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Research article

Ensure the accuracy and consistency of biochemical analyzer test results: Chemometrics for instrument and inter-instrument item comparison in Chinese hospital laboratory

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ABSTRACT

Biochemical analyzers are vital instruments that utilize the principle of photoelectric colorimetry to quantify a specific chemical composition in body fluids. This analysis provides critical data for the diagnosis, treatment, prognosis, and overall health status of various diseases in clinical practice. However, the performance of a biochemical analyzer can vary significantly between different brands or over time within the same brand. Therefore, it is imperative to regularly assess the performance of the analyzer to ensure consistent results for longitudinal studies and to maintain day-to-day data consistency. Additionally, when multiple analyzers are utilized, it is necessary to evaluate the performance of each instrument to ensure accurate results across multiple platforms. In this study, we developed and verified an experimental evaluation scheme for the analytical performance of the instrument, chemometrics for biochemical analyzers, utilizing national reference materials and patient sera as the experimental subjects. We evaluated the performance of the optical system, temperature control system, sample-adding system, and detection system to confirm the feasibility of this scheme. We also compared the analytical performance of different brands of biochemical analyzers for routine biochemical tests, such as liver function, kidney function, ion, blood lipids, blood glucose, and myocardial enzyme spectrum. Using the AU 5400 as a control and the ADVIA 2400 as the comparison system, the relative variation in inter-instrument comparison data was found to be acceptable at the clinical medicine decision level. In conclusion, the performance of a biochemical analyzer can vary significantly between different brands or over time within the same brand. Regular evaluations are necessary to ensure accurate and consistent results across different analyzers. This study provides a feasible scheme for evaluating the analytical performance of biochemical analyzers that can be used to ensure the accuracy and consistency of the results of different brands of automatic chemical analyzers in the laboratory.

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1. Introduction

Clinicians require a large number of measurements of biological quantities that clinical laboratories perform for diagnosis, prognosis, monitoring, early detection, screening, risk classification, treatment selection, and disease surveillance [1,2]. The function of a clinical laboratory is to collect, process and analyze blood, body fluids, and other human materials scientifically under controlled circumstances, and to provide the results for clinical decisions. As shown in Fig. 1A and B, the right treatment starts with the right diagnosis. Patients and healthcare professionals, therefore, need to be able to trust medical devices that help them make reliable diagnoses, such as in vitro diagnostic medical devices [3].

The instrument is an integral part of a medical laboratory. Currently, the automatic biochemical analyzer is the main detection instrument in clinical biochemistry laboratories. Biochemical analyzer belongs to optical analytical instruments, which are based on

