%, while level 2 ranged from 0.79% to 1.38%. In addition, the %CV of day-to-day precision ranged from 2.40% to 6.81% for level

1 and from 2.16% to 5.32% for level 2. Furthermore, the %RSD of intermediate precision for levels 1 and 2 ranged from 1.97-13.95% and 2.42-11.57%, respectively. In detail, TB was found at in level 2, and HDL-c and LDL-c at both levels were higher than the acceptable criteria. These results were summarized in Table 2

Table 2 Within-run, day-to-day and intermediate precision values were analyzed by BS 430 analyzer (n = 20).

Analyte	Within-run precision (%CV)		%CV Acceptable	Intermediate precision (%RSD)		Day-to-day precision (%CV)		%CV Acceptable
	Level 1	Level 2	(<0.25 TEa)	Level 1	Level 2	Level 1	Level 2	(<0.33 TEa)
GLU	2.05	1.17	2.50	2.50	3.80	2.74	3.29	3.30
BUN	1.71	1.38	2.25	4.36	4.92	2.51	2.65	2.97
Cr	0.82	0.92	2.50	1.97	2.45	2.40	2.78	3.30
AST	2.60	0.86	5.00	2.74	3.38	2.82	4.02	6.60
ALT	3.31	0.91	5.00	4.10	4.82	4.19	2.65	6.60
ALP	3.07	0.80	7.50	6.09	2.81	5.60	3.62	9.90
TP	1.05	1.12	2.50	2.10	2.27	2.82	2.96	3.30
ALB	1.33	1.27	2.50	2.35	2.42	3.07	2.55	3.30
TB	2.99	1.44	5.00	4.58	10.36	5.53	5.32	6.60
DB	2.63	0.94	5.00	3.10	7.06	2.97	2.16	6.60
TC	0.49	1.03	2.50	7.20	9.47	3.03	3.05	3.30
TG	3.34	0.79	6.25	3.7	3.36	3.95	4.52	8.25
HDL-c	3.07	1.01	7.50	10.90	11.57	6.81	4.56	9.90
LDL-c	0.70	0.95	5.00	13.95	10.77	4.51	4.79	6.60
UA	2.75	1.18	4.25	3.16	6.74	3.59	3.16	5.61

Coefficient of variation (%CV) and Relative standard deviation (%RSD) are SD divided by mean and multiply by 100.

Evaluation of the accuracy of the Mindray BS 430 automated clinical chemistry analyzer using a method comparison with the Cobas pro Chemistry Analyzer (Roche) showed acceptable accuracy, as determined by systematic error, including bias and TEcal. The results showed that most tests had acceptable criteria, except for GLU. Moreover, most of the tests showed an r value of 0.975 or higher, which indicates a strong correlation and means that the data adequately cover the reportable range. Based on this criterion, the tests for BUN, Cr, AST, ALT, ALP, TB, DB, TC, TG, HDL-c, LDL-c, and UA met the stated acceptable correlation. Only three tests had r values of less than 0.975: GLU, TP, and ALB. Moreover, all of test have significantly statistically at p value less than 0.000. These results were detailed in Table 3 and Figure 1.

Table 3 Accuracy evaluation using the comparison of method approach was analyzed by BS 430 analyser.

Analyte	n	Bias	Acceptable Ea	TEcal	Acceptable TEa	r (p<0.000)
GLU	50	8.98	12.00	16.94	10.00	0.973
BUN	103	1.06	2.40	2.64	9.00	0.996
Cr	108	0.02	0.30	0.12	10.00	0.999
AST	100	3.13	14.00	8.47	20.00	0.999
ALT	100	1.54	10.00	6.46	20.00	0.996
ALP	40	0.90	-	9.37	30.00	1.000
TP	75	0.05	0.70	0.31	10.00	0.935
ALB	80	0.11	0.35	0.27	10.00	0.949
TB	79	0.004	0.40	0.08	20.00	0.994
DB	78	0.14	0.40	0.35	20.00	0.990
TC	71	5.50	20.00	9.73	10.00	0.986
TG	74	4.32	40.00	14.11	25.00	0.997
HDL-c	72	2.52	-	5.85	20.00	0.976
LDL-c	74	1.90	-	6.41	20.00	0.988
UA	44	0.06	6.00	0.46	17.00	0.999

To determine the reportable range, we determined the lowest and highest measurable value for each test. For this purpose, a series of diluted standard solutions with different concentrations were prepared. Each prepared sample was then analyzed in triplicate. We calculated the average of these triplicate measurements and then calculated %bias by comparing the observed values with their calculated theoretical concentrations. For a test to be considered acceptable, %bias had to be less than TEa. In this study, all 15 tests met this criterion, with the respective errors remaining within acceptable limits. Furthermore, the linearity plots for all tests showed a consistent linear relationship across the respective reportable ranges, as presented in Table 4.

