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ANALYTICAL COMPARISON OF THE PORTABLE ENNOLIFE HCA-TC-200 ANALYSER AND THE BECKMAN UNICEL DXC 880I FOR HEPATORENAL AND URINARY BIOMARKERS: IMPLICATIONS FOR FUTURE POINT-OF-CARE USE

ANALITIČKO POREĐENJE PRENOSIVOG ENNOLIFE HCA-TC-200 ANALIZATORA I BECKMAN UNICEL DXC 880I ZA HEPATORENALNE I URINARNE BIOMARKERE: IMPLIKACIJE ZA BUDUĆU PRIMENU

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Summary

Background: Accurate and efficient chemical analysers play a critical role in modern healthcare, particularly in community medicine, where early diagnosis and intervention can significantly improve patient outcomes. This study evaluated the analytical performance of the novel portable ENNO-

Kratak sadržaj

Uvod: Tačni i efikasni hemijski analizatori imaju ključnu ulogu u savremenoj zdravstvenoj zaštiti, posebno u domenu primarne medicine, gde rano postavljanje dijagnoze i blagovremena intervencija mogu značajno poboljšati ishod lečenja. Ova studija procenjuje analitičke perfor-

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List of abbreviations: ACR, albumin-creatinine ratio; ALB, albumin; ALP, alkaline phosphatase; ALT, alanine transaminase; AMP, 2-amino-2-methyl-1-propanol; AST, aspartate transaminase; BCG, bromcresol green; BUN, blood urea nitrogen; CHB, chronic hepatitis B; CKD, chronic kidney disease; CLD, chronic liver disease; CI, confidence interval, CRE, creatinine; mALB, microalbumin; P5P, pyridoxal-5-phosphate; PNPP, p-nitrophenyl phosphate; UA, uric acid; UCRE, urine creatinine; UP, urine protein; Uricase-POD, uricase peroxidase; Urease-GLDH, urease glutamate dehydrogenase

LIFE HCA-TC-200 analyser compared to the established Beckman UniCel DxC 880i analyser.
Methods: A total of 600 individuals were recruited from Shuang Ho Hospital, Taiwan. The analytical performance of ENNOLIFE HCA-TC-200 was validated using clinical chemistry assays, specifically assessing hepatic, renal, and urinary biomarkers. The analysers were compared based on method comparison, accuracy, and inter-method agreement.
Results: The ENNOLIFE HCA-TC-200 analyser demonstrated strong agreement with the Beckman UniCel DxC 880i. Passing-Bablok regression showed good agreement for albumin (ALB), microalbumin (mALB), and urine protein (UP), while proportional or constant biases were observed in other analytes. Bland-Altman analysis revealed minimal bias, with blood urea nitrogen (BUN) showing the smallest mean difference (-0.18 mg/dL) and alanine transaminase (ALT) the largest (5.99 U/L). Accuracy exceeded 97% for all parameters after excluding extreme outliers, with 100% agreement for hepatic and renal markers. High linear correlations (R>0.97) were found for most markers, with minor deviations observed for ALB (R=0.92) and urine creatinine (R=0.80), which remained within clinically acceptable diagnostic ranges
Conclusions: The ENNOLIFE HCA-TC-200 analyser demonstrated strong analytical performance and high concordance with the reference laboratory analyser, the Beckman UniCel DxC 880i, across hepatic, renal, and urinary parameters. These findings, combined with its portability, support its potential use as a reliable tool for biochemical analysis in outpatient and community-based settings.

Keywords: analytical performance evaluation; portable analyser, clinical chemistry, hepatorenal diagnostics, urinary biomarker, community medicine

manse novog prenosivog analizatora ENNOLIFE HCA-TC-200 u poređenju sa etabliranim analizatorom Beckman UniCel DxC 880i.
Metode: Ukupno 600 ispitanika regrutovano je u bolnici Shuang Ho na Tajvanu. Analitičke performanse uređaja ENNOLIFE HCA-TC-200 validirane su korišćenjem kliničko-hemijskih testova, sa posebnim fokusom na hepatične, renalne i urinarne biomarkere. Analizatori su upoređivani na osnovu poređenja metoda, tačnosti i međusobne usaglašenosti rezultata.
Rezultati: Analizator ENNOLIFE HCA-TC-200 pokazao je visoku usaglašenost sa uređajem Beckman UniCel DxC 880i. Passing-Bablok regresija ukazala je na dobro slaganje za albumin (ALB), mikroalbumin (mALB) i proteine u urinu (UP), dok su kod drugih analita uočene proporcionalne ili konstantne pristrasnosti. Bland-Altman analiza pokazala je minimalnu pristrasnost: azot uree u krvi (BUN) imao je najmanju prosečnu razliku (-0,18 mg/dL), a alanin-aminotransferaza (ALT) najveću (5,99 U/L). Tačnost je prelazila 97% za sve parametre nakon isključivanja ekstremnih odstupanja, uz 100% usaglašenosti za hepatične i renalne markere. Visoke linearne korelacije (R>0,97) zabeležene su za većinu markera, sa nešto nižim vrednostima za ALB (R=0,92) i kreatinin u urinu (R = 0,80), ali koje su i dalje u klinički prihvatljivim dijagnostičkim okvirima.
Zaključak: ENNOLIFE HCA-TC-200 pokazao je snažne analitičke performanse i visoku usklađenost sa referentnim laboratorijskim analizatorom Beckman UniCel DxC 880i u okviru hepatičnih, renalnih i urinarnih parametara. Ovi nalazi, zajedno sa njegovom prenosivošću, ukazuju na njegov potencijal kao pouzdanog alata za biohemijsku analizu u ambulantnim uslovima i primarnoj zdravstvenoj zaštiti.

Ključne reči: procena analitičkih performansi, prenosivi analizator, klinička hemija, hepatorenalna dijagnostika, urinarni biomarkeri, primarna medicina

Introduction

Chemical analysers play a pivotal role in clinical diagnostics by enabling effective disease screening, chronic disease management, and therapeutic monitoring (1). With the increasing burden on healthcare systems due to population ageing and rising medical demands, the efficiency and efficacy of chemical analysers have become key considerations (2). Technological advancements, such as automation and high-throughput multiparameter analyses, have substantially improved the performance of laboratory medicine (3). The adoption of standardised protocols further enhances the precision and accuracy of diagnostic processes (4). Moreover, integrating various serum testing platforms into unified systems has reduced processing times and minimised personnel requirements (5), thereby increasing operational efficiency.

