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Performance Verification of the LOCMEDT C200 Automatic Biochemistry Analyzer Using Routine Clinical Samples

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ABSTRACT

Analytical verification is an essential prerequisite before implementing a new automated biochemistry analyzer in routine clinical laboratories to ensure reliability, accuracy, and compliance with recognized quality standards. This study aimed to verify the analytical performance of the LOCMEDT C200 Automatic Biochemistry Analyzer in accordance with CLSI and ISO 15189 principles by evaluating precision, accuracy (bias), and method comparison against an established routine analyzer using CLIA allowable error limits as performance benchmarks. Precision was assessed using a modified CLSI EP15-A3 approach with two levels of internal quality control materials to determine within-run and between-day coefficients of variation (CV%). Accuracy and method comparison were evaluated according to CLSI EP09-A3 by analyzing 40 patient serum samples in duplicate across clinically relevant concentration ranges. Statistical analyses included correlation assessment, percentage bias, and paired significance testing, with interpretation based on CLIA total allowable error criteria. The LOCMEDT C200 demonstrated acceptable analytical precision for most parameters, with between-day CV values largely within CLIA limits. Method comparison showed very strong correlation between the LOCMEDT C200 and the reference analyzer across all analytes. Most parameters, including glucose (3.58%), urea (4.06%), creatinine (7.07%), triglycerides (7.28%), and HDL (1.85%), showed bias within CLIA allowable limits. However, AST (32.30%) and total cholesterol (22.32%) exceeded CLIA total error thresholds, indicating systematic bias that requires further technical evaluation. Although statistically significant differences were observed for albumin and total protein ($p < 0.05$), the mean deviations remained within clinically acceptable limits. Overall, the LOCMEDT C200 demonstrated acceptable analytical performance for routine clinical chemistry testing, although targeted calibration assessment is recommended for analytes with elevated bias.

Keywords:
Analytical verification; Automatic biochemistry analyzer; LOCMEDT C200; Precision; Method comparison

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1. Introduction

Clinical laboratory testing plays a pivotal role in modern healthcare and is estimated to inform a substantial proportion of medical decisions related to diagnosis,

prognosis, and therapeutic monitoring [1]. The reliability of laboratory test results is therefore essential to ensure patient safety and effective clinical management [2]. Automatic biochemistry analyzers have become indispensable tools in clinical laboratories because of their high throughput, standardized analytical processes, and reduced risk of human error [3],[4]. However, despite continuous advances in analytical technology, the accuracy and precision of laboratory results remain highly dependent on analyzer performance under actual operating conditions [1].

Before an analytical system is implemented for routine patient testing, laboratories are required to conduct verification studies to confirm that the analyzer meets predefined performance specifications [5]. Verification serves as a critical quality assurance process to demonstrate that manufacturer-stated claims can be consistently achieved within the user's laboratory environment [4]. International laboratory accreditation standards also emphasize analytical verification as an essential component of good laboratory practice, risk management, and result reliability [6].

Analytical performance verification generally includes the evaluation of precision, accuracy (bias), and comparability with established reference or routine methods [2],[5]. Precision assessment ensures the repeatability and reproducibility of measurements, whereas accuracy evaluation confirms the closeness of measured values to assigned or comparative target values [4]. Method comparison studies are also essential to assess the agreement between a new analytical system and an established routine method, thereby minimizing the risk of clinically significant discrepancies in patient results [3],[7].

Inadequate verification of analytical systems may lead to systematic errors, misinterpretation of laboratory findings, and adverse clinical consequences [1]. This issue is particularly important in routine clinical laboratories, where automatic biochemistry analyzers are used for the measurement of high-volume and clinically relevant biochemical parameters [2]. Therefore, comprehensive verification studies are necessary not only to fulfill regulatory and accreditation requirements, but also to support clinical confidence in laboratory-generated data [6],[5].

The LOCMEDT C200 Automatic Biochemistry Analyzer is a newly introduced analytical system intended for routine clinical chemistry testing. Although manufacturer-provided performance claims are available, independent verification under routine laboratory conditions remains necessary before the system can be adopted for clinical use [5],[4]. At present, published evidence regarding the independent analytical performance verification of the LOCMEDT C200 using routine clinical samples remains limited. This gap is important because analyzer performance may vary across laboratory settings, sample characteristics, and implementation conditions.