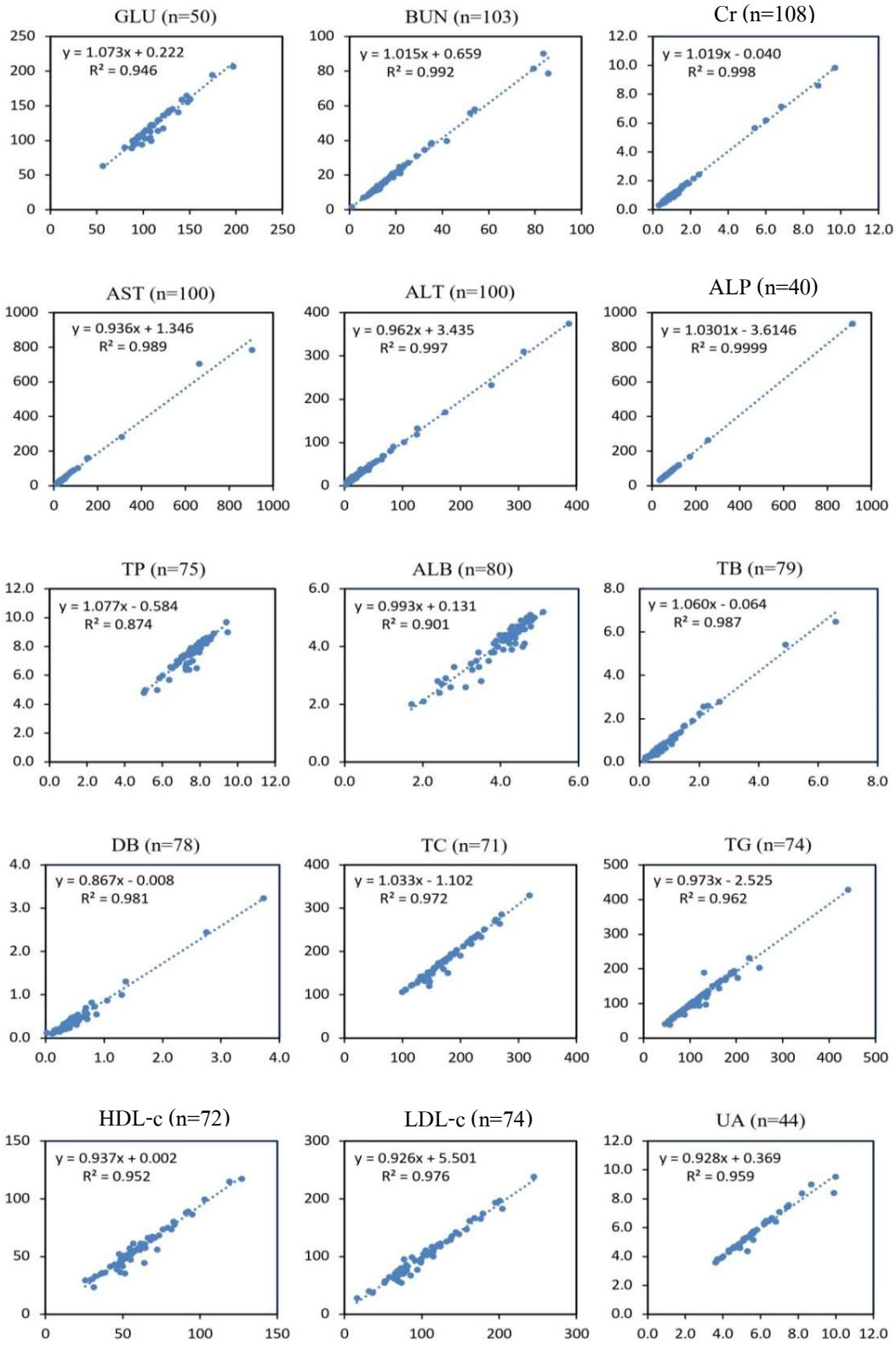


Figure 1 The comparative testing showed the correlation between the Cobas®pro Chemistry Analyzer (displayed on the X-axis) and the Mindray BS 430 analyzer (displayed on the Y-axis).
Units of GLU, BUN, Cr, TB, DB, TC, TG, HDL-c, LDL-c, and UA were expressed as mg/dL.
Units of TP and, ALB were expressed as g/dL
Units of AST, ALT, and ALP were expressed as U/L.

