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Research Article

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Thirteen serum biochemical indexes and five whole blood coagulation indices in a point-of-care testing analyzer: ideal protocol for evaluating pulmonary and critical care medicine

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Abstract: The accurate and timely detection of biochemical coagulation indicators is pivotal in pulmonary and critical care medicine. Despite their reliability, traditional laboratories often lag in terms of rapid diagnosis. Point-of-care testing (POCT) has emerged as a promising alternative, which is awaiting rigorous validation. We assessed 226 samples from patients at the First Affiliated Hospital of Guangzhou Medical University using a Beckman Coulter AU5821 and a PUSHKANG POCT Biochemistry Analyzer MS100. Furthermore, 350 samples were evaluated with a Stago coagulation analyzer STAR MAX and a PUSHKANG POCT Coagulation Analyzer MC100. Metrics included thirteen biochemical indexes, such as albumin, and five coagulation indices, such as prothrombin time. Comparisons were drawn against the PUSHKANG POCT analyzer. Bland-Altman plots (MS100: 0.8206–0.9995; MC100: 0.8318–0.9911) evinced significant consistency between methodologies. Spearman correlation pinpointed a potent linear association between conventional devices and the PUSHKANG POCT analyzer, further underscored by a robust correlation coefficient (MS100: 0.713–0.949; MC100: 0.593–0.950). The PUSHKANG POCT was validated as a dependable tool for serum and whole blood biochemical and coagulation diagnostics. This emphasizes its prospective clinical efficacy, offering clinicians a swift diagnostic tool and heralding a new era of enhanced patient care outcomes.

Key words: Thirteen serum biochemical indexes; Five whole blood coagulation indices; Point-of-care testing (POCT); Pulmonary and critical care medicine; Diagnostic protocol

1 Introduction

Serum biochemical tests, including total phosphorus (TP), blood urea nitrogen (BUN), triglyceride (TG), total bilirubin (TBIL), creatinine (Cr), cholesterol (CHOL), direct bilirubin (DBIL), uric acid (UA), albumin (ALB), aspartate aminotransferase (AST), high-density lipoprotein (HDL), alanine aminotransferase (ALT), and glucose (GLU), are common and essential indices for evaluating function of vital organs such as the liver and kidneys, and for monitoring lipid metabolism (Torres et al., 2006; Mansour and Mossa, 2010). Their swift and precise administration optimizes patient monitoring, augments bedside care, and guides clinical decisions (Luppa et al., 2016). Whole blood coagulation tests, including fibrosis (FIB), thrombin time (TT), prothrombin time (PT), activated partial thromboplastin time (APTT), and D-dimer (DD), critically gauge both endogenous and exogenous coagulation systems, influencing the prognosis of various diseases (Athale and Chan, 2003; Song et al., 2020; Liu et al., 2023a). Notably, the combined measures of PT,

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DD, and platelet (PLT) have been identified as potent prognostic tools for severe pneumonia (Lin et al., 2021), with high DD levels also indicating worse outcomes in critical coronavirus disease 2019 (COVID-19) cases (Ichkawa et al., 2020; Liu et al., 2023b). The Beckman Coulter AU5821 and Stago coagulation analyzer STAR MAX, considered traditional reference systems, are renowned for their high automation and reliability, bolstering their usage within China's tertiary hospitals. Nonetheless, the dynamic nature of pulmonary and critical care medicine underscores a need for swifter, more precise testing (Parshall et al., 2012; Liu et al., 2023c).

In the last decade, point-of-care testing (POCT) has emerged as an innovative diagnostic approach (Chase et al., 2018). POCT's significance has been accentuated against the landscape of COVID-19, especially in pulmonary and critical care sectors (Greenhalgh et al., 2020; Zhu et al., 2020; Herrmann et al., 2021). Essential attributes of POCT tools include rapid testing while maintaining accuracy (St-Louis, 2000). These devices amalgamate technologies such as colloidal gold with microfluidic chips (Gervais et al., 2011; Cui and Wang, 2019), paving the way for compact, user-friendly instruments (Xiao et al., 2022). The effectiveness of microfluidic technology lies in its efficiency, speed, and portability, making it crucial for the evolution of POCT (Sher et al., 2017; Zhang and Zhou, 2022). ISO 22870 governs the quality and competence of in vitro POCT reagents, underscoring the necessity for alignment with international standards, thereby amplifying diagnostic proficiency in central laboratory methods based on ISO 15189 medical laboratory accreditation at the First Affiliated Hospital of Guangzhou Medical University (National Center for Respiratory Medicine, National Clinical Research Center for Respiratory Disease, State Key Laboratory of Respiratory Disease) (Clinical and Laboratory Standards Institute, 2012, 2013). Yet, literature comparing various POCT technologies with traditional tools remains sparse, signaling a gap in the understanding of their comparative diagnostic capacities (Stoot et al., 2014).

Zhejiang PUSHKANG Biotechnology Co., Ltd. (Shaoxing, China) has completed the design, development, performance evaluation, trial production, registration application, and quality assessment of the "Biochemical Analyzer MS100" (hereinafter referred to as MS100) and the "Coagulation Analyzer MC100" (hereinafter referred to as MC100) experimental systems, and has obtained the product registration certificate. In order to validate the instrument's applicability to, and accuracy in, actual clinical applications, clinical trials have been conducted to evaluate the clinical performance of the reagent kit in accordance with the "Guidelines for Clinical Trials of In Vitro Diagnostic Reagents" (China Food and Drug Administration, 2014).

Clinical trials are an essential component of the regulatory process for medical devices, providing crucial data on the safety, efficacy, and performance of the product in real-world settings. PUSHKANG's commitment to conducting rigorous clinical trials underscores their commitment to providing healthcare professionals with reliable and accurate diagnostic tools to improve patient outcomes.