Therefore, this study aimed to verify the analytical performance of the LOCMEDT C200 Automatic Biochemistry Analyzer by evaluating precision, accuracy (bias), and method comparison in accordance with internationally accepted verification principles [5], [6]. The findings of this study are expected to provide supporting evidence for the reliability of the LOCMEDT C200 in routine clinical laboratory use and to contribute to the broader body of knowledge on analytical verification of automated biochemistry analyzers [2].

2. Methods

Study Design

This study was an analytical performance verification study conducted prior to the routine clinical implementation of the LOCMEDT C200 Automatic Biochemistry

Analyzer. Verification was performed to confirm that the analytical performance claimed by the manufacturer could be achieved under actual laboratory operating conditions. The study focused on three analytical performance characteristics, namely precision, accuracy (bias), and method comparison, in accordance with CLSI verification principles and ISO 15189 requirements [8], [9], [6].

Instrumentation

Analytical verification was performed using the LOCMEDT C200® LOC-200 Automatic Biochemistry Analyzer (LOCMEDT C200®, Indonesia), a fully automated clinical chemistry system based on photometric measurement principles. The analyzer uses single-use cartridge-based reagents with integrated centrifugation, requires a sample volume of approximately 90–120 µL, and provides analytical results within 8–12 minutes per test. Method comparison was conducted using the Indiko® biochemistry analyzer as the routine laboratory reference method.

Verification Strategy

Method verification was undertaken because the analyzer had previously undergone manufacturer validation and was intended for routine laboratory use. The purpose of this study was to verify whether the analytical system could achieve acceptable performance in the user laboratory setting. The evaluated parameters included analytical precision, analytical accuracy (bias), and comparability with an established routine analyzer. These parameters were selected because they represent essential verification elements for routine implementation and clinical reliability [6], [8], [9].

Precision Study

Precision verification was conducted using internal quality control (IQC) material at a clinically relevant concentration level. Precision was assessed using a modified CLSI EP15-A3 design [8]. For within-run precision, the control material was analyzed 20 consecutive times in a single analytical run. For between-day precision, the control material was analyzed in triplicate per day for five consecutive days. Precision was expressed as the coefficient of variation (CV%), and the observed values were evaluated against manufacturer claims and CLIA allowable performance limits [8], [11].

Accuracy (Bias) Verification

Analytical accuracy was assessed using 40 residual patient serum samples representing clinically relevant concentration ranges for each analyte. All samples were analyzed in duplicate on both the LOCMEDT C200 and the reference analyzer in accordance with CLSI EP09-A3 recommendations [9]. For bias estimation, the assigned target value for each analyte was defined as the mean result obtained from the reference analyzer (Indiko®), and percentage bias was calculated as the relative difference between the mean value generated by the LOCMEDT C200 and the corresponding mean target value from the reference method. Bias acceptability was interpreted using CLIA total allowable error (TEa) criteria [9], [11]. This approach was adopted to standardize the sample number throughout the manuscript and to clarify the definition of target value, as required during peer review.

Method Comparison Study

Method comparison was performed using the same 40 residual patient serum samples analyzed in duplicate on both the LOCMEDT C200 and the Indiko® analyzer. The evaluated analytes included albumin, total protein, alkaline phosphatase, GGT, ALT, AST, total bilirubin, uric acid, urea, creatinine, glucose, total cholesterol, triglycerides, and HDL-cholesterol. Agreement between methods was assessed by comparing mean values, correlation coefficients, percentage bias, and paired statistical

significance. The purpose of this analysis was to determine whether the LOCMEDT C200 produced results comparable to those of the established routine analyzer across clinically relevant analyte ranges [9], [7].

Data Analysis

All analytical results were tabulated and statistically analyzed. Precision was expressed as mean, standard deviation (SD), and CV%. Accuracy was reported as percentage bias relative to the reference method. Method comparison results were evaluated using correlation coefficients (R), paired significance testing, and percentage bias (D%), with interpretation based on CLIA total allowable error criteria [11]. Statistical significance was considered at $p < 0.05$; however, parameters showing statistically significant differences were further interpreted in relation to clinical acceptability rather than statistical significance alone. This distinction was made to differentiate analytical differences that were statistically detectable from those that were clinically meaningful.

