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Verification of Quantitative Analytical Methods for Routine Clinical Biochemistry Analytes on Alinity ci Series and Architect ci 8200 at the Mohammed VI University Hospital of Oujda (Morocco)

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Abstract

This study aimed to independently assess the analytical performance of 56 routine clinical biochemistry parameters on the ABBOTT Alinity ci Series and Architect ci 8200 automated systems, ensuring compliance with ISO 15189 standards. The verification followed Scope A criteria from the Medical Biology Method Verification/Validation Guide, focusing on repeatability and reproducibility. The coefficient of variation (CV) was compared to limits established by recognized learned societies such as the French Society of Clinical Biology (SFBC). Three concentration levels (low, medium, high) were analyzed for each parameter to assess precision. The results demonstrated satisfactory repeatability and reproducibility across all tested analytes, confirming the reliability of the automated systems. The obtained CV values were within acceptable limits, validating the precision of the analytical methods. This verification process ensures adherence to regulatory and normative requirements, reinforcing the laboratory's commitment to quality assurance. By systematically evaluating analytical performance, the study contributes to the optimization of routine biochemical analysis, enhancing result reliability for clinical decision-making. Furthermore, these findings support the Central Laboratory Department's ongoing efforts to implement robust quality management systems. The laboratory aims to be one of the first public hospital laboratories in the country to achieve ISO 15189 accreditation, demonstrating its dedication to mastering advanced analytical systems and ensuring high standards in patient care.

Subject Areas

Clinical Biochemistry

Keywords

Analytical Verification, Clinical Biochemistry, ISO 15189, Accreditation

1. Introduction

Analytical method verification is a cornerstone of clinical biochemistry laboratories, directly influencing the quality of patient care and clinical decision-making [1] [2]. Ensuring the reliability of test results is essential because clinical diagnoses, treatment plans, and patient outcomes depend on the integrity of laboratory data [3] [4]. If an analytical method is unreliable or inaccurate, it can lead to misdiagnoses, inappropriate treatments, or even harm to patients [5] [6]. As such, every laboratory test must be rigorously validated to confirm that it performs as expected across a range of conditions and variables. This process is not only about meeting regulatory and normative standards but also about maintaining the credibility of laboratory practices. Moreover, given the complexity and diversity of clinical biochemistry tests, verification must account for factors such as the diversity of patient population, specimen handling, and fluctuations in environmental conditions. Managing sample variability in a diverse patient population is crucial to ensuring consistent and reliable analytical performance. Several key measures are typically implemented to minimize these variations. One approach is the use of internal control matrices, which help ensure that results accurately represent a wide range of biological profiles. Additionally, analyzing multiple concentration levels (low, medium, high) allows for a thorough assessment of analytical performance across different sample conditions, ensuring precision and consistency. Strict protocols ensure sample integrity by controlling storage temperature, transport time, and container suitability to prevent analyte degradation. Standardized handling procedures minimize pre-analytical variability, while environmental monitoring further safeguards sample stability. These measures enhance analytical reliability, improving diagnostic precision and patient care. By rigorously evaluating key performance characteristics like repeatability and reproducibility, laboratories can guarantee that the results are reliable, and truly reflective of the analytes they aim to measure [7] [8]. In doing so, laboratories foster trust in their results, which ultimately leads to better clinical decision-making and, most importantly, improved patient care outcomes. The present study aims to support the Central Laboratory Department's goal to achieve ISO 15189 accreditation and ongoing efforts to build a robust quality management system documentation, reflecting the laboratory's commitment to advanced analytical systems and high standards in patient care [9].

2. Materials and Methods

2.1. Repeatability

In the repeatability test, patient samples were analyzed 30 times for each concentration level (low, medium, and high) under identical conditions, using the same operator, instrument, and reagent lot, with the same calibration, within a short time frame to minimize external variations. For each concentration level, the mean, standard deviation, and coefficient of variation (CV) were calculated. The CV, which is the ratio of the standard deviation to the mean, was used to assess the consistency of the results at different concentration levels. These results were then compared to the CV values established by the French Society of Clinical Biology (SFBC) to evaluate the laboratory's performance against accepted standards [10].