2 Methods

2.1 Study design

Blood samples were harvested from patients hospitalized in the Department of Pulmonary and Critical Care Medicine at the First Affiliated Hospital of Guangzhou Medical University (National Center for Respiratory Medicine) from August 29 to November 17, 2022, without gender or respiratory disease type restrictions. Fig. 1 elucidates the primary distribution of thirteen biochemical and five coagulation parameters. To maintain rigorous scientific integrity, we employed stringent criteria for sample selection. Excluded were samples with indeterminate collection time and insufficient volumes, or those compromised by factors such as hemolysis,

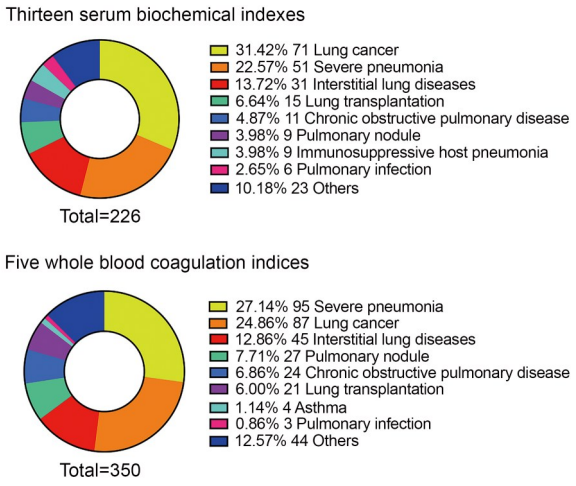


Fig. 1 Distributions of pulmonary and critical care patients across biochemical and coagulation parameters.

elevated lipemia, turbidity, or extended storage. Consequently, we secured 226 serum samples for assessing thirteen biochemical markers and an additional 350 samples for scrutinizing five essential coagulation parameters.

2.2 Procedure of PUSHKANG point-of-care testing

This investigation embodies a paired and double-blind diagnostic type I trial. Two dedicated researchers independently deployed both reference and experimental systems to analyze the 226 serum and 350 whole blood samples. The obtained data were assessed by a seasoned statistical analyst. Instruments including the AU5821 biochemical analyzer by Beckman Coulter Trading (China) Co., Ltd. and the Stago STAR MAX coagulation analyzer by Stago Diagnostics Technology Co., Ltd., both established benchmarks in their respective fields, served as our reference systems. In contrast, our experimental systems comprised the MS100 biochemical and MC100 coagulation analyzers developed by Zhejiang PUSHKANG Biotechnology Co., Ltd. (Fig. 2). The MS100, a paragon of bioanalytical precision, leverages centrifugal microfluidics and photometric colorimetry for exact component identification. This pivotal POCT biochemical system relies on expertly crafted disc-shaped microfluidic chips. The MC100, an avant-garde optical POCT coagulation detector, employs a centrifugal microfluidic platform, presenting clinicians with a swift, reliable method to evaluate blood's coagulation potential—a critical diagnostic tool for diverse medical scenarios. Both MS100 and MC100 embrace a unified testing framework, encompassing test preparation, sample detection, result printing, and system shutdown.

2.2.1 Test preparation

(1) The instrument on the back of the [O/I] power switch is switched to the [I], on the self-checking instrument after the login page. In the login dialog, input the correct user name and password, and click "OK" in the main interface. The instrument then starts thawing. (2) After about 10 min, the temperature on the upper right of the main interface of the instrument is displayed as (37.0±0.3) °C.

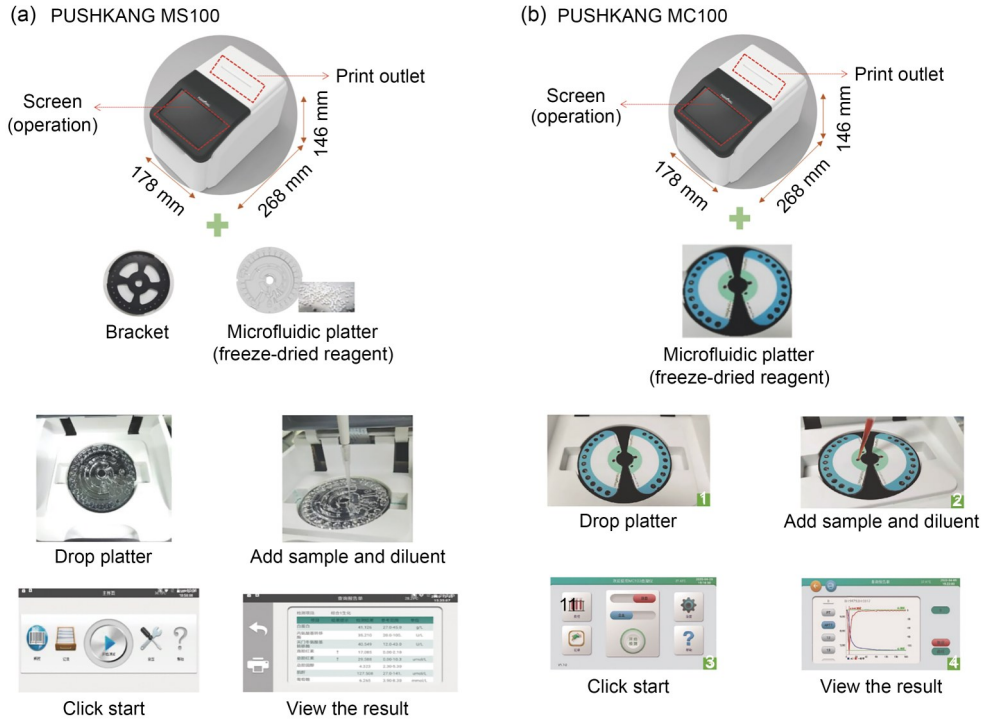


Fig. 2 Architectural and operational schemas of the PUSHKANG point-of-care testing (POCT) analytical systems. (a) PUSHKANG MS100, a POCT tool to quickly detect thirteen serum biochemical indexes (reprinted from https://www.pushkangbio.com/biochemistry, Copyright 2024, with permission from Zhejiang PUSHKANG Biotechnology Co., Ltd.); (b) PUSHKANG MC100, a POCT tool to quickly detect five whole blood coagulation indices (reprinted from https://www.pushkangbio.com/coagulation, Copyright 2024, with permission from Zhejiang PUSHKANG Biotechnology Co., Ltd.).

2.2.2 Sample detection

(1) After the reagent tray is removed from the freezer, leave it at room temperature for 10 min to reheat. Click to start the test and scan the two-dimensional code of the test tray. The interface pops up asking whether to test comprehensive one biochemical package; click "OK." (2) Open the plate area cover, take out the tray holder, align the bayonet of the quality reference plate with the buckle on the tray holder, insert the plate, add 750 μL diluent to the blue hole, then add 140 μL serum sample to the red hole in the MS100 test, and close the plate area cover. (3) After 3 min, the temperature in the upper right corner of the interface is displayed in the range of (37.0±0.3) ℃. Click the triangle start button on the right side of the interface, enter the sample number, name, and other information into the interface, and then click the check button on the left side of the interface to start the sample test together.

2.2.3 Result printing

(1) When the sample test is completed, the result report sheet interface will pop up and the test result will be automatically printed. After the printing is completed, click "OK" and return to the main interface. (2) All tests are completed on time. Open the area cover, take out the test platter, put the tray back on the instrument, close the area cover, and click "OK."