Table 4 Evaluation of reportable range using the linearity experiment method was analyzed by BS 430 analyser.

Analyte	Analytical range	%Bias	Acceptable TEa	Linearity
GLU (mg/dL)	0 - 249	2.11 - 7.65	10.00	5 - 594
BUN (mg/dL)	0 - 61	0.40 - 4.52	9.00	1 – 112
Cr (mg/dL)	0 - 4.2	0.03 - 0.07	10.00	0.1 - 79.3
AST (U/L)	0 - 155	0.07 - 5.28	20.00	4 – 800
ALT (U/L)	0 - 149	1.40 - 3.45	20.00	4 – 800
ALP (U/L)	0 - 233	3.10 - 7.73	30.00	3 – 1200
TP (g/dL)	0 - 8.4	0.26 - 0.62	10.00	0.2 - 12.0
ALB (g/dL)	0 - 4.9	0.20 - 0.37	10.00	0.3 - 6.0
TB (mg/dL)	0 - 3.3	0.03 - 0.68	20.00	0.1 - 35.1
DB (mg/dL)	0 - 2.7	0.01 - 0.10	20.00	0.1 -15.2
TC (mg/dL)	0 - 171	2.96 - 9.89	10.00	4 -769
TG (mg/dL)	0 - 209	4.15 - 11.97	25.00	9 – 1,106
HDL-c (mg/dL)	0 - 52.6	1.28 - 4.68	20.00	2 – 232
LDL-c (mg/dL)	0 - 108	3.50 - 18.34	20.00	2 - 773
UA (mg/dL)	0 - 10.8	0.08 - 0.46	17.00	0.4 - 25.2

Discussion

Mindray BS 430 automated blood chemistry analyzer was tested for performance by the manufacturer, in precision value accordance with the NCCLS Approved Guideline EP5-A (NCCLS., 1999) and method comparison that compares between Mindray system (Mindray BS series analyzers) and Hitachi/Roche system (Hitachi /Roche, IFCC). All tests were accepted in the criteria. Although the performance has been tested previously, users should be assured that this automated, despite being cheaper, offers the same quality as those made in the Western countries. Evaluation of the precision or random error of the Mindray BS 430 analyzer, based on the calculated %CV of the analyses, showed satisfactory performance in within-run and day-to-day precision.

All 15 assays met the predefined acceptance criteria. However, the calculated %RSD of intermediate precision for the TB, HDL-c and LDL-c assays exceeded the criteria. A larger value for intermediate precision indicates a greater variation in results, e.g. on different days, by different analysts, different reagent lots, different operators or different instruments within the same laboratory (CLSI., 2014). In the present study, the major factors may influence the analysis results. First, the time interval between tests can play a significant role. If tests are conducted at close intervals in a stable environment, the resulting values will be quite similar. Conducting tests over a longer period may yield results with greater variability. Second, the preparation process for material control, carried out by different technicians and the limited diversity and the properties of control materials, can also impact the results. However, the acceptable %RSD value varies significantly depending on the analytical method, the sample matrix, the sample concentration, and the purpose of the analysis (e.g., assay or impurity testing), and the criteria for RSD $\leq$ 15% from other studies are acceptable (Peters *et al*., 2009). Nevertheless, all tests demonstrated consistent within-run and day-to-day precision, aligning with criteria established in similar studies. Such as evaluating automated clinical chemistry analyzers, Mindray BS-2000M biochemical analyzer also reported satisfactory precision, with almost all assays having %CV acceptable criteria both in within-run and between-run precision (Feng-hua *et al*., 2017). Similarly, the Mindray BS-2800M was evaluated as a performance analyzer, demonstrating excellent intra-laboratory repeatability with all analytes having coefficients of variation of less than 2% (Dubo *et al*., 2024). These