In recent years, portable analysers have gained considerable attention owing to their rapid turnaround times and user-friendly operation. These features facilitate immediate diagnosis and support timely therapeutic decision-making (6).

Beckman Coulter Diagnostics, a global leader in clinical diagnostics, has pioneered a range of chemical analysers used in clinical laboratories, hospitals, and research institutions worldwide (7). Over the decades, the company has consistently innovated models such as the AU and DxC series (8, 9), designed to meet escalating healthcare demands. These analysers feature high-throughput, comprehensive test menus and advanced software. Beckman UniCel® DxC 880i (Beckman Coulter Inc., California, USA), an integrated chemical analyser, can perform a range of vital biochemical assessments, including blood chemistry panels, urine analysis, and disease marker evaluation, with exceptional accuracy and efficiency. Despite these advantages, its use remains largely confined to hospital settings due to its volume. Moreover, its reliance on skilled professionals for operation often extends processing times and necessitates multiple patient visits, particularly in high-demand medical facilities. These limitations highlight a pressing need for portable, accurate, and user-friendly alternatives that deliver laboratory-quality results outside traditional hospital settings.

The new ENNOLIFE Clinical Chemistry Analyser, Model HCA-TC-200 (ProtectLife International Biomedical Inc., Taiwan), is a portable, spectrum-based clinical chemistry analyser weighing

only 7.5 kg and designed for rapid assessment of biochemical and immunological markers. It features an innovative design that integrates a microfluidic system with a full-spectrum spectrometer, enabling rapid, accurate diagnostic results from microsamples of serum, plasma, whole blood, and urine. The instrument can simultaneously analyse up to 16 markers by using three distinct test reagent discs: the renal panel, hepatic panel, and albumin-creatinine ratio (ACR) urine panel. Each reagent disc can test up to 4 parameters. Operating on principles similar to those of large, fully automated clinical analysers, ENNOLIFE HCA-TC-200 stands out because of its portability and ease of use. The device requires no specialised training, operates on standard AC power, and does not require specific controlled environmental conditions. Notably, it delivers accurate results within 15 minutes with only 60 microliter (μL) of blood or urine.

This study aimed to evaluate the analytical performance of the ENNOLIFE HCA-TC-200 by comparing its results with those of the Beckman UniCel DxC 880i. Specifically, we assessed parameters of the hepatic panel, namely, aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP), and albumin (ALB); those of the renal panel, namely, blood urea nitrogen (BUN), creatinine (CRE), and uric acid (UA); and those of the urine panel, namely, microalbumin (mALB), urine creatinine (UCRE), and urine protein (UP) due to their clinical relevance in detecting chronic liver disease (CLD), chronic kidney disease (CKD), and diabetes-related renal complications. These conditions are among the most common non-communicable diseases encountered in community medicine and often require early detection and routine monitoring. The evaluation included assessment of method comparison, accuracy, and inter-method agreement relative to the Beckman UniCel DxC 880i.

Materials and Methods

Study cohort

A cohort of clinically stable individuals aged 20 to 80 years, attending routine outpatient care, was recruited from the community and outpatient clinics of Shuang Ho Hospital, Taiwan, between April 4, 2019, and December 20, 2021. The exclusion criteria were being aged <20 or >80 years; being pregnant; and having a history of malignancies, infections, or communicable diseases within the 3 months before recruitment (*Figure 1*). Written informed consent was obtained from all participants. Our study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Taipei Medical University.

Analyser units

Plasma biochemical profiles were obtained using Beckman UniCel DxC 880i and ENNOLIFE HCA-TC-200. Beckman UniCel DxC 880i is a large, immobile conventional unit routinely used in high-volume laboratories. It supports a wide range of clinical chemistry and immunological assays, with an onboard capacity for up to 120 assays selected from a menu of >150. The Beckman UniCel DxC 880i can process up to 1440 clinical chemistry and 400 immunological assays per hour, making it suitable for high-throughput environments. By contrast, ENNO-

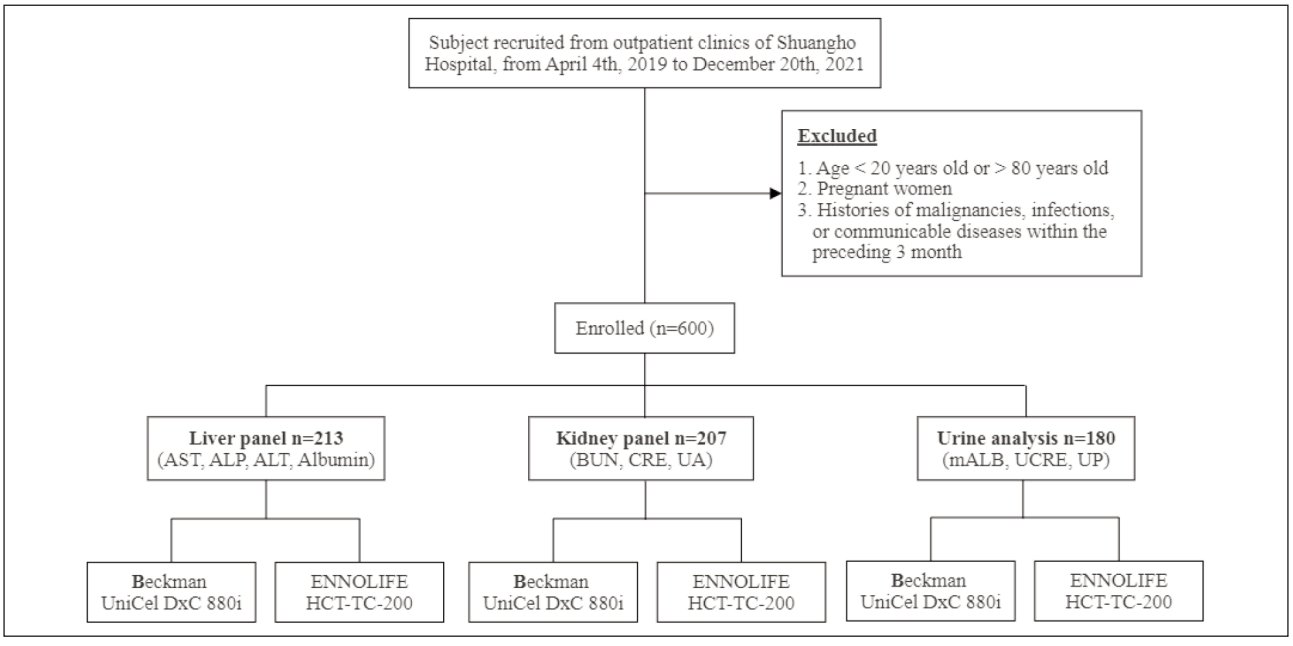

Figure 1 Flowchart depicting patient selection and sample collection.