2.2.4 System shutdown

Shut down the instrument's power, switching the instrument on the back of the [O/I] power switch to [O]. The whole testing process is then completed.

2.2.5 Main difference between the MS100 and MC100 test scenarios

(1) When restarting the MC100 instrument, it is essential to ensure that the temperature displayed in the top right corner of the main screen remains stable within the range of (37.0±1.0) ℃. Prior to initiating any test, this temperature range must be maintained to ensure proper system operation. As part of the startup process, the system will continuously display this temperature and it should be monitored to confirm that the instrument has reached the optimal working temperature for accurate results. In contrast, the MS100 requires the temperature to be maintained at (37.0±0.3) ℃.

(2) During the sample testing process on the MC100, users have the flexibility to load samples either in single or double plate formats, depending on the test requirements. Sample types can include whole blood or plasma. For plasma samples, 180 μL of plasma should be added to the well, followed by the addition of 180 μL of diluent in the same well. This specific volume ensures that the test is conducted under optimal conditions to yield accurate and reliable results. In contrast, the MS100 requires the use of a single plate reagent tray, with the sample type being serum. A volume of 750 μL diluent should be firstly added to the blue well, followed by the addition of 140 μL of serum sample to the red well.

(3) Upon completion of the sample test, the system will automatically generate and print the data and corresponding curves based on the analysis results. These results will be displayed directly on the sample result screen, allowing the user to review and analyze the test outcomes. The printed data will include key indicators necessary for further interpretation of the sample analysis. The MC100 instrument will display two sets of test results, whereas the MS100 instrument will display only one result set.

2.3 Statistical analysis

We used cutting-edge statistical analysis software, including Microsoft® Excel 2022, IBM SPSS 26.0, and GraphPad Prism 9 to process our data. Ensuring analytical rigor, outliers from the quantitative paired test data were removed. Scatter plots and linear regression analyses discerned distribution tendencies and linear associations between the detection metrics of both systems, respectively. The Bland-Altman plot and intraclass correlation coefficient (ICC) gauged the congruence and replicability between the experimental and reference platforms, respectively. Moreover, a Spearman correlation analysis was performed to scrutinize the interconnectedness between both systems. A significance threshold was established at $P<0.05$.

3 Results

3.1 Demographical data

Our study included 576 samples distributed across two analytical devices: serum (n=226) and whole blood (n=350). Detailed sample properties are referenced in Tables 1 and 2 and Fig. 1. Spanning thirteen biochemical

Table 1 Comparative analysis of thirteen serum biochemical indexes between PUSHKANG point-of-care testing (POCT) and traditional analyzer

Property	ALB (U/L)		TP (g/L)		ALT (U/L)		DBIL (μmol/L)		TBIL (μmol/L)		AST (U/L)		UA (μmol/L)	
	P	T	P	T	P	T	P	T	P	T	P	T	P	T
Mean	40.28	39.43	66.90	64.98	22.04	17.61	15.34	19.20	23.93	26.71	23.77	23.93	219.33	287.99
95% CI	[34.65, 45.90]	[33.68, 45.18]	[60.04, 73.77]	[45.87, 84.09]	[18.15, 25.93]	[14.05, 21.17]	[1.72, 32.40]	[6.85, 45.25]	[2.89, 44.98]	[6.99, 60.41]	[20.69, 26.85]	[19.95, 27.90]	[79.41, 359.25]	[168.21, 407.76]
Median	40.87	41.05	67.13	71.25	23.06	16.35	6.095	3.75	16.55	12.90	22.34	22.90	195.05	250.30
Variance	45.25	47.32	67.41	52.52	21.68	18.13	41.25	30.78	33.62	16.04	13.54	22.63	280.79	205.09
Standard deviation	6.73	6.88	8.21	22.86	4.66	4.26	20.40	31.16	25.17	40.31	3.68	4.76	167.36	143.27
Minimum	28.66	25.90	52.34	14.10	12.90	14.10	0.24	1.00	8.21	7.10	20.37	17.90	29.54	83.00
Maximum	52.58	49.90	76.99	87.14	27.65	27.00	57.47	80.10	84.50	125.80	29.61	32.20	607.50	503.20
Range	23.92	24.00	24.65	73.04	14.75	12.90	57.23	79.10	76.29	118.70	9.24	14.30	577.96	420.20
IQR	5.95	6.19	12.79	23.13	6.31	4.66	25.01	42.57	13.76	11.59	7.09	7.675	50.675	212.28

Property	TG (mmol/L)		CHOL (mmol/L)		HDL (mmol/L)		LDL (mmol/L)		Cr (μmol/L)		BUN (mmol/L)	
	P	T	P	T	P	T	P	T	P	T	P	T
Mean	0.93	0.89	5.44	5.11	1.16	1.57	3.94	3.11	58.83	86.26	14.28	6.15
95% CI	[0.70, 1.16]	[0.69, 1.10]	[3.55, 7.33]	[3.20, 7.02]	[1.15, 1.18]	[0.84, 2.30]	[2.14, 5.74]	[1.97, 4.25]	[41.05, 76.60]	[73.11, 99.42]	[8.66, 37.23]	[4.61, 7.69]
Median	0.86	0.77	4.99	4.80	1.16	1.64	3.37	2.87	54.66	83.30	4.28	5.60
Variance	0.08	0.06	5.12	5.22	0.14	0.76	0.63	1.87	45.94	4.55	5.40	3.37
Standard deviation	0.27	0.24	2.26	2.29	0.02	0.87	2.15	1.37	21.26	15.73	7.45	1.84
Minimum	0.68	0.64	2.80	2.50	1.14	0.43	1.42	1.67	42.03	69.90	2.36	4.10
Maximum	1.44	1.22	9.12	9.00	1.20	3.06	7.66	5.12	108.00	119.90	82.11	9.80
Range	0.76	0.58	6.32	6.50	0.06	2.63	6.24	3.45	65.97	50.00	79.75	5.70
IQR	0.46	0.47	4.28	4.20	0.02	1.41	3.69	2.80	16.25	16.53	3.21	2.27

ALB: albumin; TP: total phosphorus; ALT: alanine aminotransferase; DBIL: direct bilirubin; TBIL: total bilirubin; AST: aspartate aminotransferase; UA: uric acid; TG: triglyceride; CHOL: cholesterol; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Cr: creatinine; BUN: blood urea nitrogen; T: traditional analyzer; P: PUSHKANG POCT analyzer; CI: confidence interval; IQR: interquartile range.