consistent results across different analyzer evaluations underscore the importance of robust precision to the quality and reliability of laboratory results, which is fundamental to accurate diagnosis and patient monitoring. To assess accuracy, which evaluates systematic error (SE), the Cobas® pro Chemistry Analyzer from Roche, located at Phramongkutklao Hospital, was selected as the reference instrument. This decision was supported by several factors: the widespread use of this system in many Thai laboratories, the shared analytical principles with the Mindray BS 430 analyzer for most tests, and the hospital's status as an ISO 15189-certified laboratory, which confirms its high standards and suitability as a reference. Careful selection of a reference method or instrument is a cornerstone of method comparison studies, ensuring the validity of the comparison through the use of a well-established and certified benchmark (Düz ME. *et al*, 2023). The evaluation of SE, all assays evaluated showed acceptable and met the established criteria except GLU. In addition, regarding the correlation coefficient (r) between the two analytical methods, a very strong relationship was observed across all tests, with r values ranging from 0.90 to 1.00. The generally accepted criterion for method evaluation requires an r value greater than 0.975 to indicate a very high correlation and sufficient data coverage of the reportable range (Westgard OJ. , 2024). Twelve of the 15 tests met this strict criterion, including TC, TG, HD-c, LDL-c, BUN, Cr, UA, DB, TB, ALT, AST and ALP. Achieving such high correlation coefficients for most analytes underscores the substantial agreement between the Mindray BS 430 and the Cobas® pro Chemistry Analyzer, indicating their potential interchangeability for these specific tests. Similarly high correlation coefficients were found in comparisons of other modern integrated analyzers such as the Mindray BS-2000M biochemical analyzer when compare with the Roche cobas702 detection system was used as the reference system. All the correlation coefficients of all parameters between the two instruments were $r^2 > 0.95$, $p < 0.01$ (Feng-hua *et al*., 2017) providing further evidence that new systems can achieve excellent analytical performance. However, three tests showed r values below 0.975: GLU yielded r values of 0.973, while ALB and TP had r values of 0.949 and 0.935, respectively. The value was found to be below the specified criteria, yet it remains within the acceptable range. These results are consistent with previous research by Taneyhill (Taneyhill *et al*., 2015), who evaluated the Biosystems BA400 analyzer and also reported lower r values for albumin and total protein compared to other assays. The observed discrepancies in the accuracy of these specific assays could be due to several factors, including inherent methodological differences between analyzers. In this study, TP and ALB most of the samples for analysis from the hospital had neither high nor low values. This resulted in a linear regression equation and r value. Therefore, the solution to the problem may involve adding sample size and coverage at high and low levels, which can significantly impact the performance and results of regression analysis. Moreover, sample stability and the time interval between analyzes are crucial pre-analytical factors that can affect the results. It is generally recommended that measurements in comparative studies be performed simultaneously, ideally within a 2-hour window (CLSI., 2018). A notable limitation of this study was the geographical distance between Phramongkutklao Hospital (Bangkok) and the Medical Technology Clinic of Rangsit University. (Pathum Thani). Traffic congestion often extended sample transportation time beyond the recommended 2-hour limit, which may have contributed to the observed differences in results for certain tests, particularly for more labile analytes especially in glucose. This highlights the ongoing challenge of managing pre-analytical variables, which can lead to analytical errors and affect the overall quality and reliability of laboratory results (Düz *et al*., 2023). Additionally, for tests that do not meet the criteria, it is recommended to conduct a re-evaluation for each laboratory. The evaluation of the reportable range of an analyzer, also known as linearity, is a critical component of performance evaluation in clinical chemistry. This process determines the range of analyte concentrations within which the analyzer can provide accurate and reliable results without dilution or pretreatment (CLSI, 2020). For the Mindray BS 430