Table I Physical specifications and operational characteristics of ENNOLIFE HCA-TC-200 and Beckman UniCel DxC 880i.

Specification	ENNOLIFE HCA-TC-200	Beckman UniCel DxC 880i
Sample types	Whole blood, plasma, serum, and urine	Whole blood, plasma, serum, urine, and cerebrospinal fluid
Sample size	60 or 140 μL	
Analysis time	12–17 min	
Directly measured parameters (operating range)	AST (5–1500 U/L)	AST (5–400 U/L)
	ALP (4–1700 U/L)	ALP (5–1000 U/L)
	ALT (5–1500 U/L)	ALT (5–400 U/L)
	Albumin (1–7 g/dL)	Albumin (0.1–7.0 g/dL)
	BUN (2–200 mg/dL)	BUN (1–150 mg/dL)
	Creatinine (0.1–20 mg/dL)	Creatinine (0.1–25 mg/dL)
	Uric acid (0.1–30 mg/dL)	Uric acid (0.5–12.0 mg/dL)
	Microalbumin (0.5–50 mg/dL)	Microalbumin (0.2–30 mg/dL)
	UCRE (20–400 mg/dL)	UCRE (10–400 mg/dL)
	Urine protein (15–200 mg/dL)	Urine protein (6–150 mg/dL)

Figure S1 Comparison of methodologies adopted between ENNOLIFE HCA-TC-200 and Beckman UniCel DxC 880i.

Analyte	ENNOLIFE HCA-TC-200	Beckman UniCel DxC 880i
Blood		
AST	Tris buffer without P5P assay	Tris buffer without P5P assay
ALP	PNPP and AMP assays	PNPP and AMP assays
ALT	Tris buffer without P5P assay	Tris buffer without P5P assay
Albumin	BCG assay	BCG assay
BUN	Urease/conductivity test	Urease-GLDH test
Creatinine	Jaffe kinetic method	Enzymatic assay
Uric acid	Uricase-POD colourimetric assay	Uricase-POD colourimetric assay
Urine		
Microalbumin	Immunoturbidimetry	Immunoturbidimetric assay
Urine creatinine	Jaffe kinetic method	Jaffe reaction
Urine protein	Pyrogallol red assay	Pyrogallol red assay

LIFE HCA-TC-200 is a compact, portable unit designed for smaller sample volumes and faster processing. The principle is based on a compact disc platform that combines a microfluidic system and a full-spectrum spectrometer. The microfluidic system utilises microchannels etched on the disc to facilitate controlled movement, mixing, and reaction of small volumes of plasma or urine (10–12). This enables the simultaneous testing of multiple parameters from a single 60 μL sample. Complementing the microfluidic system is the full-spectrum spectrometer, which facilitates in-depth analysis. The spectrometer detects the

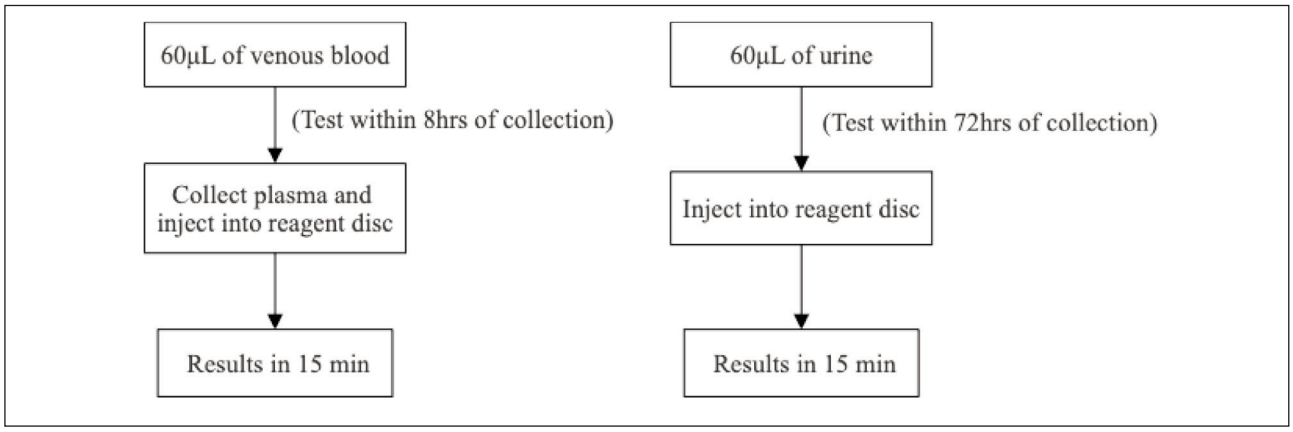

Figure 2 Flowchart depicting sample handling.

full range of transmitted or absorbed light wavelengths across the disc, allowing accurate quantification of various biochemical compounds (13). Together, these components will enable it to perform analyses and provide results within 15 minutes using only 60 μL of plasma or urine. *Table I* presents the physical specifications and operational characteristics of the two analysers. Both analysers were operated following the manufacturer's instructions and standard laboratory procedures. The methodologies employed by each unit for specific analytes are mentioned in *Figure S1*.

The 10 assays used for evaluating the performance of the two analysers are detailed in *Figure S1*, stratified by analyte.

Assay procedure

Sample collection

Participants were instructed to avoid excessive fluid intake for at least 2 hours before specimen collection. Each participant provided 10 mL of venous blood and 10 mL of midstream urine. Blood samples were collected using lithium heparin anticoagulant tubes. Immediately after collection, blood samples were centrifuged at 3000 rpm for 10 minutes at room temperature to separate plasma. The plasma samples were then stored at room temperature and analysed within 8 hours of collection. Urine samples were collected in sterile, preservative-free polypropylene containers, stored at 2–8 °C, and analysed within 72 hours of collection.