Table 2 Comparative analysis of five whole blood coagulation indices between PUSHKANG point-of-care testing (POCT) and traditional analyzer

Property	PT (s)		APTT (s)		TT (s)		FIB (g/L)		DD (ng/mL)	
	P	T	P	T	P	T	P	T	P	T
Mean	16.39	14.57	38.73	40.71	15.99	17.55	4.56	3.65	4230.23	2133.25
95% CI	[15.65, 17.13]	[14.37, 14.76]	[36.19, 41.26]	[39.67, 41.75]	[14.56, 17.40]	[17.26, 17.85]	[4.33, 4.80]	[3.48, 3.81]	[3767.97, 4692.49]	[1938.26, 2328.25]
Median	15.30	14.37	34.40	38.50	14.17	17.20	4.08	3.38	2570.00	1648.00
Variance	49.23	3.32	81.81	97.57	180.63	7.76	5.00	2.39	1933.80	2707.39
Standard deviation	7.02	1.82	24.12	9.88	13.44	2.79	2.24	1.55	4397.08	1854.80
Minimum	7.30	11.80	9.61	1.09	13.26	13.23	0.28	1.32	200.00	114.00
Maximum	123.40	31.60	214.30	108.00	240.00	39.60	12.66	16.10	20690.00	9999.00
Range	116.10	19.80	204.69	106.91	240.00	26.37	12.66	14.78	20490.00	9885.00
IQR	2.35	1.50	7.96	10.30	4.21	2.13	2.98	1.98	4627.50	2037.75

PT: prothrombin time; APTT: activated partial thromboplastin time; TT: thrombin time; FIB: fibrosis; DD: D-dimer; T: traditional analyzer; P: PUSHKANG POCT analyzer; CI: confidence interval; IQR: interquartile range.

parameters, a gender disparity was observed, with males surpassing females in serum samples (69.9% vs. 30.1%). The median ages for male and female groups were 64 years (interquartile range (IQR): 54–69 years) and 59 years (IQR: 45–70 years), respectively. The cohort predominantly manifested lung cancer (31.42%), followed by severe pneumonia (22.57%), interstitial lung diseases (13.72%), lung transplantation (6.64%), and chronic obstructive pulmonary disease (4.87%). These conditions represent critical areas of focus in pulmonary research and treatment. For the whole blood coagulation set of five parameters, males comprised 78.0%, with respective median ages of 65 years (IQR: 54–72 years) and 61 years (IQR: 42–74 years) for male and female samples, respectively. Prevalent diseases in this set included severe pneumonia (27.14%), lung cancer (24.86%), interstitial lung diseases (12.86%), pulmonary nodule (7.71%), and chronic obstructive pulmonary disease (6.86%). Shapiro-Wilk normality tests revealed a non-normal distribution (P<0.05) for both biochemical and coagulation parameters, warranting non-parametric tests for the ensuing analysis (Table 3).

3.2 Abnormal result detection (outlier)

Upon evaluating the detection data, scatter plots were derived for both thirteen biochemical and five coagulation indices using reference system outcomes. This method has proven invaluable in dissecting expansive patient datasets globally. From 18 scatter plots, 20 and 10 outliers were discerned within biochemical and coagulation indices, respectively. Post outlier removal, they constituted less than 5% of the aggregate data.

3.3 Scatter plots and linear analysis

Fig. 3 demonstrates the scatter plots and linear assessments of the evaluated POCT devices, revealing a predominantly linear distribution. Strong linear correlations were evident across both test parameters, as mirrored by high R^2 values across indices (linear coefficients R^2 of each index of the thirteen biochemical and five coagulation parameters are between 0.8389 and 0.9996 and between 0.8831 and 0.9657, respectively). Specific serum parameters, such as TP (R^2=0.9669), ALT (R^2=0.9673), DBIL (R^2=0.9801), TBIL (R^2=0.9489), AST (R^2=0.9463), UA (R^2=0.9229), TG (R^2=0.9734), CHOL (R^2=0.9078), low-density lipoprotein (LDL) (R^2=0.9388), Cr (R^2=0.9334), and BUN (R^2=0.9996), exhibited vigorous correlations, as did the whole blood

Table 3 Assessment of normality for analytical parameters in PUSHKANG point-of-care testing (POCT) versus traditional analyzer