2.2. Reproducibility

In the reproducibility test, internal quality control (IQC) samples were analyzed over a period of 30 days under varying conditions, including different operators and shifts, to assess the method's consistency across different circumstances. For each IQC sample, the mean, standard deviation, and coefficient of variation (CV) were calculated. The CV, which is the ratio of the standard deviation to the mean, was used to evaluate the consistency of the results over time and under varied conditions. The results were then compared to the CV values established by the French Society of Clinical Biology (SFBC) to assess the laboratory's performance against accepted standards [10].

The Middleware EVM was used to analyze repeatability and reproducibility data by automatically calculating the mean, standard deviation, and laboratory coefficient of variation (CV), which was then compared with the CV of the French Society of Clinical Biology (SFBC), pre-programmed and integrated into the software. The study utilized the ALINITY ci Series and ARCHITECT ci 8200 analyzers to assess the performance characteristics of the analytical methods, enabling a comprehensive evaluation of both repeatability and reproducibility, thereby contributing to the overall validation of the methods.

The analytes analyzed in ARCHIECT ci 8200 are: Beta-Human Chorionic Gonadotropin (BHCG), High-Sensitivity Troponin (hs-cTn), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Uric Acid (UA), Total Bilirubin (T Bil), Total Cholesterol (TC), Chloride (Cl), C-Reactive Protein (CRP), High-Density Lipoprotein (HDL), Potassium (K), Lactate Dehydrogenase (LDH), Magnesium (Mg), Sodium (Na), Alkaline Phosphatase (ALP), Phosphorus (P), Triglycerides (TGs), Thyroid-Stimulating Hormone (TSH), Blood Urea Nitrogen (BUN), Blood Glucose (BG) and Total Protein (TP).

The analytes analyzed in Alinity ci Series are: Angiotensin-Converting Enzyme (ACE), Alpha-Fetoprotein (AFP), Complement C4 (C4), Complement C3 (C3), Cancer Antigen 125 (CA 125), Ferritin (FER), Creatine Phosphokinase (CPK), Microalbuminuria (MA), Total Prostate-Specific Antigen (Total PSA), Apolipoprotein

A (APOA), Haptoglobin (HP), Albumin (ALB), Beta-2 Microglobulin (B2M), Parathyroid Hormone (PTH), Connection Peptide (CPEP), Urinary Glucose (UG), Progesterone (PRG), Insulin (INS), Immunoglobulin G (IgG), Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin A (IgA), Folate (FOL), Cancer Antigen 199 (CA 199), Cancer Antigen 153 (CA 153), Lambda Light Chain (LLC), Free-Triiodothyronine (FT3), Methotrexate (MTX), Urinary Urea (UUR), Transferrin (TRF) and Gamma-Glutamyl Transferase (GGT).

These methods were chosen because they are standard for evaluating precision in analytical testing, and they provide a comprehensive view of the variability in both within-run (repeatability) and between-run (reproducibility) conditions. The use of descriptive statistics like CV is preferred because of their simplicity and relevance to laboratory settings. Moreover, the statistical tests and models mentioned align with the guidelines recommended by COFRAC (Comité Français d'Accréditation) for the assessment of repeatability and reproducibility in laboratory settings. COFRAC, as the French accreditation body, adheres to international standards such as ISO/IEC 17025, which governs the general requirements for the competence of testing and calibration laboratories.

3. Results

3.1. Results of Repeatability

The results of the repeatability study are expressed as coefficients of variation (CV), with values obtained for each analyte demonstrating the degree of variability under repeatability conditions (Table 1).

Table 1. Repeatability Results (Coefficient of Variation, CV%).