Sample analysis

Both plasma and urine specimens (60 μL per sample) were loaded onto reagent discs for analysis using the ENNOLIFE analyser. The following reagent panels were used in this study: ENNOLIFE Kidney Panel (Model 001-246E) for BUN, CRE, and UA; ENNOLIFE Liver Panel (Model 001-246F) for AST, ALT, ALP, and ALB; and ENNOLIFE Urine Microalbumin, Creatinine, and Total Protein Panel (Model 001-256D) for mALB, UCRE, and UP. Results were generated within 15 minutes (*Figure 2*). The samples were first tested using the ENNOLIFE analyser and then the Beckman analyser.

All tests were performed according to the respective manufacturers' instructions. The remaining samples were stored frozen at -80 °C for potential retesting if required.

Statistical analysis

Method comparison was performed using Passing-Bablok regression, with 95% confidence intervals (CIs) calculated for the slope and intercept to evaluate proportional and constant bias. A good agreement was defined as the slope's 95% confidence interval, including 1, and the intercept's 95% CI, including 0. A Bland-Altman analysis was conducted to assess agreement and to calculate the mean bias between the two analysers. Bias was further evaluated by calculating the mean difference between paired measurements and their corresponding 95% CIs. Correlations were assessed using linear regression analysis in SPSS (version 24.0). Acceptable inter-method agreement between the ENNOLIFE and Beckman analysers was defined as a regression slope between 0.90 and 1.10 with a correlation coefficient (R) greater than 0.90. Outliers identified during initial runs were retested to confirm whether the extreme result was due to operator error or instrument variability, and to assess the reproducibility of the analysers; values that remained outside the acceptable analytical range of the ENNOLIFE analyser upon repeat testing were excluded from final agreement analysis. All statistical analyses were conducted in accordance with the Clinical and Laboratory Standards Institute EP09c guidelines (12).

Results

A total of 600 participants were recruited. In total, 213, 207, and 180 samples were obtained for the hepatic panel (AST, ALP, ALT, and ALB), renal panel (BUN, UA, and CRE), and urine panel (mALB, UCRE, and UP), respectively. Samples whose levels exceeded the detection range of the ENNOLIFE analyser were excluded from the analysis to ensure measurement reliability and comparability. The final number of samples analysed for each analyte in each panel is shown in *Table II*.

Method comparison

Passing-Bablok regression revealed inconsistent agreement across analytes (*Figure 3*). Strong agreement was noted for ALB, mALB, and UP, whereas other analytes exhibited proportional and/or constant bias. The slope, intercept, and corresponding 95% CIs for each test are summarised in *Table III*. Bland-Altman plots demonstrating bias across the range of analyte concentrations tested are shown in *Figure 4*. Among all analytes, the smallest mean bias was observed for BUN at -0.18 mg/dL, while the most significant mean bias was noted for ALT at 5.99 U/L. The proportion of samples falling within the 95% limits of agreement exceeded 93% for all analytes.

Accuracy

Hepatic panel

Samples were considered to fall outside the critical range (95% CI) when the levels of AST, ALP, ALT, and ALB exceeded the following thresholds: AST>511 U/L, ALP>575 U/L, ALT>734 U/L, and ALB>4.9 g/dL. After excluding samples whose levels exceeded these thresholds, the accuracy rates for the hepatic panel parameters were 100% for AST, 98.51% for ALP, 98.98% for ALT, and 97.3% for ALB. The accuracy of the ENNOLIFE analyser in evaluating hepatic panel parameters, both before and after calibration, is presented in *Table III*.

Renal panel

Samples were considered to fall outside the critical range (95% CI) when the levels of BUN, CRE, and UA exceeded the following thresholds: BUN>64 mg/dL, CRE>5.68 mg/dL, and UA>5.3 mg/dL. After excluding samples whose levels exceeded these thresholds, the accuracy rates for the renal panel parameters were 99.48% for BUN, 100% for CRE, and 98.39% for UA. The accuracy of the ENNOLIFE analyser in evaluating renal panel parameters, both before and after calibration, is presented in *Table IV*.

Urine panel

Samples were considered to fall outside the critical range (95% CI) when the levels of mALB, UCRE, and UP exceeded the following thresholds: mALB >50 mg/dL, UCRE>105 mg/dL, and UP>36.2 mg/dL. For mALB, among the 109 samples analysed, the ENNOLIFE analyser yielded values of either >50 or <0.5 mg/dL for 16 samples, without providing any precise values. This discrepancy might have influenced the accuracy of the results. After excluding these 16 samples, the corrected accuracy rate for

Table II Number of samples analysed for each analyte after the exclusion of samples exceeding the ENNOLIFE analyser's detection range.

Analyte	Hepatic panel	Renal panel	Urine panel
AST	211	-	-
ALT	212	-	-
ALP	213	-	-
Albumin	213	-	-
BUN	-	206	-
Creatinine	-	205	-
Uric acid	-	207	-
Microalbumin	-	-	109
Urine creatinine	-	-	176
Urine protein	-	-	96