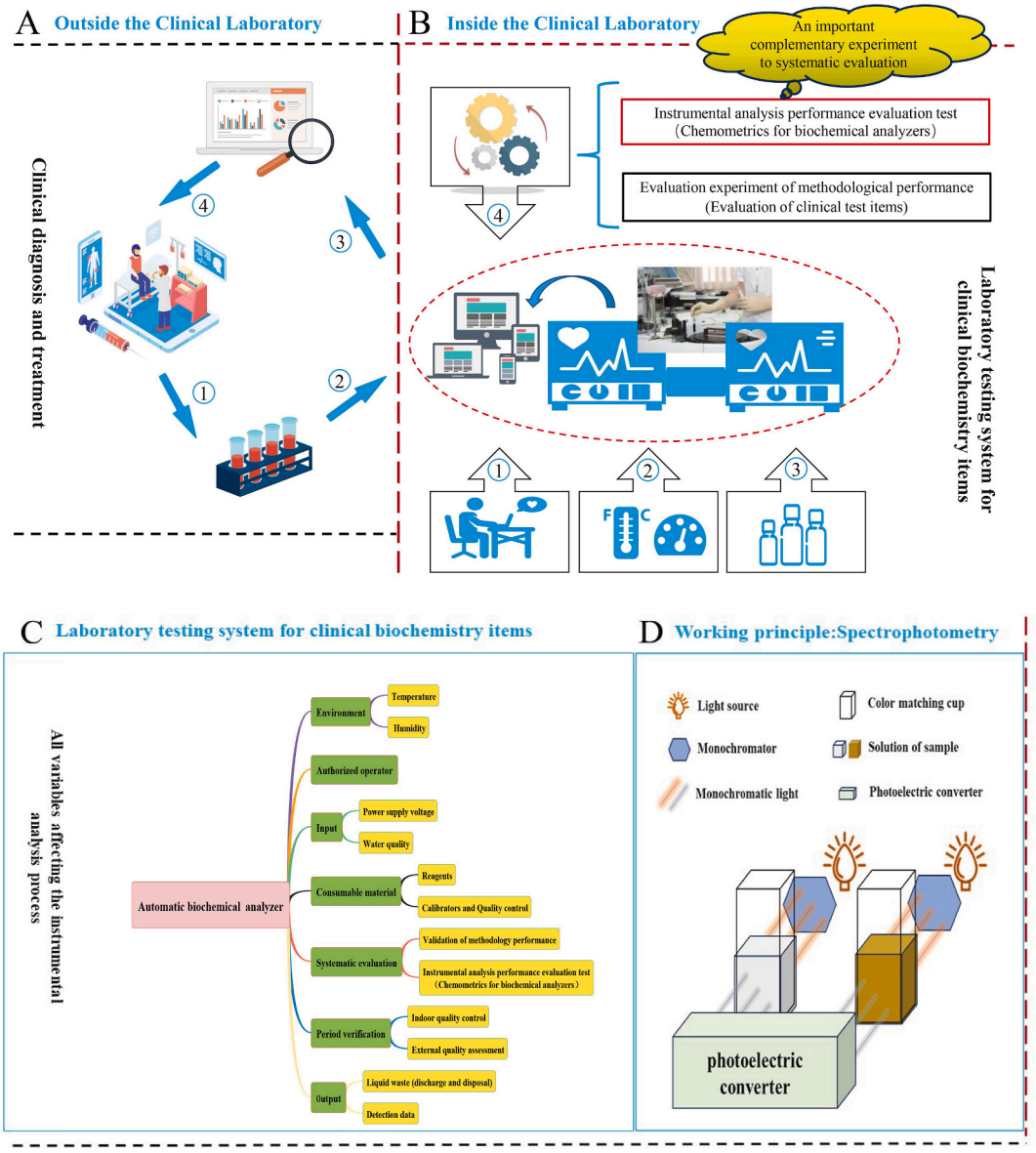

Fig. 1. Clinical diagnosis and treatment and Laboratory testing
Outside the clinical laboratory (A): the process of clinician's clinical diagnosis and patient's treatment, including ① Draw blood, ② Delivery of blood samples, ③ Issue laboratory test report, ④ Clinical diagnosis and treatment. Inside the clinical laboratory. (B): influencing factors of laboratory test accuracy, including ① The operation of authorized personnel, ② Ambient temperature and humidity, ③ Reagents and consumables, ④ Quality management of testing system. Laboratory testing system for clinical biochemistry items. (C): All variables affecting the instrumental analysis process, including ambient temperature and humidity, authorized operators, consumables, systematic evaluation, period verification, input and output, etc. Working principle of biochemical analyzer: Spectrophotometry (D).

the selective absorption of light by substances (that is spectrophotometry). As shown in Fig. 1D, the monochromator divides the polychromatic light emitted by the light source into monochromatic light. The monochromatic light of a specific wavelength passes through the colorimetric cell containing the sample solution, and the photoelectric converter converts the transmitted light into an electrical signal and sends it to the signal processing system for analysis. In Fig. 1C, we can observe all the variables that affect the instrument analysis process, including ambient temperature and humidity, input power supply voltage, input water quality, authorized operators, consumables, systematic evaluation, period verification, output, etc. With the accumulation of instrument running time, the increase of daily detection frequency, and the aging of some parts, these factors will affect the analytical performance of the instrument. It even causes systematic bias, which results in detection results that are far from the true value. We hope to develop a performance evaluation scheme for instrument analysis to detect such systematic deviations and make targeted corrections to ensure the accuracy and consistency of test results, to achieve the chemometrics for biochemical analyzers.

Quality in laboratory medicine, a never-ending quest, has been defined as “an unfinished journey” [4]. Testing quality is the lifeblood of our laboratory, and quality control is a process of continuous improvement that is always on the way. No less than 2000 tubes of biochemical samples should be tested daily in the clinical biochemistry laboratory of Handan Central Hospital. Under such a large test load, our laboratory must regularly conduct a systematic evaluation of equipment and period verification to ensure the accuracy of experimental data. At present, there are many pieces of research on period verification, such as internal quality control and external quality assessment [5–8]. Almost all research on the systematic evaluation of instruments focuses on methodological performance verification and validation experiments of clinical items [9–13], and almost no one pays attention to the analytical performance evaluation of the instrument itself. Therefore, the research direction of our team focuses on the automatic biochemical analysis instrument itself stoichiometric scheme design and feasibility analysis.