Analytes	Concentration Levels	Units	Mean	Standard Deviation	Coefficient of variation	Coeffecient of variation of SFBC	Conclusion
	N1		3.91	0.239	6.10%	SFBC (1999): 13.62%	
β-hCG	N2	mIU/mL	22.1	0.718	3.25%	SFBC (1999): 9.08%	Compliant
	N3		8433.73	111.236	1.32%	SFBC (1999): 9.06%	
	N1		12.2	0.706	5.79%	SFBC (1999): 10%	
TROP US	N2	ng/l	32.06	1.252	3.91%	SFBC (1999): 10%	Compliant
	N3		11085.1	305.381	2.75%	SFBC (1999): 10%	
	N1		11.26	0.445	3.95%	SFBC (1999): 5.45%	
ALAT	N2	UI/l	130.2	0.484	0.37%	SFBC (1999): 5.45%	Compliant
	N3		836.87	2.403	0.29%	SFBC (1999): 4.54%	
	N1		21	0	0%	SFBC (1999): 4.5%	
ASAT	N2	UI/l	90.45	1.199	1.33%	SFBC (1999): 4.5%	Compliant
	N3		308.65	1.843	0.60%	SFBC (1999): 4.73%	
AU	N1	mg/l	24.62	0.141	0.57%	SFBC (1999): 3.26%	Compliant

Continued

	N2		52.96	0.527	1%	SFBC (1999): 2.9%	
	N3		78.63	0.703	0.89%	SFBC (1999): 2.54%	
	N1		5.9	0.139	2.36%	SFBC (1999): 6.18%	
BILT	N2	mg/l	21.8	0.213	0.98%	SFBC (1999): 5.09%	Compliant
	N3		173.82	1.169	0.67%	SFBC (1999): 3.81%	
	N1		0.88	0.016	1.78%	SFBC (1999): 3.65%	
CHOLT	N2	g/l	1.81	0.021	1.15%	SFBC (1999): 3.65%	Compliant
	N3		1.96	0.022	1.14%	SFBC (1999): 3.65%	
	N1		85.77	0.43	0.50%	SFBC (1999): 1.45%	
Cl	N2	mmol/l	96.03	0.183	0.19%	SFBC (1999): 1.45%	Compliant
	N3		108.63	0.49	0.45%	SFBC (1999): 1.45%	
	N1		2.87	0.056	1.96%	SFBC (1999): 10.90%	
CRP	N2	mg/l	13.7	0.198	1.44%	SFBC (1999): 10.90%	Compliant
	N3		123.73	0.977	0.79%	SFBC (1999): 4.54%	
	N1		0.394	0.07	1.70%	SFBC (1999): 5.45%	
HDL	N2	g/l	0.492	0.009	1.82%	SFBC (1999): 5.45%	Compliant
	N3		0.82	0.007	0.89%	SFBC (1999): 5.45%	
	N1		2.62	0.038	1.46%	SFBC (1999): 1.79%	
K	N2	mmol/l	3.72	0.036	0.98%	SFBC (1999): 1.44%	Compliant
	N3		6.26	0.049	0.78%	SFBC (1999): 1.44%	
	N1		127.93	4.283	3.35%	SFBC (1999): 5.45%	Compliant
LDH	N2	UI/l	240.64	3.991	1.66%	SFBC (1999): 5.40%	
	N3		376.56	41.265	10.90%	SFBC (1999): 4.52%	Non compliant
	N1		8.66	0.134	1.55%	SFBC (1999): 3.63%	
MG	N2	mg/l	22.97	0.26	1.13%	SFBC (1999): 2.91%	Compliant
	N3		39.91	0.411	1.03%	SFBC (1999): 2.91%	
	N1		122.59	1.343	1.10%	SFBC (1999): 1.16%	
NA	N2	mmol/l	141	1.29	0.80%	SFBC (1999): 0.90%	Compliant
	N3		162.67	1.241	0.76%	SFBC (1999): 0.82%	
	N1		68.23	2.648	3.88%	SFBC (1999): 5.45%	
PAL	N2	UI/l	180.63	3.538	1.96%	SFBC (1999): 5.45%	Compliant
	N3		341.13	2.389	0.70%	SFBC (1999): 4.54%	
	N1		20.55	0.218	1.06%	SFBC (1999): 3.63%	
PHOS	N2	mg/l	42.5	0.394	0.93%	SFBC (1999): 3%	Compliant
	N3		73.74	0.756	1.03%	SFBC (1999): 2.18%	