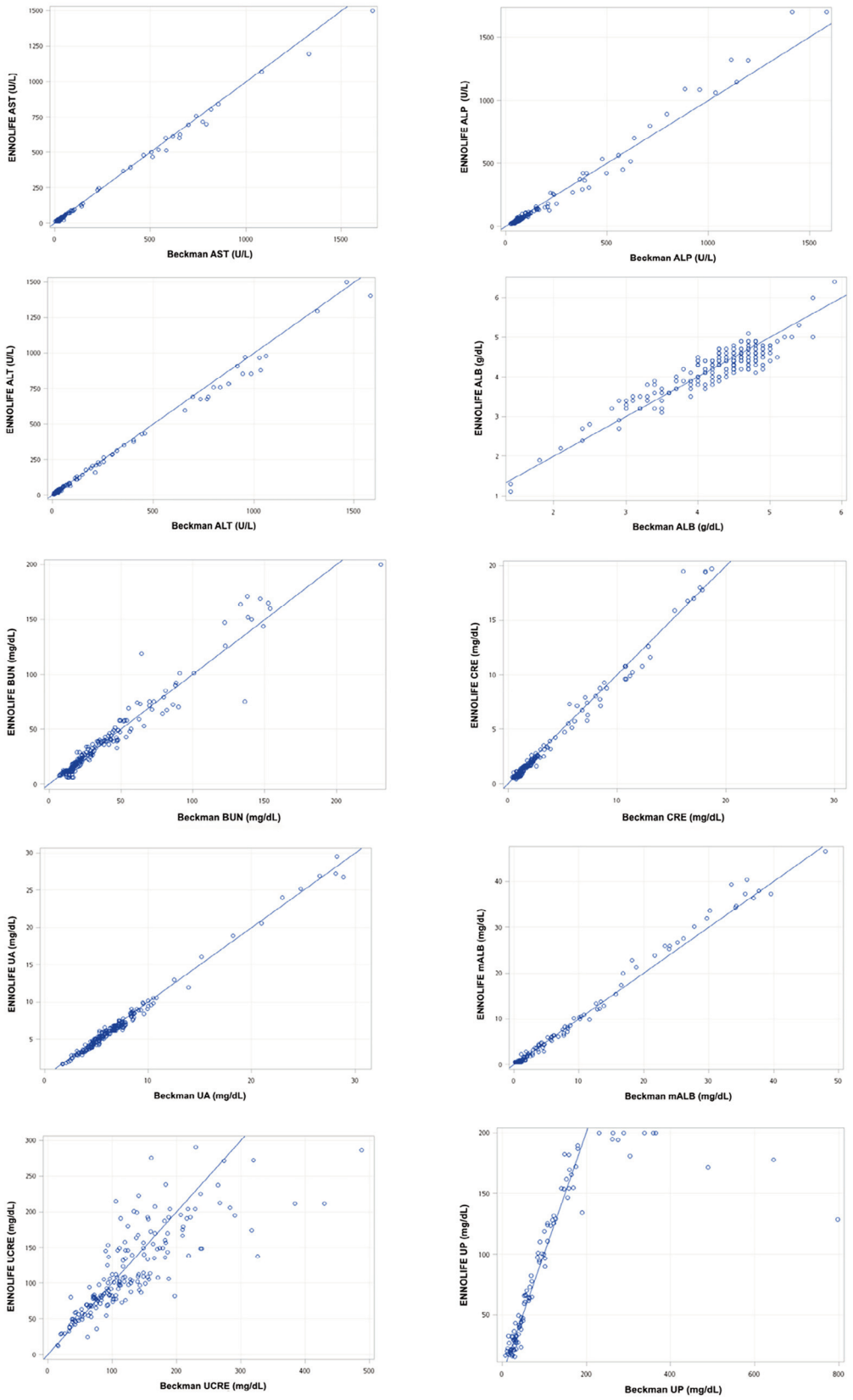

Figure 3 Passing-Bablok regression analysis of chemistry analytes between the ENNOLIFE Chemical Analyser and the Beckman UniCel DxC 880i.

Abbreviations: AST, aspartate aminotransferase; ALP, alkaline phosphatase; ALT, alanine transaminase; ALB, albumin; BUN, blood urea nitrogen; CRE, creatinine; UA, uric acid; mALB, microalbumin; UCRE, urine creatinine; UP, urine protein.

Table III Summary of Passing-Bablok regression analysis.

Parameter	n	Slope (CI)	Intercept (CI)
AST	211	0.981 (0.949, 0.994)	1.288 (0.178, 1.917)
ALP	213	0.951 (0.903, 1.000)	-7.948 (-11, -5.129)
ALT	212	0.963 (0.942, 0.984)	0.671 (0.220, 1.159)
ALB	210	0.889 (0.821, 1.000)	0.428 (3.553E-15, 0.721)
BUN	206	1.076 (1.040, 1.111)	-1.994 (-2.667,-0.920)
CRE	205	0.989 (0.958, 1.009)	-0.063 (-0.097, -0.013)
UA	206	1.000 (0.991, 1.034)	-0.27 (-0.455, -0.226)
mALB	109	1.002 (0.979, 1.027)	0.059 (-0.010, 0.108)
UCRE	176	0.840 (0.772, 0.914)	9.686 (3.807, 16.03)
UP	96	0.973 (0.910, 1.029)	1.220 (-1.076, 4.941)

Abbreviations: AST, aspartate aminotransferase; ALP, alkaline phosphatase; ALT, alanine transaminase; ALB, albumin; BUN, blood urea nitrogen; CRE, creatinine; UA, uric acid; mALB, microalbumin; UCRE, urine creatinine; UP, urine protein.

Table IV Accuracy of the ENNOLIFE analyser in evaluating hepatic panel parameters.

Parameter	Before calibration			After calibration		
	n	Sample range	Accuracy (%)	*n*	Sample range	Accuracy (%)
AST	211	8.3–1332.1 U/L	204/211=96.68%	196	>511 U/L	196/196=100%
ALP	213	25–1585 U/L	200/213=93.90%	201	>575 U/L	198/201=98.51%
ALT	212	5–1462 U/L	200/212= 94.34%	197	>734 U/L	195/197=98.98%
ALB	210	1.4–5.9 g/dL	199/210=94.76%	185	>4.9 g/dL	180/185=97.3%

Abbreviations: AST, aspartate aminotransferase; ALP, alkaline phosphatase; ALT, alanine transaminase; ALB, albumin.

mALB was 100%. For UCRE and UP, after excluding samples whose levels exceeded the established thresholds, the accuracy rates were 98.6% and 99%, respectively. The accuracy of the ENNOLIFE analyser in evaluating urine panel parameters, both before and after calibration, is presented in *Table V*.

Inter-method agreement

Acceptable correlations were noted between the two analysers for all parameters. The correlation, bias, and R values for the hepatic panel (AST, ALP, ALT, and ALB), renal panel (BUN, CRE, and UA), and urine panel (mALB, URCE, and UP) are presented in *Figure 5*.

Both the analysers exhibited strong correlations (R>0.99) for all hepatic panel parameters, except for ALB (R=0.9246). Although the coefficient for ALB was slightly lower than those observed for other analytes, it still indicated a significant between-analyser correlation for ALB.

All renal panel analytes showed strong linear correlations (R>0.97), indicating high agreement between the two analysers.