Ethical Considerations

This study used anonymized residual patient serum samples obtained from routine clinical laboratory testing. No patient-identifiable information was accessed at any stage of the study. Ethical approval was waived by the Institutional Ethics Committee because the study used leftover clinical specimens in anonymized form and posed no additional risk to patients. The study was conducted in accordance with ethical laboratory practice and the principles of the Declaration of Helsinki [4].

3. Results and Discussion

Precision Verification

Precision was evaluated using within-run and between-day measurements with internal quality control materials, and the results are presented in **Table 1** and **Table 2**. Overall, the LOCMEDT C200 demonstrated acceptable analytical precision for most routine clinical chemistry parameters under the study conditions. As shown in **Table 1**, the between-day coefficient of variation (CV) ranged from 6.31% to 12.52% for most analytes and remained within the corresponding CLIA acceptance limits. Albumin, alkaline phosphatase, GGT, ALT, AST, total bilirubin, urea, creatinine, glucose, total cholesterol, triglycerides, and HDL-cholesterol all showed between-day precision that was still clinically acceptable according to CLIA criteria [11].

Table 1. Between-Day Precision Performance of the LOCMEDT C200 Analyzer

Analyte	Mean	SD	Between-Day CV (%)	Manufacturer Claim (%)	CLIA Acceptance Limit (%)
Albumin (ALB)	4.37	0.32	7.32	5.0	10
Total Protein (TP)	6.27	0.50	7.97	5.0	8
Alkaline Phosphatase (ALP)	200.45	17.86	8.91	10.0	20
GGT	49.90	4.93	9.88	10.0	15
ALT	36.40	4.16	11.43	10.0	15
AST	31.55	3.95	12.52	10.0	15
Total Bilirubin (TBIL)	2.13	0.23	10.80	10.0	20
Uric Acid (UA)	5.74	0.63	10.98*	6.0	10
Urea	44.23	2.79	6.31	10.0	9
Creatinine (CREA)	1.32	0.13	9.85	10.0	15
Glucose (GLU)	113.60	8.48	7.46	10.0	8

Total Cholesterol (CHOL)	177.20	14.32	8.08	6.0	10
Triglycerides (TG)	115.60	9.57	8.28	10.0	15
HDL-Cholesterol	62.00	6.53	10.53	10.0	20

Note: **Exceeds the CLIA acceptance limit.*

However, a small number of parameters require attention. Uric acid showed a between-day CV of 10.98%, which exceeded the CLIA acceptance limit of 10%, indicating suboptimal intermediate precision under routine operating conditions. Total protein showed a between-day CV of 7.97%, which remained acceptable but was very close to the CLIA threshold of 8%, suggesting that its analytical stability should be monitored carefully in continued use. In addition, several analytes, including albumin, total protein, total cholesterol, and uric acid, showed precision performance less favorable than the corresponding manufacturer claims, although most of them still remained within clinically acceptable limits according to CLIA. This pattern suggests that performance under real laboratory conditions may differ from manufacturer-declared specifications, particularly for analytes that are more sensitive to reagent stability, calibration consistency, or day-to-day environmental variation.

Table 2. Precision Performance Summary of the LOCMEDT C200 Analyzer

Parameter	**Mean**	**Within-Run CV (%)**	**Between-Day CV (%)**	**Manufacturer Claim (%)**	**CLIA Acceptance Limit (%)**
Albumin (ALB)	4.35–4.37	6.21	7.32	2.0–5.0	10
Total Protein (TP)	6.17–6.27	7.78	7.97	2.0–5.0	8
Alkaline Phosphatase (ALP)	196.2–200.4	3.87	8.91	5.0–10.0	20
GGT	47.5–49.9	8.28	9.88	5.0–10.0	15
ALT	35.8–36.4	8.53	11.43	5.0–10.0	15
AST	30.5–31.5	8.71	12.52	5.0–10.0	15
Total Bilirubin (TBIL)	2.09–2.13	8.13	10.80	5.0–10.0	20
Uric Acid (UA)	5.65–5.74	12.04*	10.98*	4.0–6.0	10
Urea	43.4–44.2	5.10	6.31	5.0–10.0	9
Creatinine (CREA)	1.31–1.32	9.92	9.85	5.0–10.0	15
Glucose (GLU)	113.6–114.1	7.04	7.46	5.0–10.0	8
Total Cholesterol (CHOL)	174.2–177.2	5.26	8.08	4.0–6.0	10
Triglycerides (TG)	112.6–115.6	8.46	8.28	5.0–10.0	15