This study referred to the Chinese industry specification document YY/T 0654–2017 ″Automatic Biochemical Analyzer”, the National Center for Clinical Laboratories (NCCL) –" External Quality Assessment Program”, “Application Requirements of Accreditation Criteria for the Quality and Competence of Medical Laboratories” CNAS-CL02-A001, and the international standard for the quality and competency of medical laboratories is the International Organisation for Standardisation’s ISO 15189:2012 [14–16]. Taking the automatic biochemical analyzer as the experimental object, the analytical performance of the instrument was experimentally evaluated in the following aspects: operating environment and state, stray light, the linear range of absorbance, accuracy of absorbance, repeatability of absorbance, stability of absorbance, accuracy, and fluctuation of temperature, contamination rate for sample needles, accuracy and repeatability of sample addition, and inter-instrument item comparison. The reference materials selected in this study were the standard solutions that were determined and corrected by the China Institute of Metrology and can objectively reflect the analytical performance of the biochemical analyzer. It was hoped that the performance evaluation scheme for instrument analysis could provide a reference for medical laboratory accreditation, hospital grade accreditation, and daily equipment management. More importantly, it could help us provide more accurate experimental data for clinicians and patients.

2. Materials and methods

2.1. Instruments and reagents

ADVIA2400 automatic biochemical analyzer (Siemens), AU5400 automatic biochemical analyzer (Beckman Coulter), and portable multi-probe thermometer (accuracy 0.1 °C, range 0–50 °C, Calibrated by a third party). All measurements were performed following the standardized operating procedures provided by the manufacturer. All assays were carried out in the central laboratory by experienced operators at the Handan Central Hospital in a blinded manner

National reference material (Produced by the Chinese Academy of Metrology): Certificate numbers GBW(E)130629–130630 (Batch No. 22093), GBW(E)130631–130635 (Batch No. 22074), and NIM-RM 2025-2 (Batch No. 22084). Beckman Coulter and Siemens originally assembled a biochemical kit and calibration solution.

2.2. Sample of experiment

This study collected samples that underwent biochemical testing by Handan Central Hospital, with reports issued and ample residual samples in each tube for possible further examination. Serum samples were collected after testing to prepare pooled serum, mixed, and divided into two aliquots for intra-batch precision of the clinical test. Meanwhile, fresh serum was collected for inter-instrumental comparison of quantitative items in clinical biochemistry, and the analyte concentration in the sample was required to cover the linear range as far as possible, including clinical medicine decision level. The study was approved by the Ethics Committee of Handan Central Hospital.

2.3. Optical system experiment

2.3.1. Stray light detection

Stray light detection of biochemical analyzer filters: the optical density value (OD) of reference material for the verification of clinical chemistry analyzers (Chinese Academy of Metrology, NIM-RM 2025-2) was measured at 340 nm with distilled water as a blank. Triplicate experiments were averaged and the $OD_{(Stray\ light,\ 340nm)}$ was required to be ≥ 2.3000 [14]. The calculation formula is as follows:

$OD_{(Stray\ light,\ 340nm)} = OD_{(Reference\ material)} - OD_{(Distilled\ water)}$

2.3.2. Linear range of absorbance

Distilled water was used as the reagent at 505 nm (ADIA 2400) and 520 nm (AU 5400), while the linear range reference material (Chinese Academy of Metrology, GBW(E) 130631–130635) was taken as the sample. The detection sequence is *3-1, 3-2, 3-3, 3–4, and 3–5*. Each concentration was measured three times, and the correlation coefficient ($R^2 > 0.95$) and deviation (less than ±10 %) were calculated. The maximum absorbance should be no less than 2.3000 with a relative bias within ±5 % [14].

2.3.3. Accuracy of absorbance

Using distilled water as a blank, the biochemical absorbance reference materials *1-1* and *1–2*(Chinese Academy of Metrology, GBW(E)130629–130630) were determined at 340 nm. Each reference sample was triply measured. The difference between the arithmetic Mean and the target value was an error, and the allowable errors of absorbance were ±0.025 and ± 0.07, respectively [14].

2.3.4. Stability of absorbance

The stability of the 340 nm primary wavelength, the biochemical absorbance reference material *1-1* (Chinese Academy of Metrology, GBW(E)130629) was evaluated using distilled water as the blank. The range between maximum and minimum absorbance should not exceed 0.01 [14].