analyzer, the reportable range assessment was performed in accordance with established guidelines, CLIA standards, to ensure that the analyzer is capable of accurately quantifying analytes across a clinically relevant range of concentrations. This is critical to patient care as it ensures that results are reliable for both very low and very high concentrations, minimizing the need for sample manipulation and reducing potential errors. Other analytical evaluations of clinical chemistry analyzers, such as the Mindray BS-2000M, similarly include linearity assessments to confirm their robust analytical measurement capabilities over their intended operating ranges (Feng-hua *et al*., 2017). The demonstrated acceptable precision and accuracy across the 15 assays assessed implicitly suggest that the analyzer has a robust analytical measurement range suitable for routine use in clinical laboratories. The analyzer's ability to provide consistent results across its measurement range is crucial for reliable patient diagnosis and monitoring. However, there may be a limitation in this study due to Mindray's material control; both values have a narrower range than the linearity value reported by the company. As a result, the values obtained in the study may not cover the linearity value. Nevertheless, the range for determining in our study was appropriate because most of the Medical Technology Clinic of Rangsit University utilizes students and staff whose test results are slightly abnormal. Therefore, the results are comprehensive for the group receiving the service. Suggesting in this result, it is recommended that general laboratories in hospitals use material controls or standard substances to obtain values that cover the linearity value of the automated method and add the analytical percentage recovery for completeness in the reportable range. The comprehensive evaluation of the Mindray BS 430 automated clinical chemistry analyzer at the Medical Technology Clinical of Rangsit University yielded significant findings regarding its analytical performance. Across all assessed parameters—precision, accuracy, and reportable range—the analyzer demonstrated acceptable performance, meeting the stringent criteria set by manufacturer specifications and regulatory guidelines, such as CLIA standards. Furthermore, the strong correlation observed between the Mindray BS 430 and the Cobas pro Chemistry Analyzer for most assays underscores its reliability as a comparable analytical platform, even with noted discrepancies in a few specific analytes that are influenced by pre-analytical factors.

The successful validation of the Mindray BS 430 is of considerable significance for clinical laboratory practice. In an era where rapid and accurate diagnostic information is paramount, automated analyzers play a pivotal role in enhancing patient care by reducing turnaround times, improving result accuracy, and minimizing human error (Ruffing *et al*., 2024). The demonstrated analytical capabilities of the Mindray BS 430 confirm its suitability for integration into routine laboratory operations, contributing to efficient workflow and reliable patient management. This aligns with the broader demand for new-generation diagnostics that provide highly detailed data for precise diagnoses and faster treatment plans (Takkalaki *et al*., 2025). Furthermore, in the present study, the results of method validation are similar to a previous study that evaluates method performance of the Mindray CL-2000i chemiluminescence system (Puttaruk P., 2016), the Mindray BS-2000M for biochemical analyzer (Feng-hua, 2017), the Mindray BS2000M for myocardial enzyme and immunological tests (Mingxing *et al*., 2022), and for the detection of biochemical parameters in cerebrospinal fluid (Dubo *et al*., 2024). Moreover, these findings reinforce the importance of continuous quality management in clinical laboratories. The acceptable performance of the Mindray BS 430 contributes positively to maintaining the reliability and accuracy of clinical laboratory results, which is essential for accurate diagnosis and monitoring treatment outcomes (Sindhu *et al*., 2025). Despite the minor discrepancies noted for certain analytes, the overall robust performance of the Mindray BS 430, supported by rigorous evaluation, positions it as an asset for the Medical Technology Clinical Laboratory at Rangsit University.

Due to the increasing use of automated analyzers from Asian manufacturers in Thai laboratories, this study

represents the first study in method evaluation of the Mindray BS 430 analyzer under natural laboratory conditions. The results of the Mindray BS 430 analyser test show that the accuracy, precision and linearity meet the company's specifications and are within acceptable standards. This ensures the usability of the analyzer for routine analysis. If more than one analyzer is used for the same test with the same principle, a method evaluation can help operators and service recipients and ensure the accuracy and consistency of laboratory analysis reports, regardless of when and with which instrument they are used. In addition, method evaluation is available to ensure that operators and service recipients can be confident in the accuracy and consistency of laboratory analysis reports, regardless of the time of use or the instrument used. Moreover, the cost of the analyser is lower than that of traditional Western manufacturers, which shows cost-effectively. Therefore, the data obtained from this study is potentially useful for evaluating and deciding on the selection and use of an automated analyzer in other laboratories.

Conclusion

The Evaluation of the Mindray BS 430 automated clinical chemistry analyzer indicated its acceptable analytical performance across all assessed parameters. Specifically, the study demonstrated satisfactory precision, acceptable accuracy, and a confirmed reportable range for all 15 evaluated assays. A strong correlation was observed between the Mindray BS 430 and the Cobas® pro Chemistry Analyzer, suggesting substantial agreement between the two methods for most analytes. These findings collectively support the Mindray BS 430's capability to provide reliable results, making it suitable for routine diagnostic use within the Medical Technology Clinic of Rangsit University.

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Conflict of interest

The authors declare no conflict of interest

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