HDL-Cholesterol	61.5–62.0	8.62	10.53	4.0–10.0	20

Note: **Exceeds the CLIA acceptance limit.*

The within-run and between-day summary shown in **Table 2** further supports the overall stability of the system. Most analytes demonstrated consistent repeatability and intermediate precision, indicating that the LOCMEDT C200 is generally reliable for routine biochemistry testing. Nevertheless, the relatively higher imprecision observed for uric acid and the borderline result for total protein indicate that intermediate precision may be influenced by real-world operational factors, including reagent stability after reconstitution, day-to-day environmental fluctuations, and routine laboratory handling conditions. From a clinical laboratory perspective, these findings remain acceptable for most parameters and support routine application of the analyzer, while also highlighting the need for ongoing quality monitoring for selected analytes [6], [11],[12].

Method Comparison and Bias Evaluation

Method comparison and bias evaluation were performed using 40 residual patient serum samples analyzed in duplicate on both the LOCMEDT C200 and the Indiko® reference analyzer, and the results are presented in **Table 3**. Overall, the LOCMEDT C200 showed very strong correlation with the reference method across all evaluated analytes, with correlation coefficients ranging from 0.993 to 0.999. This finding indicates a high degree of analytical comparability between the two systems. However, high correlation alone does not necessarily indicate acceptable clinical agreement; therefore, the results were further interpreted using relative bias (D%) and CLIA total allowable error (TEa) criteria [9],[7],[11],[14].

Table 3. Method Comparison and Bias Evaluation of the LOCMEDT C200 Versus the Indiko® Reference Analyzer

Analyte	LOCMEDT C200 Mean	Indiko Mean	Bias, D (%)	CLIA TEa (%)	p-value	Correlation (R)
Albumin	4.16	3.96	5.12	10	0.002	0.993
Total Protein	7.80	7.90	1.36	8	<0.001	0.998
Alkaline Phosphatase (ALP)	91.36	87.80	4.05	20	0.862	0.999
GGT	39.42	37.19	6.00	15	0.904	0.999
ALT	18.82	16.91	11.30	15	0.670	0.999
AST	28.58	21.60	32.30*	15	0.039	0.999
Total Bilirubin (TBIL)	0.54	0.50	9.82	20	0.639	0.999
Uric Acid	4.94	5.35	7.67	10	0.232	0.997
Urea	27.64	28.81	4.06	9	0.792	0.997
Creatinine	0.88	0.95	7.07	15	0.549	0.999
Glucose	152.22	157.89	3.58	8	0.589	0.998
Total Cholesterol	221.40	181.00	22.32*	10	0.026	0.999
Triglycerides	154.82	166.98	7.28	15	0.209	0.999
HDL-Cholesterol	50.18	51.12	1.85	20	0.331	0.999

Note: *D (%) represents the relative bias between the LOCMEDT C200 and the Indiko® reference analyzer. TEa = total allowable error according to CLIA criteria. Exceeds the CLIA allowable limit.*

Most analytes demonstrated bias values within the corresponding CLIA allowable limits. Glucose (3.58%), urea (4.06%), creatinine (7.07%), triglycerides (7.28%),

HDL-cholesterol (1.85%), albumin (5.12%), total protein (1.36%), alkaline phosphatase (4.05%), GGT (6.00%), ALT (11.30%), total bilirubin (9.82%), and uric acid (7.67%) all remained within their respective CLIA TEa thresholds. These findings suggest that, for the majority of routine chemistry parameters, the LOCMEDT C200 provides clinically acceptable results when compared with the established routine analyzer [11].

Nevertheless, two analytes showed clinically relevant deviations. AST demonstrated a bias of 32.30%, which exceeded the CLIA allowable total error of 15%, while total cholesterol showed a bias of 22.32%, exceeding the CLIA limit of 10%. These results indicate that, despite excellent correlation, the agreement for these analytes was not clinically acceptable under the present verification conditions. Therefore, AST and total cholesterol require further technical evaluation, particularly with regard to calibration alignment, reagent formulation, and analytical standardization between the two platforms [11],[14].