2.3.5. Repeatability of absorbance

The repeatability of the 340 nm primary wavelength, the biochemical absorbance reference material *1–2* (Chinese Academy of Metrology, GBW(E)130630) was evaluated using distilled water as the blank. The coefficient of variation (CV) of the absorbance repeatability test should not exceed 1.5 % [14].

2.4. Temperature control system experiment

2.4.1. Temperature accuracy and fluctuation detection

The portable temperature sensor was inserted into the colorimetry tube. After reaching temperature equilibrium, the detection process was repeated 20 times with a 30-s interval between each measurement. The temperature accuracy value (the difference between the mean and the set temperature value) was required to be less than ±0.3 °C, and the fluctuation (half of the difference between the maximum and the minimum) did not greater than ±0.2 °C [14].

2.5. Sample adding system experiment

2.5.1. Accuracy and repeatability of sample addition

Distilled water was used as the blank for 505 nm measurements on ADVIA 2400 and 520 nm measurements on AU 5400. Reference material 3–5(Chinese Academy of Metrology, GBW(E) 130635) was utilized as the sample. The reaction volume was the minimum specified by the instrument, and the detection was repeated 20 times to determine the concentration value [14].

2.6. Testing system experiment

2.6.1. Sample needle carrying contamination rate

Using distilled water as the blank, Low and High concentration values of reference materials (Chinese Academy of Metrology, GBW(E)130631, 130635) as samples, and the reaction volume was the minimum specified by the instrument. Samples were taken in the order of *Low, Low, Low, High, Low, High, Low, High, Low, Low, Low* and *Low* for testing. The carrying contamination rate of the sample needle was then calculated on both instruments. Carrying contamination rate = $[(Mean_{LH} - Mean_{LL})/(Mean_{HH} - Mean_{LL}] *100$, and the maximum carrying contamination rate of the sample needle was not more than 0.1 % [14].

2.6.2. Intra-batch precision of clinical test

Using the prepared pooled serum, clinical items were tested, and the assay was repeated 20 times for each item. The coefficient of variation was required to be ≤ 5 % for ALT and ≤2.5 % for Urea and TP, respectively [14].

2.7. Protocol for inter-instrument comparison of quantitative items in clinical biochemistry

Beckman AU5400 and Siemens ADVIA2400 were used as reference and comparison systems, respectively. We performed the protocol for inter-instrumental comparison of quantitative items in clinical biochemistry, including liver function, kidney function, ion, blood lipids, blood glucose, and myocardial enzyme spectrum and other items. Twenty samples for each clinical quantification program were measured on each assay system in the order of 1,2,3 … 18,19,20, and then 20,19,18 … 3,2,1. Linear regression analysis was performed to calculate the systematic bias (relative bias) at each sample concentration level and medical decision level. The

relative bias at each medical level should not exceed 1/2 of the allowable total error (Tea), which was selected according to the National Center for Clinical Laboratories (NCCL) - Inter-examination Quality Assessment Program [14–16].

2.8. Statistics

All data were statistically analyzed by SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). Data were checked for normality and homogeneity of variances. The Wilcoxon rank-sum test was used to analyze the difference between the 2 groups, and $P \leq 0.05$ was considered significant. GraphPad Prism software version 9.0.0 (La Jolla, CA) was utilized to plot the graphs.

3. Results

3.1. Instrument operating environment and status detection

Before performing the experimental evaluation, we checked the operating environment and status of the instrument. The ambient temperature and humidity of the experimental instrument were 24° Celsius and 50 % relative humidity, the input voltage was 220 V, and the electrical conductivity of the water supply to the instrument was 0.550 μS/cm (ADVIA 2400) and 0.625 μS/cm (AU5400), respectively.

3.2. Evaluation experiment of the automatic biochemical analyzer in the optical system

The results of the evaluation experiments on the optical system of the automatic biochemical analyzer are shown in Table S1. The absorbance values of stray light were 5.1200(±0.0073) and 5.8116(±0.0598), respectively. At 505 nm (ADVIA 2400: $y = 1.0008x + 0.0498$) and 520 nm (AU5400: $y = 2.0107x - 0.028$), the correlation coefficients for the absorbance linearity of the tested reference materials were all $R^2 = 1.0000$, and the largest deviations of the linear reference substances were −2.00 % and 1.87 %. The error in absorbance accuracy at 340 nm did not exceed the allowable errors. The range of absorbance stability between maximum and minimum was 0.00995 (ADVIA 2400) and 0.0040 (AU 5400), and the coefficient of variation of the absorbance repeatability test was 0.4719 % (ADVIA 2400) and 0.6167 % (AU 5400), respectively.