Continued

PROT	N1	g/l	49.38	0.255	0.52%	SFBC (1999): 2.91%	Compliant
	N2		68.4	0.337	0.49%	SFBC (1999): 2.18%	
	N3		84.37	0.42	0.50%	SFBC (1999): 2.18%	
TRIG	N1	g/l	0.59	0.012	2.05%	SFBC (1999): 5.09%	Compliant
	N2		1.93	0.011	0.58%	SFBC (1999): 4.36%	
	N3		2.08	0.018	0.85%	SFBC (1999): 4.36%	
UR	N1	g/l	0.14	0.003	2.28%	SFBC (1999): 5.45%	Compliant
	N2		0.83	0.012	1.45%	SFBC (1999): 3.63%	
	N3		1.27	0.013	1.03%	SFBC (1999): 2.27%	
ALB	N1	g/l	28.43	0.504	1.77%	SFBC (1999): 5.45%	Compliant
	N2		38.97	0.183	0.47%	SFBC (1999): 4.54%	
	N3		54	0.263	0.49%	SFBC (1999): 3.63%	
B2M	N1	mg/l	1	0.015	1.50%	SFBC (1999): 7.27%	Compliant
	N2		1.21	0.023	1.89%	SFBC (1999): 6.36%	
	N3		1.61	0.016	1.01%	SFBC (1999): 6.36%	
GGT	N1	UI/l	25.83	0.379	1.47%	SFBC (1999): 5.45%	Compliant
	N2		78.97	0.85	1.08%	SFBC (1999): 5.45%	
	N3		146.1	0.759	0.52%	SFBC (1999): 4.54%	
GLY	N1	g/l	0.4	0.004	0.94%	SFBC (1999): 2.91%	Compliant
	N2		1.06	0.004	0.41%	SFBC (1999): 2.18%	
	N3		2.87	0.01	0.34%	SFBC (1999): 1.45%	
HAPTO	N1	g/l	0.67	0.007	1.10%	SFBC (1999): 5.45%	Compliant
	N2		1	0.008	0.78%	SFBC (1999): 4.53%	
	N3		1.41	0.015	1.07%	SFBC (1999): 3.63%	
APOA	N1	g/l	1.16	0.004	0.36%	SFBC (1999): 7.27%	Compliant
	N2		1.6	0.008	0.47%	SFBC (1999): 5.45%	
	N3		2.42	0.01	0.40%	SFBC (1999): 4.54%	
PSAT	N1	ng/ml	0.67	0.021	3.22%	SFBC (1999): 18.17%	Compliant
	N2		3.31	0.139	4.21%	SFBC (1999): 6.36%	
	N3		22.73	1.339	5.89%	SFBC (1999): 6.36%	
UMALB	N1	mg/l	29.05	0.303	1.04%	SFBC (1999): 7.27%	Compliant
	N2		88.52	0.978	1.11%	SFBC (1999): 5.45%	
CPK	N1	UI /l	79.9	1.826	2.29%	SFBC (1999): 5.45%	Compliant
	N2		183.21	2.717	1.48%	SFBC (1999): 5.45%	
	N3		393	2.944	0.75%	SFBC (1999): 4.53%	