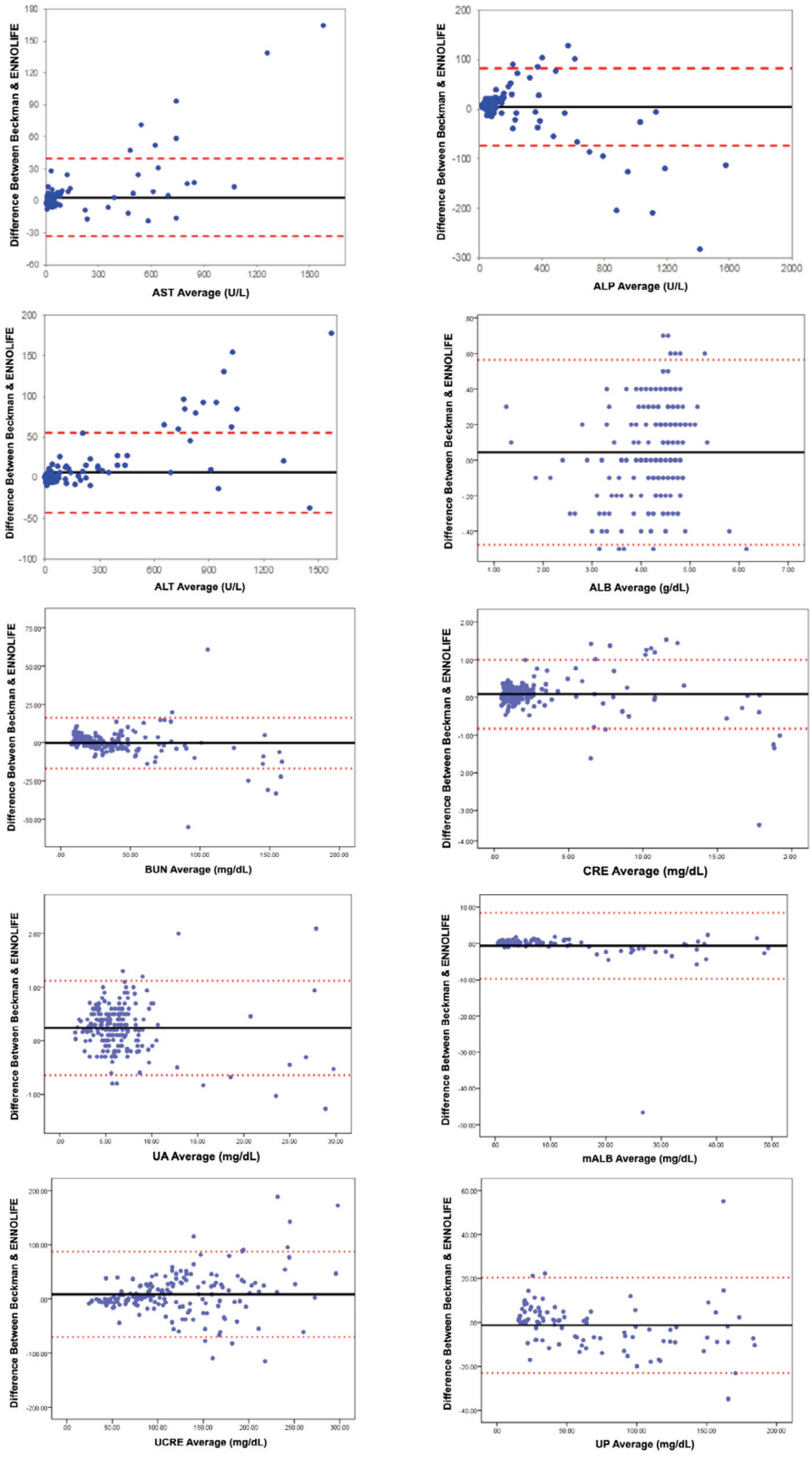

Figure 4 Bland-Altman plots showing differences between the ENNOLIFE Chemical Analyser and the Beckman UniCel DxC 880i chemistry analytes.

The solid line indicates the mean of differences, and the dashed lines indicate the 95% confidence interval.

Abbreviations: AST, aspartate aminotransferase; ALP, alkaline phosphatase; ALT, alanine transaminase; ALB, albumin; BUN, blood urea nitrogen; CRE, creatinine; UA, uric acid; mALB, microalbumin; UCRE, urine creatinine; UP, urine protein.