3.3. Evaluation experiment of the automatic chemical analyzer in temperature control

We assessed the accuracy and fluctuation of the temperature in the incubation tank and reagent compartment, as outlined in Table S2 of the findings. The incubation tank and reagent compartment of the ADVIA 2400 were set at 37 °C and 12 °C, while those of the AU 5400 were set at 37 °C and 8 °C, respectively. The accuracy and fluctuation of the temperature of the Siemens were 0.02 °C, 0.10 °C (incubation tank 37.02 ± 0.05 °C), 0.05 °C, 0.05 °C (R1 reagent chamber 12.05 ± 0.05 °C), and −0.04 °C, 0.05 °C (R2 reagent chamber 11.97 ± 0.05 °C). The accuracy and fluctuation of the temperature of the Beckmann Coulter were −0.03 °C, 0.05 °C (incubation tank 36.98 ± 0.04 °C), −0.04 °C, 0.10 °C (R1 reagent chamber 7.96 ± 0.07 °C), and 0.01 °C, 0.10 °C (R2 reagent chamber 8.01 ± 0.06 °C).

3.4. Evaluation experiment of the automatic biochemical analyzer in sample adding system

The accuracy and repeatability of the sample volume taken by the sample needle are shown in Table S3. In the minimal reaction system, the accuracy and repeatability of sample needle uptake were detected as follows: −1.16 %, 0.86 % (ADVIA 2400), and −2.53 %, 1.21 % (AU 5400).

3.5. Evaluation experiment of the automatic biochemical analyzer in the detection system

The sample needle carrying contamination rate and intra-batch precision of clinical test items were tested, and the results are shown in Table S4. The maximum carrying contamination rate detected by the sampling needle on both instruments was 0.021 %. Using the prepared pooled serum, the intra-batch precision of clinical biochemistry quantitative items showed that the CV of ADVIA 2400 was 3.05 % for ALT, 1.55 % for Urea, and 0.84 % for TP, and the CV of AU 5400 was 3.68 % for ALT, 1.76 % for Urea, and 1.24 % for TP, respectively.

3.6. Inter-instrumental comparison of quantitative items in clinical biochemistry

Beckman AU5400 and Siemens ADVIA2400 were used as reference and comparison systems, respectively. We performed the protocol for inter-instrumental comparison of quantitative items in clinical biochemistry, including liver function, kidney function, ion, blood lipids, blood glucose, and myocardial enzyme spectrum and other items. As shown in Table S5, the distribution of the difference between the two systems did not meet the normality test. Using AU5400 as a control, the Wilcoxon rank-sum test was used to analyze the difference between the two groups, and statistically significant differences were observed in detection data between the two instruments for ALT ($Z = -3.758$, $P<0.001$), Urea ($Z = -3.065$, $P = 0.002$), and TP ($Z = -3.724$, $P<0.001$).

We also performed a linear regression analysis of the measured data between the two instruments. As shown in Fig. 2 and Fig. S1,

we made the horizontal axis and vertical axis of the linear regression plot with reference system instruments (AU 5400) and comparison system instruments (ADVIA 2400), respectively. The regression equation for the ALT item was $Y = 1.029*X + 0.2098$, $R^2 = 0.9999$. The regression equation for the TP item was $Y = 0.9690*X + 2.508$, $R^2 = 0.9925$. The regression equation for the Urea item was $Y = 1.029*X - 0.08511$, $R^2 = 0.9997$. A linear regression analysis was performed to calculate the relative bias at each sample concentration level and medical decision level. From Table S6, using the AU 5400 as a control and the ADVIA 2400 as the comparison system, the relative variation in inter-instrument comparison data was found to be acceptable at the clinical medicine decision level, including liver function, kidney function, ion, blood lipids, blood glucose, and myocardial enzyme spectrum and other items.

4. Discussion

Clinical laboratories perform over 7 billion tests per year, the results of which affect patient care decisions, so it is imperative that the results of these tests are as accurate as possible [17]. Moreover, most laboratories issue test reports after only one test, so it is very important to conduct systematic evaluation experiments of equipment regularly. Systematic evaluation experiments can usually be carried out from two aspects: the verification or validation of the methodological performance of clinical testing items [9–13] and the experimental evaluation of the analytical performance of the instrument itself, but the latter is rarely studied. This study took the AU5400 and ADVIA2400 biochemical analyzers as the research objects and designed and verified the analytical performance evaluation experiments of the instruments according to the industry norms of our country and the world standards [14–16]. To achieve the chemometrics and traceability of quantity value for biochemical analyzers, we focused on evaluating the analytical performance of the instrument, specifically that of the optical system, temperature control system, sample-adding system, detection system and inter-instrument item comparison.