Paired significance testing further showed that most analytes did not differ significantly between methods, including alkaline phosphatase, GGT, ALT, total bilirubin, uric acid, urea, creatinine, glucose, triglycerides, and HDL-cholesterol ($p > 0.05$). In contrast, albumin, total protein, AST, and total cholesterol showed statistically significant differences. However, the clinical interpretation of these differences should not rely on p-values alone. Although albumin and total protein were statistically different, their relative bias remained within CLIA allowable limits, indicating that the observed deviations were unlikely to compromise clinical interpretation. By contrast, AST and total cholesterol were not only statistically different but also exceeded TEa thresholds, making them more relevant from a clinical and analytical quality perspective [11], [14].

Clinical Interpretation of Statistically and Clinically Relevant Deviations

Although the LOCMEDT C200 showed very strong correlation with the reference analyzer across all evaluated analytes, clinical acceptability cannot be determined by correlation coefficients alone. In method comparison studies, high correlation primarily reflects the strength of association between two methods, whereas clinical interchangeability must be assessed by examining the magnitude of bias relative to established total allowable error (TEa) limits [11],[14]. Therefore, the present findings should be interpreted by considering both statistical significance and clinical relevance in parallel with CLIA-based analytical quality specifications [6],[11]. Detailed results for individual analytes are presented in **Table 3**, while the overall clinical interpretation is summarized in **Table 4**.

AST and total cholesterol demonstrated clinically important deviations because their observed bias exceeded the corresponding CLIA TEa thresholds. The bias for AST reached 32.30%, which was substantially higher than the allowable limit of 15%, while total cholesterol showed a bias of 22.32%, exceeding the CLIA limit of 10%. These findings indicate that, despite excellent correlation with the reference analyzer, the agreement for these two analytes was not clinically acceptable under the present verification conditions. This magnitude of deviation suggests the presence of systematic bias that may affect result interpretation if the two methods are used interchangeably without further technical evaluation [11],[14].

For AST, one plausible explanation for the observed discrepancy is methodological variation related to reagent formulation, particularly the use or absence of pyridoxal-5-phosphate (P5P) activation in aminotransferase assays. IFCC-based reference procedures incorporate P5P supplementation to optimize enzyme activity measurement, and differences in this component between analytical systems may produce systematic shifts in AST results [13]. From a clinical laboratory perspective, this

finding suggests that recalibration, additional method verification, or the establishment of method-specific interpretive limits may be necessary before AST results from the LOCMEDT C200 can be considered fully interchangeable with those of the reference system [6],[11],[13].

Table 4. Summary of Clinically Relevant Analytical Performance of the LOCMEDT C200

Analyte/Category	Key Finding	Clinical Interpretation
Most analytes	Bias within CLIA TEa limits	Clinically acceptable
Albumin	Statistically significant difference, but bias within TEa	Acceptable for clinical use
Total Protein	Statistically significant difference, but bias within TEa	Acceptable for clinical use
AST	Bias 32.30%, exceeding CLIA TEa 15%	Requires further technical evaluation
Total Cholesterol	Bias 22.32%, exceeding CLIA TEa 10%	Requires further technical evaluation

Note: *Clinical interpretation was based on bias relative to CLIA total allowable error (TEa), not on p-value alone.*

A similar concern applies to total cholesterol, for which the observed bias exceeded the CLIA allowable threshold despite the very high correlation coefficient. This pattern indicates that the issue is not random imprecision, but rather a systematic difference between methods, potentially related to calibration traceability, reagent matrix effects, or standardization differences between manufacturers [14]. Because total cholesterol is widely used in cardiovascular risk assessment, even analytically consistent but systematically shifted results may have consequences for patient classification when decision thresholds are narrow. Accordingly, this analyte should undergo targeted calibration review and additional comparative assessment before full routine interchangeability is assumed [11],[14].

By contrast, albumin and total protein showed statistically significant differences between methods, yet their relative bias values remained within the corresponding CLIA allowable limits. This indicates that the observed between-method differences, although statistically detectable, were still analytically acceptable from a clinical standpoint. These findings underscore an important principle in analytical verification: statistical significance does not necessarily imply clinically meaningful disagreement. In high-correlation datasets with relatively small analytical dispersion, small mean differences may produce significant p-values without exceeding permissible analytical error limits. Therefore, interpretation should prioritize clinical acceptability criteria rather than significance testing alone [11],[14].

Taken together, these findings emphasize that analytical verification should integrate correlation, bias estimation, and clinically relevant quality specifications rather than relying on a single statistical indicator. In addition to CLIA-based criteria, biological variation-based quality specifications may provide complementary benchmarks for judging the practical relevance of observed bias and imprecision, particularly for analytes used in longitudinal monitoring or clinical decision thresholds [15]. Under the present study conditions, most analytes demonstrated acceptable clinical comparability, whereas AST and total cholesterol remain the main parameters requiring additional

technical assessment before unrestricted routine interchangeability can be recommended [6],[11],[15].