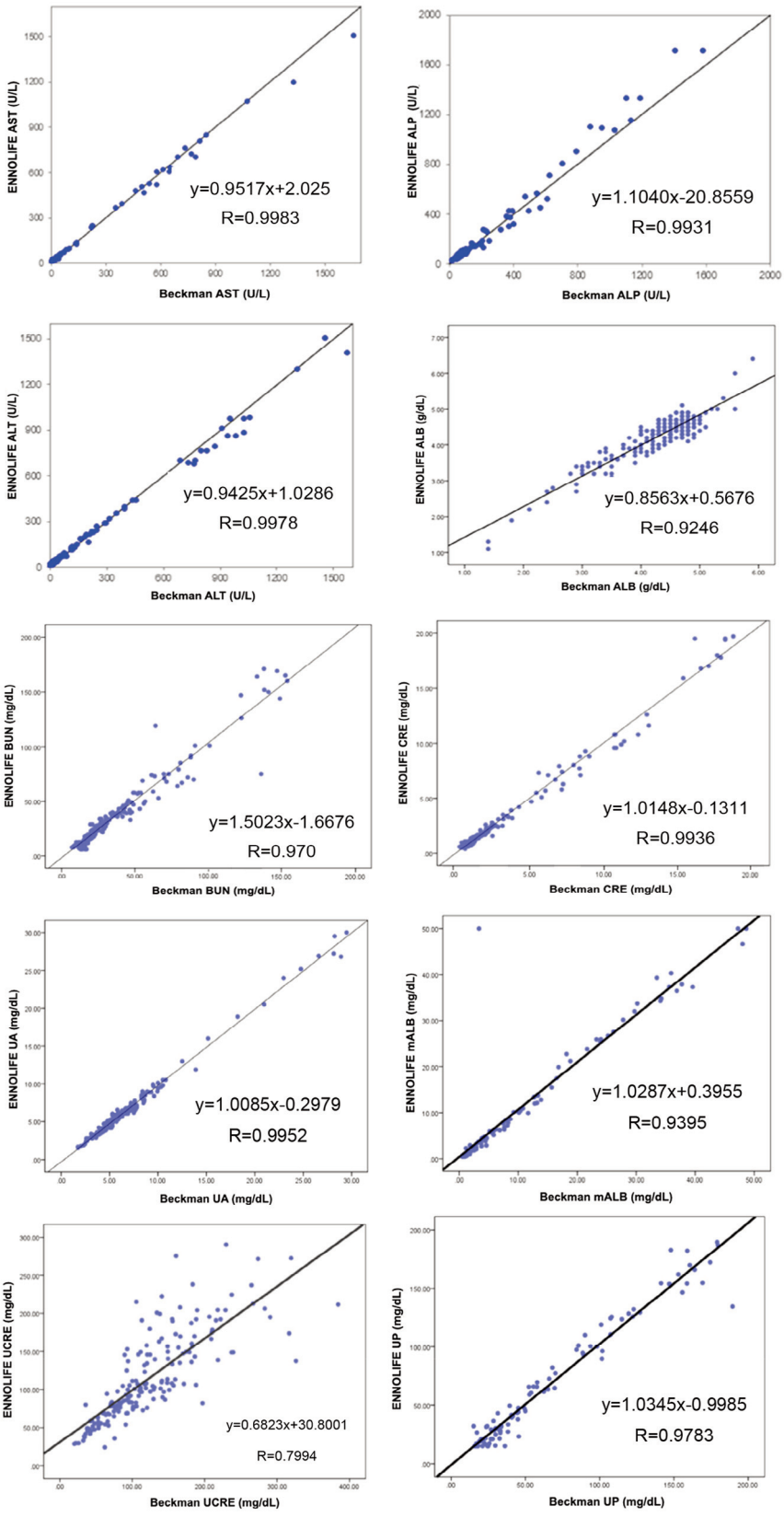

Figure 5 Linear correlation between the Beckman and ENNOLIFE analysers.

Abbreviations: AST, aspartate aminotransferase; ALP, alkaline phosphatase; ALT, alanine transaminase; ALB, albumin; BUN, blood urea nitrogen; CRE, creatinine; UA, uric acid; mALB, microalbumin; UCRE, urine creatinine; UP, urine protein.

Table V Accuracy of the ENNOLIFE analyser in evaluating renal panel parameters.

Parameter	Before calibration			After calibration		
	n	Sample range (mg/dL)	Accuracy (%)	*n*	Sample range (mg/dL)	Accuracy (%)
BUN	206	7–200	199/206=96.60%	194	7–89	193/194=99.48%
CRE	205	0.39–20.0	192/205=93.66%	176	0.39–5.60	176/176=100%
UA	206	1.73–30.0	196/206=95.15%	186	1.73–9.5	183/186=98.39%

Abbreviations: BUN, blood urea nitrogen; CRE, creatinine; UA, uric acid.

Table VI Accuracy of the ENNOLIFE analyser in evaluating urine panel parameters.

Parameter	Before calibration			After calibration		
	n	Sample range (mg/dL)	Accuracy (%)	*n*	Sample range (mg/dL)	Accuracy (%)
mALB	109	0.55–48.65	108/109=99.08%	93	0.59–48.01*	93/93=100%
UCRE	176	20–384.2	166/176=94.32%	142	20–160.4	140/142=98.6%
UP	96	15.1–189.5	91/96=94.79%	71	15.1–147.5	69/71=97.2%

*Excluding mALB samples with values of >50 or <0.5 mg/dL.
Abbreviations: mALB, microalbumin; UCRE, urine creatinine; UP, urine protein.

Both the analysers exhibited strong correlations for all urine panel parameters, except for UCRE (R=0.7994). Although the coefficient for UCRE was lower than those for other analytes, it still indicated a significant between-analyser correlation for UCRE.

Discussion

Overall, this study demonstrated good analytical performance of the new ENNOLIFE chemical analyser when compared to the Beckman Unicel DxC 880i. Bland–Altman plots showed minimal mean biases across all analytes, with over 93% of samples falling within the 95% limits of agreement, indicating strong consistency in measurements. Accuracy analysis revealed high concordance rates, ranging from 97.2% to 100%, within the analyser's defined detection limits. Moreover, most analytes exhibited strong correlation coefficients (R>0.97), supporting the clinical reliability of the ENNOLIFE device.

The Bland-Altman analysis demonstrated high agreement between the ENNOLIFE HCA-TC-200 and the Beckman UniCel DxC 880i across the full range of analyte concentrations tested. The mean bias for most analytes was minimal, ranging from -0.18 mg/dL for BUN to 5.99 U/L for ALT, indicating that measurement differences were clinically negligible in most cases. This suggests that, despite minor deviations, the ENNOLIFE HCA-TC-200 provides results comparable to a high-end reference analyser and may be suitable for clinical applications that prioritise rapid, accessible biochemical assessments.

In contrast to Bland-Altman plots, which demonstrated high agreement and practical interchangeability, Passing-Bablok regression revealed analyte-specific differences in the measurement relationship between the ENNOLIFE and Beckman analysers. Good agreement was observed for ALB, mALB, and UP, with slope and intercept CIs including 1 and 0, respectively. However, other analytes exhibited proportional and/or constant bias, suggesting differences in measurement scaling. These findings indicate that Passing-Bablok regression is more sensitive to proportional deviations and mathematical consistency, even when the mean difference is small. Notably, such biases are not uncommon when comparing assays from different manufacturers, as differences in assay methodology, instrument design, and analytical interferences can contribute to variation in absolute measurement values.

Under conditions requiring small sample volumes and rapid measurements, ENNOLIFE HCA-TC-200 achieved high accuracy, ranging from 97.2% to 100%, for each analyte within a narrower measurement range. Although its measurement range is limited, most values exceeding the critical range were notably higher than the normal thresholds expected in healthy individuals. Such elevated values often indicate potential health concerns that necessitate detailed evaluation in hospital settings, using advanced instrumentation for precise diagnostics and comprehensive assessment. In this context, ENNOLIFE HCA-TC-200 is a potentially effective tool for initial screening and chronic disease monitoring in community health care, particularly in hospital-at-home and resource-limited settings.

CLD remains a global health concern with increasing prevalence. It leads to approximately two million deaths every year, with hepatitis B identified as the primary contributing factor, followed by hepatitis C (14). In response to this public health burden, the World Health Organisation proposed a plan to eliminate viral hepatitis by 2030 (15). In 2019, approximately 296 million individuals worldwide were living with chronic hepatitis B (CHB), but only 10% of these individuals were aware of their condition (16). Notably, individuals with undiagnosed CHB may unknowingly transmit the hepatitis B virus, posing a risk to the broader population. Therefore, identifying these individuals is crucial, particularly in developing countries where the majority of CHB cases are concentrated. Unlike many other chronic diseases, CLD can be cured (chronic hepatitis C) and prevented or treated (CHB) (17). This emphasises the importance of early detection and intervention to optimise management strategies in preventing and controlling CLD. The ENNOLIFE analyser facilitates efficient, accurate, and rapid screening, thereby enabling primary healthcare professionals to identify hepatic problems at an early stage and thus improve clinical outcomes.