The optical system is the core of the automatic biochemical analyzer. Biochemical analyzers belong to optical analysis instruments, based on Lambert-Beer law and spectrophotometry. This study mainly evaluates the optical system in terms of stray light, linear range,

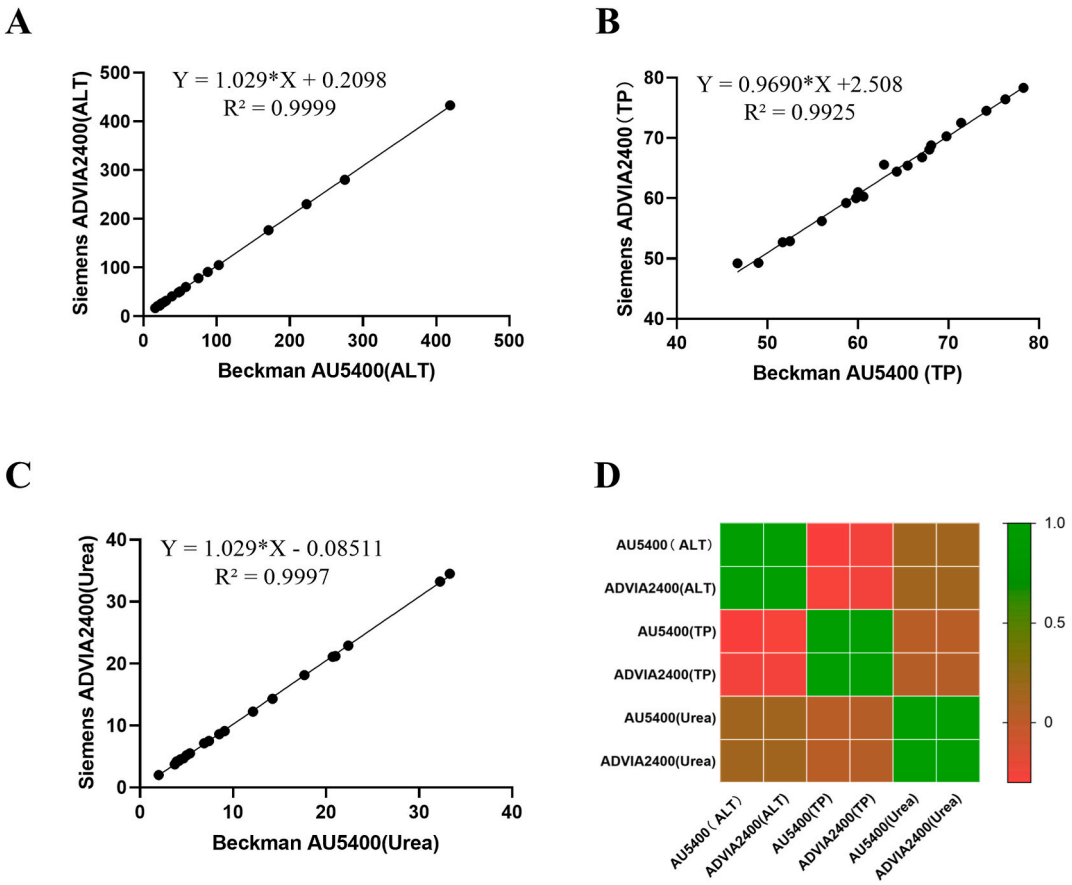

Fig. 2. Simple linear regression plots and HeatMap of Spearman correlation coefficient between instruments for clinical biochemical quantitative items. The mean values measured by the reference system instruments (Beckmann AU5400) were taken as the horizontal axis, and the mean values measured by the comparison system instruments (Siemens ADVIA2400) were taken as the vertical axis. The clinical biochemistry quantitative items represented in panels A, B, and C are simple linear regression plots for Alanine aminotransferase (ALT), Urea nitrogen (Urea), and Total protein (TP), respectively. Spearman correlation coefficient HeatMap between instruments for clinical biochemical quantitative items (D).