Practical Implications for Routine Clinical Use

The findings of this study have important implications for the routine clinical implementation of the LOCMEDT C200 Automatic Biochemistry Analyzer. Overall, the analyzer demonstrated acceptable analytical performance for most routine chemistry parameters, indicating that it can support routine laboratory service under appropriate quality assurance conditions. From a practical perspective, this suggests that the LOCMEDT C200 may be integrated into routine clinical workflows for commonly requested biochemical tests, provided that implementation is accompanied by structured internal quality control, calibration verification, and periodic performance review in accordance with laboratory quality management principles [6],[11],[12].

At the same time, the present findings indicate that routine implementation should not be approached as uniform across all analytes. Although most parameters met clinically acceptable criteria, AST and total cholesterol showed bias beyond the corresponding CLIA total allowable error thresholds. This means that, in routine practice, results for these analytes should be interpreted with greater caution until further technical verification has been completed. Practical follow-up measures may include recalibration assessment, review of reagent traceability and method alignment, and, where necessary, evaluation of method-specific interpretive thresholds or reference intervals before unrestricted interchangeability with the reference analyzer is assumed [6],[11],[15].

These findings also reinforce the importance of distinguishing overall analyzer suitability from analyte-specific analytical limitations. A system may perform satisfactorily for the majority of routine tests while still requiring targeted optimization for selected parameters. In this context, the LOCMEDT C200 appears suitable for routine clinical chemistry use for most evaluated analytes, but its implementation should remain supported by continuous analytical surveillance rather than one-time verification alone. Ongoing monitoring using internal quality control materials, external quality assessment when available, and periodic comparison against an established routine method would strengthen confidence in long-term analytical stability and reduce the risk of clinically meaningful bias over time [6],[12].

From a broader laboratory management perspective, these results highlight that method verification is not only a technical requirement for accreditation, but also a practical safeguard for patient care. Reliable analytical performance supports consistency in diagnosis, follow-up testing, and therapeutic monitoring, whereas unresolved systematic bias may affect interpretation when clinical decisions are based on narrow cut-off values. Therefore, the practical value of this study lies not only in supporting the use of the LOCMEDT C200, but also in identifying the specific analytes for which additional optimization is needed before full routine deployment can be considered analytically secure [6],[11],[15].

Limitations of the Study

This study has several limitations that should be considered when interpreting the findings. First, the verification was conducted in a single laboratory setting, which may limit the generalizability of the results to other institutions with different environmental conditions, workflow characteristics, or calibration practices. Second, method comparison and bias estimation were based on 40 residual patient serum samples, which, although acceptable for verification purposes, may still provide limited representation of the full analytical and clinical concentration ranges encountered in

broader routine practice. Third, the study focused on short-term analytical verification and did not include extended longitudinal monitoring using third-party quality control materials or external quality assessment data, which would be valuable for confirming long-term analytical stability. In addition, although most analytes showed acceptable performance, the present study did not fully explore all potential sources of systematic bias, particularly for analytes such as AST and total cholesterol that exceeded CLIA allowable limits. Therefore, further multicenter studies with larger sample sets, broader analyte coverage, and continued post-implementation quality monitoring are recommended to strengthen the evidence for routine clinical use of the LOCMEDT C200 analyzer.

4. Conclusion

The LOCMEDT C200 Automatic Biochemistry Analyzer demonstrated generally acceptable analytical performance for routine clinical chemistry testing, with most evaluated analytes meeting CLIA-based precision and bias criteria. Method comparison showed very strong correlation with the reference analyzer, and most parameters remained within clinically acceptable limits. However, AST and total cholesterol exhibited bias exceeding the corresponding allowable error thresholds, indicating the need for further technical evaluation before full routine interchangeability can be assumed for these analytes. Overall, the findings support the use of the LOCMEDT C200 in routine clinical laboratory practice with appropriate quality monitoring, while future studies involving broader sample ranges, extended long-term evaluation, and additional calibration assessment are recommended to strengthen implementation confidence.

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Conflict of Interest:

The authors declare that there are no conflicts of interest related to the publication of this article.

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