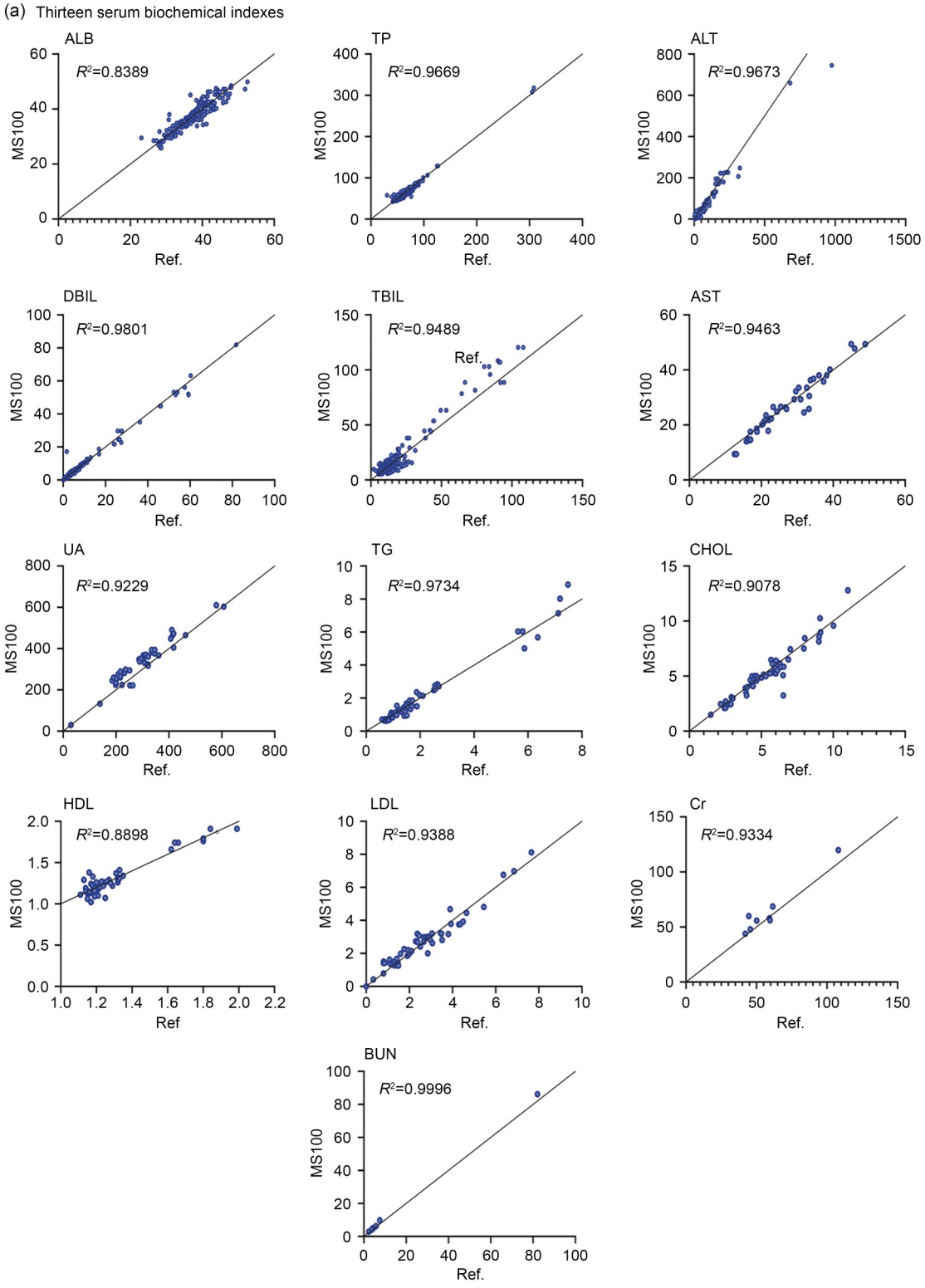
Parameter	Shapiro-Wilk		
	Value	*df*	*P*-value
Thirteen serum biochemical indexes			
MS100-ALB	0.932	225	0.535
ref.-ALB	0.922	225	0.450
MS100-TP	0.952	225	0.733
ref.-TP	0.815	225	0.041
MS100-ALT	0.908	225	0.338
ref.-ALT	0.805	225	0.033
MS100-DBIL	0.709	225	0.003
ref.-DBIL	0.641	225	0.000
MS100-TBIL	0.634	225	0.000
ref.-TBIL	0.525	225	0.000
MS100-AST	0.824	225	0.051
ref.-AST	0.942	225	0.632
MS100-UA	0.708	225	0.003
ref.-UA	0.834	225	0.065
MS100-TG	0.862	225	0.127
ref.-TG	0.808	225	0.035
MS100-CHOL	0.939	225	0.601
ref.-CHOL	0.940	225	0.614
MS100-HDL	0.886	225	0.217
ref.-HDL	0.939	225	0.604
MS100-LDL	0.933	225	0.540
ref.-LDL	0.901	225	0.296
MS100-Cr	0.736	225	0.006
ref.-Cr	0.858	225	0.115
MS100-BUN	0.469	225	0.000
ref.-BUN	0.899	225	0.284
Five whole blood coagulation indices			
MC100-PT	0.329	349	<0.001
ref.-PT	0.750	349	<0.001
MC100-APTT	0.411	349	<0.001
ref.-APTT	0.820	349	<0.001
MC100-TT	0.241	349	<0.001
ref.-TT	0.678	349	<0.001
MC100-FIB	0.947	349	<0.001
ref.-FIB	0.871	349	<0.001
MC100-DD	0.817	349	<0.001
ref.-DD	0.847	349	<0.001

df: degree of freedom; ALB: albumin; TP: total phosphorus; ALT: alanine aminotransferase; DBIL: direct bilirubin; TBIL: total bilirubin; AST: aspartate aminotransferase; UA: uric acid; TG: triglyceride; CHOL: cholesterol; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Cr: creatinine; BUN: blood urea nitrogen; PT: prothrombin time; APTT: activated partial thromboplastin time; TT: thrombin time; FIB: fibrosis; DD: D-dimer.

parameters, such as PT (R^2=0.9657), APTT (R^2=0.9657), TT (R^2=0.9514), and DD (R^2=0.9270). These findings corroborate the evaluated POCT system's finesse in proficiently discerning the 18 blood parameters.

3.4 Consistency analysis

Fig. 4 depicts the Bland-Altman plots, elucidating the differences between evaluated and reference systems



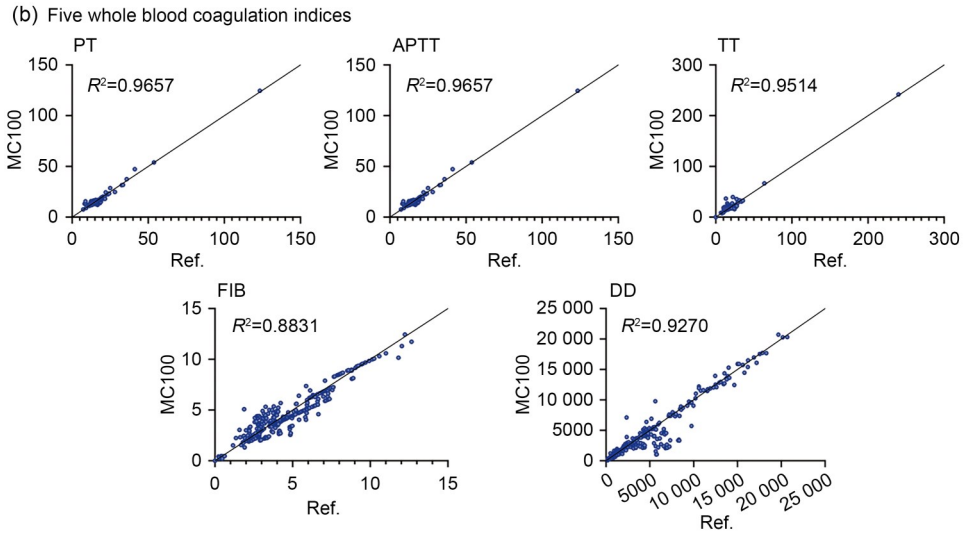


Fig. 3 Scatter plot and linear distribution analyses between PUSHKANG point-of-care testing (POCT) and reference systems. (a) Correlation analysis of thirteen serum biochemical indexes by PUSHKANG MS100; (b) Correlation analysis of five whole blood coagulation indices by PUSHKANG MC100. ALB: albumin; TP: total phosphorus; ALT: alanine aminotransferase; DBIL: direct bilirubin; TBIL: total bilirubin; AST: aspartate aminotransferase; UA: uric acid; TG: triglyceride; CHOL: cholesterol; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Cr: creatinine; BUN: blood urea nitrogen; PT: prothrombin time; APTT: activated partial thromboplastin time; TT: thrombin time; FIB: fibrosis; DD: D-dimer.

across indices. The majority of the data points cluster within the 95% agreement band, with the mean difference line approximating zero for parameters such as ALB (0.000 615 9) and HDL (0.002 115), underscoring system congruence. The POCT systems thereby demonstrate their acuity and veracity in evaluating target indicators.