accuracy, stability, and repeatability of absorbance results. Stray light is light outside the measurement wavelength that deviates from the normal light path and reaches the detector. It is one of the main sources of analytical errors in optical analytical instruments, which directly limits the upper limit of the sample concentration to be analyzed and tested [14,18,19]. Therefore, manufacturers and users need to study the stray light carefully to reduce its influence on the biochemical analyzer. It is very necessary to detect stray light in the experimental evaluation of the analytical performance of the instrument. The stray light, linear range, accuracy, stability and repeatability of absorbance results are shown in Table S1. If any of these components cannot be passed, consideration should be given to replacing either the light source or the cuvette to ensure optimal analytical performance of the optical system. Experimental data showed that both automatic biochemical analyzers achieved the target analytical performance within their optical systems, in accordance with our preset specifications.

The temperature control system is the guarantee of instrument analysis. All kinds of chemical reactions in the biochemical analyzer, especially enzymes, are very sensitive to temperature fluctuations [20–23] and require a constant temperature to obtain reliable and accurate results. Generally, the temperature accuracy is controlled within 0.3 °C, and the temperature fluctuation is controlled within 0.2 °C. We tested the temperature in the incubation tank and reagent compartment for accuracy and fluctuation, as detailed in Table S2 of the results. The temperature control system met the evaluation criteria set out in our experiment. Helmuth Haslacher et al. evaluated the impact of repeated temperature fluctuations, as they occur in most research biobanks due to repetitive opening and closing of freezer doors, on the stability of 26 biochemical analytes [24]. If any anomalies were detected in the accuracy or stability of the temperature control system during the evaluation experiment, it is imperative that appropriate measures be taken as such deviations can significantly affect the results of the chemical reaction.

The sample-adding system is the basis for the analysis. With constant technological progress, the minimum sample volume that can be drawn by the sample injection needle within the specified error limits has gradually decreased. We found that the reference material was tested 20 times in duplicate under the minimum reaction volume specified by the instrument. The coefficient of variation and error of the measured absorbance were calculated, and in the minimal reaction system, the accuracy and repeatability of the sample needle uptake sample were detected as follows: −1.16 %, 0.86 % (ADVIA 2400), and −2.53 %, 1.21 % (AU 5400). Therefore, we can infer that under the normal sample intake reaction system, the accuracy and repeatability of the injection of this instrument can be affirmed and trusted. In cases where the sample contains high concentrations of metabolites or active enzymes, it is advisable to use the minimum sample volume for the analyzer to expand the upper limit of the detection range. Therefore, it is important to evaluate the accuracy and repeatability of the sample adding system.

The detection system, also known as the analysis system, converts sample information into output detection data. Since most clinical decisions are based on laboratory results, timely and accurate reporting of these results is critical [17,25]. The intra-batch precision of clinical biochemical quantitative items, comparisons between instruments, and the sample needle carrying contamination rate were all used in the experimental evaluation of the detection system. The maximum carrying contamination rate of ADVIA 2400 and AU 5400 was less than 0.1 %. Quantitative clinical biochemistry testing with in-batch precision showed that the CV for ALT on ADVIA 2400 was 3.05 %, whereas for Urea and TP, it was 1.55 % and 0.84 %, respectively. Similarly, the CVs for ALT, Urea, and TP on AU 5400 were 3.68 %, 1.76 %, and 1.24 %, respectively. The two instruments displayed quite strong detection capabilities in both regards.

Nevertheless, it is common in clinical laboratories to indistinctly measure a biological quantity with more than one identical measuring system (or different modules of the same measuring system) [2]. We therefore conducted an inter-instrument comparison experiment for clinical biochemical quantitative items in order to ensure the consistency of the detection data provided by various analytical systems. As shown in Table S5, the distribution of the difference between the two systems did not meet the normality test. Hence, using AU5400 as a control, the Wilcoxon rank-sum test was used to analyze the difference between the two groups, and statistically significant differences were observed in detection data between the two instruments for ALT ($Z = -3.758$, $P<0.001$), Urea ($Z = -3.065$, $P = 0.002$), and TP ($Z = -3.724$, $P<0.001$). Next, we also performed a linear regression analysis of the measured data between the two instruments. A linear regression analysis was performed to calculate the relative bias at each sample concentration level and medical decision level. Using AU5400 as a control, we found that the maximum expected deviations from ADVIA 2400 at the medical decision level were 5.7 % for ALT, 2.3 % for Urea, and 0.4 % for TP. As can be seen from Table S6, the relative deviation of routine liver function, kidney function, blood lipids, myocardial enzymes and other items at their clinical decision level did not exceed 1/2 TEa. Accordingly, after the experimental evaluation of the instrument test system, we believed that such a difference was inevitable. We considered that although the difference between the two instruments was statistically significant, it was expected to be acceptable at the clinical medicine decision level. Simple linear regression plots and HeatMap of spearman correlation coefficient were shown in Fig. S1 between instruments for clinical biochemical quantitative items, in order to guarantee the consistency of the testing results of two instruments, calibration was carried out on the ADVIA 2400 biochemical analyzer, compare again after correction for the slope of the regression equation is more close to 1, the cutting torque is also significantly reduced, The results of the two instruments are consistent, and the correlation coefficient is greater than 0.975, which meets the requirements of laboratory work and clinical needs. Both instruments demonstrated excellent analytical capabilities, and the experimental data indicated a robust linear correlation and consistency.