The incidence of chronic kidney disease (CKD) is projected to continually increase globally (18), driven by population ageing and increasing diabetes prevalence. Notably, diabetes is the leading cause of CKD worldwide. By 2030, an estimated 5.4 million individuals will require dialysis due to end-stage renal disease (19). Recent national studies and annual reports from the Taiwan Society of Nephrology have shown that Taiwan continues to have among the highest incidence and prevalence of chronic kidney disease (CKD) and end-stage kidney disease (ESKD) worldwide (20), the incidence and prevalence of CKD and end-stage renal disease in Taiwan are among the highest in the world, placing a considerable burden on the country's healthcare system. Despite the increasing prevalence and the substantial clinical economic burden associated with CKD's complications, awareness of the disease remains considerably low because early-stage kidney disease is often asymptomatic and progresses silently (21, 22). Globally, only 6% of the general population and 10% of the high-risk individuals are aware of their CKD status (23). This underscores the pressing need for screening and early detection of CKD at the primary care level. The ENNOLIFE analyser's ability to provide accurate BUN and CRE measurements within a short time frame enables primary healthcare providers to promptly detect potential kidney dysfunction and initiate necessary follow-up or refer to specialists. Elevated UA levels are associated with an increased risk of CKD progression (24). Thus, UA is an essential component of renal function monitoring tests for patients with kidney disease.

In addition to blood examinations, the ENNOLIFE analyser can analyse urine samples. Urine mALB, UP, and UCRE serve as key indicators of renal function and can help monitor kidney disease. The mALB/UCRE and UP/UCRE ratios are widely used for estimating daily protein excretion in urine (25). Albuminuria is the gold standard for detecting glomerular injury (26). Early detection of albuminuria presents an opportunity to delay kidney damage and preserve renal function. Because CKD currently has no cure, routine monitoring is crucial for effective disease management. The portability and user-friendly design of the ENNOLIFE analyser can facilitate regular assessments across settings such as clinics, community healthcare centres, and nursing homes. This not only reduces the need for frequent hospital visits but also enables the early detection of changes in kidney function, thereby delaying the progression of CKD and related complications.

An ageing population and increasing demand for patient-centred health care are imposing a considerable burden on healthcare systems (27). In this context, portable diagnostic technologies have emerged as essential components of modern healthcare delivery, enabling rapid, on-site assessments that facilitate timely clinical decision-making. Advances in miniaturisation, nanotechnology, and microfluidics have enabled the development of compact analysers capable of delivering molecular-level diagnostic information (28). These innovations have made such devices not only more affordable and easier to use but also more accurate and sensitive. Although numerous portable instruments are available on the market, most measure only a single or a few parameters. However, ENNOLIFE HCA-TC-200 offers a comprehensive range of diagnostic tests for both blood and urine samples.

Sang et al. measured hepatic biomarkers AST and ALT using a dual-channel blood enzyme analyser and compared the results with those obtained with a high-precision clinical biochemistry analyser, Roche Cobas C702 (29). Their study revealed favourable linearity, but only within a narrower concentration

range. Notably, the researchers did not analyse ALP or albumin. Kosack et al. compared performance between the Nova StatSensor Xpress Creatinine analyser and the central laboratory method Vitros 5.1FS (Ortho Clinical Diagnostics) (30). Their findings regarding the Clinical Laboratory Improvement Amendments criteria for acceptable performance are consistent with ours. The researchers highlighted key challenges in accurately measuring low and high pathological creatinine levels using the Nova StatSensor analyser. However, the Nova StatSensor analyser covers a slightly broader range for creatinine, deviating from the reference method at values exceeding 6.8 mg/dL, whereas the ENNOLIFE analyser deviates at 5.6 mg/dL. To optimise the benefits of portable analysers, the range of measurable parameters must be expanded in the future.

Urine dipsticks are widely used for urine analysis because of their speed, cost-effectiveness, and convenience. However, many of the available dipsticks fail to provide quantitative measurements and often exhibit compromised sensitivity, specificity, and accuracy compared with those of central laboratory techniques (31). Currin et al. assessed the diagnostic accuracy of the semiquantitative ACR by using the Sysmex UC-1000 urine dipstick system (32). Their analysis involved calculating the sensitivity, specificity, positive predictive value, and negative predictive value for the ACR. Although their findings indicated a favourable negative predictive value for excluding albuminuria, their study did not include a quantitative analysis. By contrast, the ENNOLIFE analyser stands out for its ability to provide accurate, highly reproducible quantitative measurements. The Nova StatSensor Xpress Creatinine analyser and Sysmex UC-1000 urine test strip analyser focus primarily on creatinine levels and urine specimens, respectively. In contrast, the ENNOLIFE analyser includes a broader renal panel, encompassing BUN, CRE, and UA, as well as urine analysis parameters. This enables a more comprehensive assessment of renal function.

This study has several strengths that enhance the reliability of its findings. The exclusion of pregnant women and individuals with recent histories of malignancies, infections, or communicable diseases ensured an accurate representation of data. Retesting the outliers further strengthened the precision and reproducibility of the results. Moreover, this study assessed a wide range of diagnostic parameters, including blood and urine analyses, thereby enabling a comprehensive assessment of various physiological factors.

This study has several limitations. It was conducted at a single centre with a relatively small sample. Although participants were recruited from real-world outpatient settings, they did not represent a broad spectrum of patients with advanced hepatic or renal dysfunction. These factors may limit the generalizability of our findings to other clinical settings. To address these limitations, large-scale studies involving diverse populations, including those with varying disease severities, and various healthcare settings, should be conducted. Furthermore, the comparative analysis was limited to a single in vitro testing system, Beckman UniCel DxC 880i, raising concerns about potential systemic bias in the results.

Conclusion

Our evaluation of the ENNOLIFE HCA-TC-200 analyser demonstrated analytical performance comparable to that of the Beckman UniCel DxC 880i. It showed strong agreement and high accuracy across a range of hepatic and renal biomarkers when compared with a high-throughput conventional laboratory reference. The portability and operational efficiency of the ENNOLIFE analyser make it potentially applicable for outpatient and community-based settings, where it can improve accessibility in resource-limited regions. Future studies are warranted to validate its performance across more diverse patient populations and real-world environments.

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Ethics committee approval

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Taipei Medical University (protocol code N201910039, approved on 2024/03/05).

Use of AI for writing assistance

No AI technologies utilised.

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Conflict of interest statement

All the authors declare that they have no conflict of interest in this work.

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