3.5 Intraclass correlation coefficient analysis

The ICC serves as an indispensable measure, offering profound insights into consistency, and encapsulating both reliability and standardization. Within the context of this research, the ICC was employed to discern the degree of system congruence, spanning both biochemical and coagulation indicators. Remarkably, ICC values surpassed the 0.75 threshold, which is emblematic of superior repeatability and consistency. This not only establishes the POCT system's fidelity in mirroring the meticulousness of experimental methodologies but also underscores its reproducibility.

Table 4 presents the ICC results, capturing both counted and categorized data across the thirteen biochemical and five coagulation indicators. Concurrently, the POCT and reference systems recorded ICC values that consistently exceeded 0.75 when enumerating the parameters of the biochemical and coagulation indicators in serum and whole blood samples. Such findings, particularly with values ranging from 0.8206 to 0.9995 for MS100 and 0.8318 to 0.9911 for MC100, attest to the consistency between the POCT and reference systems. This symbiotic relationship further exemplifies the POCT device's adeptness at reliably and reproducibly measuring the indicators, reflecting the experimental design's precision. Conclusively, the findings underscore the paramount significance of adopting impeccable scientific protocols to ensure the fidelity and repeatability of research outcomes.

3.6 Spearman correlation analysis

Utilizing Spearman correlation, we discerned the congruence between POCT and reference systems across 18 blood parameters. Tables 5 and 6 present these findings, with Spearman correlation coefficients evincing an obvious interrelation, emphasizing the synchronous efficacy of both systems, being between 0.713 and 0.949 and between 0.593 and 0.950, respectively.

4 Discussion

Amidst the escalating demands catalyzed by the COVID-19 pandemic, the realm of laboratory medicine has witnessed unprecedented advancements. Notably, POCT stands out, credited for its compactness, speed,

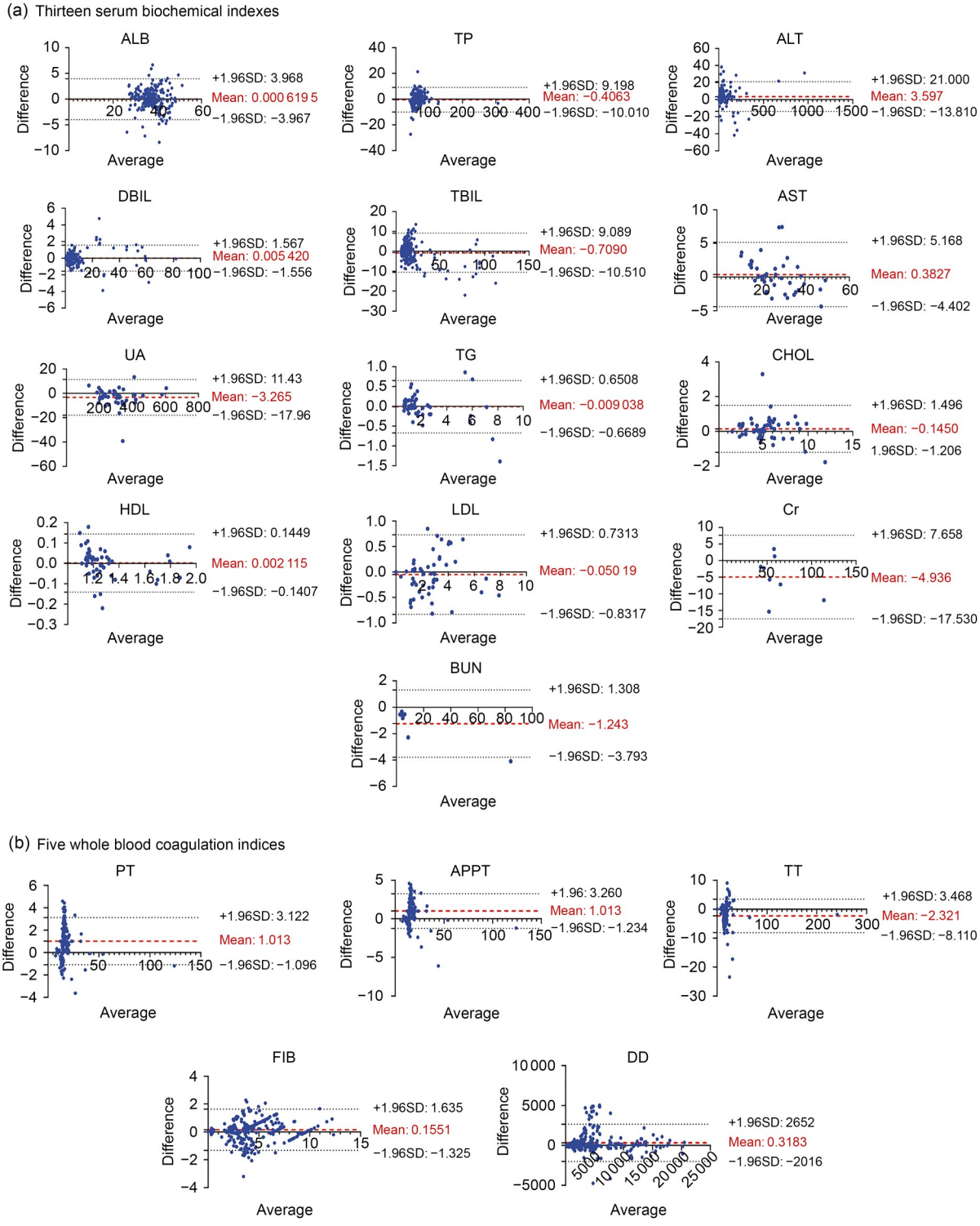


Fig. 4 Bland-Altman plots of the discrepancy quantification between PUSHKANG point-of-care testing (POCT) and reference systems. (a) Differential analysis of thirteen serum biochemical indexes by PUSHKANG MS100; (b) Differential analysis of five whole blood coagulation indices by PUSHKANG MC100. ALB: albumin; TP: total phosphorus; ALT: alanine aminotransferase; DBIL: direct bilirubin; TBIL: total bilirubin; AST: aspartate aminotransferase; UA: uric acid; TG: triglyceride; CHOL: cholesterol; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Cr: creatinine; BUN: blood urea nitrogen; PT: prothrombin time; APTT: activated partial thromboplastin time; TT: thrombin time; FIB: fibrosis; DD: D-dimer; SD: standard deviation.