Quality has traditionally been the main focus of medical laboratories, up to the degree that no result is better than the wrong result [26]. Our study better reflected the fact that the evaluation experiment of the analytical performance of the instrument was a supplementary experiment to the systematic evaluation. In the process of carrying out the experimental evaluation of the analytical performance of the instrument, we may encounter a failed test item, and correcting it will reduce the risk of inaccurate test data. In the analytical performance evaluation experiment, we used the standard solution, which has been assigned and corrected by the Chinese Institute of Metrology. These standard materials can objectively reflect the analytical performance of instruments, and achieve

traceability of quantity values and chemometrics for biochemical analyzers. It is equally important to carry out the experimental evaluation of the analytical performance of the instrument and the performance verification or validation of the clinical project methodology. Laboratory procedures do not only comprise single devices for a corresponding measurement but often include complex multi-step schemes such as microscopic examinations, tuned spectroscopy, etc., requiring skilled laboratorians to make on-the-spot judgment calls [27]. We should observe all the factors affecting the instrument analysis process, including ambient temperature and humidity, input power supply voltage, input water quality, authorized operators, consumables, systematic evaluation, period verification, output, etc. The whole life cycle management of instruments and equipment should be carried out more scientifically to ensure that clinicians and patients have more real clinical laboratory test data.

At the same time, the evaluation of the analytical performance of medical laboratory instruments should not be limited to large-scale testing instruments such as biochemical analyzers, hemocytometers, coagulation analyzers, luminescence analyzers, etc. Other auxiliary instruments should also be included in the instrument performance assessment cycle and instrument calibration plans, such as water bath, vernier calliper, turbidity meter, medical refrigerator, medical centrifuge and pipettor, etc. Regardless of the size of the instrument, it can affect the accuracy of test results and then affect clinical diagnosis and treatment, which should attract the attention of laboratory colleagues.

In summary, we designed and validated a stoichiometric experimental evaluation scheme of the instrument analysis, which was feasible in identifying the deviation of the instrument system and making targeted corrections to ensure the accuracy and consistency of biochemical analyzer test results. Therefore, it is essential to regularly conduct stoichiometric experiments using the biochemical analyzer and conduct comparative evaluations of these instruments against clinical testing protocols in Chinese hospital laboratories.

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Informed consent

Not applicable.

Ethical approval

The study was approved by the Ethics Committee of Handan Central Hospital.

CRediT authorship contribution statement

Xue-Dong Song: Writing – review & editing, Writing – original draft, Visualization, Supervision, Funding acquisition, Data curation, Conceptualization. **Shou-Xia Li:** Visualization, Supervision, Project administration, Investigation, Funding acquisition, Conceptualization. **Zhi-Mei Qin:** Methodology, Investigation, Formal analysis, Data curation. **Ding-Li Chen:** Resources, Investigation, Formal analysis, Data curation. **Li-Li Guo:** Resources, Methodology, Investigation, Formal analysis, Data curation. **Cai-Ru Liu:** Resources, Methodology, Investigation, Data curation. **Xiao Yang:** Methodology, Investigation, Formal analysis, Data curation. **Ke-Nan Peng:** Resources, Investigation, Formal analysis, Data curation. **Er-Hei Dai:** Visualization, Supervision, Resources, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Xuedong Song, Shouxia Li, Zhimei Qin, Dingli Chen, Lili Guo, Cairu Liu reports financial support was provided by Handan Central Hospital. Xuedong Song reports a relationship with Handan Science and Technology Bureau that includes: funding grants.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e24306.

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