Table 4 Intraclass correlation coefficient outcomes for comparative data analysis: reference versus MS100/MC100 devices

Comparison	Intraclass correlation coefficient	95% Confidence interval (CI)
Thirteen serum biochemical indexes		
ref. vs. MS100-ALB	0.9559	0.9427 to 0.9661
ref. vs. MS100-TP	0.9916	0.9891 to 0.9935
ref. vs. MS100-ALT	0.9866	0.9826 to 0.9897
ref. vs. MS100-DBIL	0.9964	0.9953 to 0.9972
ref. vs. MS100-TBIL	0.9811	0.9755 to 0.9855
ref. vs. MS100-AST	0.9683	0.9420 to 0.9827
ref. vs. MS100-UA	0.8206	0.6758 to 0.9007
ref. vs. MS100-TG	0.9922	0.9864 to 0.9955
ref. vs. MS100-CHOL	0.9755	0.9575 to 0.9858
ref. vs. MS100-HDL	0.9747	0.9561 to 0.9854
ref. vs. MS100-LDL	0.9839	0.9720 to 0.9907
ref. vs. MS100-Cr	0.9794	0.8971 to 0.9959
ref. vs. MS100-BUN	0.9995	0.9973 to 1.0000
Five whole blood coagulation indices		
ref. vs. MC100-PT	0.9911	0.9890 to 0.9928
ref. vs. MC100-APTT	0.8318	0.6216 to 0.9019
ref. vs. MC100-TT	0.9875	0.9846 to 0.9899
ref. vs. MC100-FIB	0.9702	0.9632 to 0.9758
ref. vs. MC100-DD	0.9810	0.9766 to 0.9846

ALB: albumin; TP: total phosphorus; ALT: alanine aminotransferase; DBIL: direct bilirubin; TBIL: total bilirubin level; AST: aspartate aminotransferase; UA: uric acid; TG: triglyceride; CHOL: cholesterol; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Cr: creatinine; BUN: blood urea nitrogen; PT: prothrombin time; APTT: activated partial thromboplastin time; TT: thrombin time; FIB: fibrosis; DD: D-dimer.

Table 5 Spearman correlation analysis of thirteen serum biochemical indexes in PUSHKANG point-of-care testing (POCT) and traditional analyzer

Biochemical index	ref.-ALB	ref.-TP	ref.-ALT	ref.-DBIL	ref.-TBIL	ref.-AST	ref.-UA	ref.-TG	ref.-CHOL	ref.-HDL	ref.-LDL	ref.-Cr	ref.-BUN
MS100-ALB	0.921**	0.575**	−0.037	0.074	−0.165*	−0.033	−0.239	−0.044	−0.072	−0.137	−0.048	−0.238	0.311
MS100-TP	0.593**	0.918**	0.063	0.157*	−0.118	0.241	−0.067	−0.054	−0.081	−0.166	−0.058	0.238	−0.060
MS100-ALT	−0.053	0.028	0.936**	0.214**	0.308**	0.043	−0.032	0.177	−0.179	0.201	−0.080	−0.405	−0.048
MS100-DBIL	0.066	0.014	0.249	0.982**	0.483	−0.057	0.068	0.160	−0.075	0.180	−0.040	−0.524	0.826*
MS100-TBIL	0.058	0.046	0.259	0.541	0.775*	0.160	−0.233	−0.094	−0.021	−0.009	−0.132	−0.595	−0.012
MS100-AST	0.123	0.292	0.088	0.043	0.013	0.927**	0.329*	0.018	0.010	−0.123	−0.397	0.167	−0.216
MS100-UA	−0.060	−0.027	0.095	−0.051	−0.405	0.298*	0.761*	0.358*	−0.201	0.176	−0.515	0.476	−0.120
MS100-TG	0.004	0.006	0.115	0.099	0.097	−0.040	0.105	0.949**	0.210	0.575	−0.064	0.214	−0.072
MS100-CHOL	−0.228	−0.095	−0.270	0.089	0.060	0.041	−0.060	0.289*	0.937**	0.377	0.508	0.857	−0.287
MS100-HDL	0.056	−0.030	0.044	0.096	0.101	0.036	0.230	0.791	0.265	0.713*	−0.025	0.344	0.056
MS100-LDL	−0.233	−0.027	−0.135	0.051	0.089	−0.356*	−0.381	−0.129	0.632	0.158	0.935**	0.857	−0.287
MS100-Cr	−0.143	0.214	−0.310	−0.575	−0.167	−0.024	0.048	0.144	0.551	0	0.524	0.738*	−0.934
MS100-BUN	0	−0.405	0.476	0.826*	−0.119	0.048	0.095	0.180	−0.252	0.395	−0.214	−0.571	0.922**

ALB: albumin; TP: total phosphorus; ALT: alanine aminotransferase; DBIL: direct bilirubin; TBIL: total bilirubin; AST: aspartate aminotransferase; UA: uric acid; TG: triglyceride; CHOL: cholesterol; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Cr: creatinine; BUN: blood urea nitrogen.

Table 6 Spearman correlation analysis of five whole blood coagulation indices in PUSHKANG point-of-care testing (POCT) and traditional analyzer

Coagulation index	ref.-PT	ref.-APTT	ref.-TT	ref.-FIB	ref.-DD
MC100-PT	0.779**	0.218**	0.133*	−0.276**	0.061
MC100-APTT	0.322**	0.876**	−0.030	−0.010	0.058
MC100-TT	0.315**	0.055	0.593**	−0.479**	0.121*
MC100-FIB	−0.326**	−0.005	−0.236**	0.884**	−0.028
MC100-DD	0.074	0.129*	−0.001	−0.038	0.950**

PT: prothrombin time; APTT: activated partial thromboplastin time; TT: thrombin time; FIB: fibrosis; DD: D-dimer.

and suitability for patients exhibiting dynamic symptoms (Soler et al., 2020). We explored the potential of integrating PUSHKANG POCT analyzers for such patients, aiming to transition from the prevalent reactive medical paradigms (Fig. 2). Implementing these analyzers in critical care could facilitate swift, precise results, fostering timely interventions and enhancing clinical decision-making. Despite their promise, it is imperative to acknowledge that, for conditions such as acute respiratory distress syndrome (ARDS), POCT tools complement, rather than replace, established diagnostic benchmarks like the Berlin criteria (Parikh, 2009; Florkowski et al., 2017; Herrmann et al., 2021; Taneja and Batra, 2021).

The agility and precision of diagnostic outcomes pave the way for proactive interventions and bespoke treatment regimens, enhancing patient prognosis while curtailing medical expenditures. Given the diversity in clinical laboratories, the quest for consistent instrument comparison tests is paramount, especially for pulmonary and critical care patients whose conditions evolve rapidly (Volpicelli et al., 2012). Conventional devices such as Beckman Coulter and Stago coagulation systems, which are predominant in tertiary care settings, have their merits, such as multi-project detection, high accuracy, good stability, large sample volume, and reduced labor and material resources (Luppa et al., 2011; Florkowski et al., 2017; Zhu et al., 2020; Herrmann et al., 2021). Yet, their drawbacks of high cost, large size, heavy weight, complex operation, and a variety of reagents, often overshadow their benefits, particularly for critical care patients (Briggs et al., 2012; Zaczek-Moczydlowska et al., 2021; Xue et al., 2022). Thus, these traditional devices still cannot satisfy the urgent requirements of patients in the realm of pulmonary and critical care medicine, though they can meet most of the needs of outpatients and most inpatients.

Advancements in modern diagnostic tools are characterized by automation, intelligence, and portability. The PUSHKANG POCT devices exemplify these attributes, offering superior efficiency over their larger predecessors. Their promptness in delivering results eliminates the delays inherent to remote laboratories, enhancing decision-making in urgent medical situations. This mirrors the benefits found in the POCT instrument by Zhu et al. (2022). Consistency across instruments remains a linchpin for laboratory quality control (Vesper et al., 2016). Our research sourced patients from the Department of Pulmonary and Critical Care Medicine at the First Affiliated Hospital of Guangzhou Medical University. A comprehensive comparison of sample data is outlined in Tables 1 and 2 and Fig. 1, including metrics such as mean, 95% confidence interval (CI), and variance for both PUSHKANG POCT and its reference analyzer. Table 3 presents the normality tests for each metric across both devices. This study predominantly focused on elderly patients diagnosed with respiratory ailments such as lung cancer and severe pneumonia, underscoring the prevalence of these diseases among older populations (Fragoso, 2017). Outliers, representing less than 5% of the data, were omitted from the quantitative analysis—a standard threshold for data reliability. Linear coefficients revealed a robust linear fit between the two analyzers (Beckman Coulter vs. MS100: R^2 0.8389–0.9996; Stago coagulation vs. MC100: R^2 0.8831–0.9657). Notably, eleven biochemical indicators, typified by BUN, and four coagulation metrics, exemplified by PT, showcased exceptional linear fits (R^2>0.9), as visualized in Fig. 3. Spearman correlation analysis identified pronounced correlations for DBIL (rs=0.982) and DD (rs=0.950) tests, detailed in Tables 5 and 6.

Drawing from insights into PUSHKANG POCT MC100 from https://www.pushkangbio.com/mc100-2-product, we surmise that this instrument may adeptly

address the challenges highlighted by Ebner et al. (2017) regarding emergency coagulation assessments in patients on direct oral anticoagulant regimens. The Bland-Altman plots revealed a commendable degree of consistency in test results between the two devices. Most data points converged within the 95% limits of agreement, with a marginal mean difference (Fig. 4). Notably, certain indicators diverged from the baseline, which is potentially attributable to limited sample sizes or instrumental discrepancies. This underscores the potential need for broader specimen collection and enhanced calibration by the device manufacturers.

The PUSHKANG POCT analyzer harnesses the synergy of centrifugal microfluidic technology with the foundational Beer-Lambert law in spectrophotometry to determine substance concentration changes via absorbance measurements. When deploying this system, adherence to several critical operational guidelines is paramount. It is imperative to allow the instrument to stabilize at the designated temperature prior to conducting measurements, ensuring the consistency and reliability of data across samples. Despite similarities in the operational procedures for biochemical and coagulation analyses, meticulous care must be exercised during sample dilution to maintain precision. Additionally, vigilance in distinguishing between sample and diluent wells is essential to ensure accurate loading onto the reagent tray.

The POCT analyzer's attributes—expeditious results, cost-efficiency, straightforward operation, and enhancement of patient care outcomes—render it indispensable in acute scenarios. It is optimally positioned for deployment in pulmonary and critical care departments, enriching the landscape of extant POCT clinical tools. Envisioning its nationwide integration, large medical establishments should prioritize its availability in critical care units, while grassroots healthcare setups can leverage its potential for expedited diagnostic and prognostic evaluations. The PUSHKANG POCT stands as a revolutionary biochemical and coagulation analysis tool, combining affordability, portability, user-friendliness, and swift precision. Relative to its traditional large-scale counterparts, it exhibits robust correlation, coherence, and trustworthiness. A salient limitation, however, is our study's scope, encompassing only thirteen biochemical and five coagulation parameters on the PUSHKANG POCT, warranting further exploration of other prevalent and condition-specific indicators.

5 Conclusions

In our comprehensive study, 226 serum samples (covering 13 biochemical parameters) and 350 whole blood samples (pertaining to 5 coagulation parameters) were sourced from the Department of Pulmonary and Critical Care Medicine at the First Affiliated Hospital of Guangzhou Medical University (National Center for Respiratory Medicine). Both scatter plots and linear evaluations unveiled a direct linear association between the PUSHKANG POCT reagent panels for biochemical (MS100) and coagulation (MC100) analyses with the designated reference systems. The Bland-Altman plots, paired with ICC assessments, underscored a pronounced concordance between the two. Spearman correlation studies further cemented the robust interrelation between the test devices and their benchmark systems. Hence, this device proves to be instrumental for the in vitro analysis of human venous blood, delivering trustworthy data for the stipulated biochemical and coagulation parameters. The evident synergy between these tools accentuates the potential of PUSHKANG POCT devices for sustained and broader clinical integration.

Data availability statement

The present article contains original contributions that have been thoroughly reviewed and discussed. Those seeking further information on the subject matter may direct their queries to the corresponding authors.

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Author contributions

Mingtao LIU, Li LIU, and Jiaxi CHEN conceived and designed the study, analyzed the data, and drafted and revised the paper. Their commitment throughout the process was unparalleled. Zhifeng HUANG, Huiqing ZHU, Shengxuan LIN, Weitian QI, and Zhangkai J. CHENG contributed to the clinical and laboratory work for the study. Mingtao LIU and Shengxuan LIN were responsible for the data collection. Mingtao LIU and Li LIU then interpreted the results. Ning LI and Baoqing SUN provided invaluable supervision of the study. All authors offered critical comments on the manuscript and approved the final version. It is thanks to their collective insight and dedication that this work has come to fruition.

Compliance with ethics guidelines

Mingtao LIU, Li LIU, Jiaxi CHEN, Zhifeng HUANG, Huiqing ZHU, Shengxuan LIN, Weitian QI, Zhangkai J. CHENG, Ning LI, and Baoqing SUN declare that they have no conflict of interest.

The present study was approved by the Ethics Committee of the First Affiliated Hospital of Guangzhou Medical University (Approval No. GYFYY-2016-73).

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