Continued

FER	N1	ug/dl	113.63	1.655	1.46%	SFBC (1999): 7.08%	Compliant
	N2		152.28	1.086	0.71%	SFBC (1999): 4.44%	
	N3		220.93	1.185	0.54%	SFBC (1999): 3.55%	
IGE	N1	UI/ml	67.31	2.593	3.85%	SFBC (1999): 10.90%	Compliant
	N2		398.39	6.2	1.56%	SFBC (1999): 7.27%	
IGG	N1	g/l	7.04	0.057	0.81%	SFBC (1999): 5.45%	Compliant
	N2		9.76	0.148	1.52%	SFBC (1999): 4.49%	
	N3		13.62	0.186	1.37%	SFBC (1999): 3.62%	
MTX	N1	umol/l	0.07	0.001	1.99%	SFBC (1999): 13.63%	Compliant
	N2		0.42	0.007	1.68%	SFBC (1999): 9.09%	
	N3		0.94	0.025	2.71%	SFBC (1999): 9.09%	
ACE	N1	ng/ml	2.09	0.091	4.37%	SFBC (1999): 13.48%	Compliant
	N2		15.39	0.311	2.02%	SFBC (1999): 7.21%	
	N3		45.4	0.82	1.81%	SFBC (1999): 7.21%	
AFP	N1	ng/ml	5.38	0.075	1.39%	SFBC (1999): 13.63%	Compliant
	N2		65.08	1.431	2.20%	SFBC (1999): 7.27%	
	N3		168.22	3.896	2.32%	SFBC (1999): 7.27%	
C3	N1	g/l	0.82	0.009	1.04%	SFBC (1999): 7.27%	Compliant
	N2		1.32	0.015	1.13%	SFBC (1999): 5.45%	
	N3		1.92	0.019	0.97%	SFBC (1999): 4.54%	
C4	N1	g/l	0.15	0.001	0.89%	SFBC (1999): 7.27%	Compliant
	N2		0.24	0.003	1.29%	SFBC (1999): 5.45%	
	N3		0.34	0.003	0.90%	SFBC (1999): 4.54%	
CA125	N1	UI/ml	21.04	0.456	2.17%	SFBC (1999): 8.18%	Compliant
	N2		23.85	0.487	2.04%	SFBC (1999): 6.36%	
	N3		71.03	0.983	1.38%	SFBC (1999): 6.36%	
CA153	N1	UI/ml	5.4	0.133	2.45%	SFBC (1999): 8.18%	Compliant
	N2		33.42	0.76	2.27%	SFBC (1999): 6.36%	
	N3		60.21	1.082	1.80%	SFBC (1999): 6.36%	
CA199	N1	UI/ml	38.14	0.995	2.61%	SFBC (1999): 10.87%	Compliant
	N2		66.6	1.848	2.78%	SFBC (1999): 9.03%	
	N3		147.82	4.814	3.26%	SFBC (1999): 9.01%	
FOLAT	N1	ng/ml	4.97	0.241	4.84%	SFBC (1999): 9.09%	Compliant
	N2		9.37	0.32	3.41%	SFBC (1999): 7.27%	
	N3		17.22	0.326	1.89%	SFBC (1999): 7.27%	

Continued

IGM	N1	g/l	0.62	0.031	5.10%	SFBC (1999): 5.21%	Compliant
	N2		0.86	0.012	1.43%	SFBC (1999): 4.54%	
	N3		1.35	0.014	1.04%	SFBC (1999): 3.62%	
INSU	N1	uU/ml	8.19	0.2	2.44%	SFBC (1999): 9.09%	Compliant
	N2		38.59	0.68	1.76%	SFBC (1999): 7.27%	
	N3		122.47	1.632	1.33%	SFBC (1999): 7.27%	
PROG	N1	ng/ml	1.14	0.05	4.37%	SFBC (1999): 22.71%	Compliant
	N2		14.2	0.414	2.92%	SFBC (1999): 9.09%	
	N3		27.44	2.033	7.41%	SFBC (1999): 9.09%	
UUR	N1	g/l	9.31	0.275	2.95%	SFBC (1999): 5.33%	Compliant
	N2		19.2	0.278	1.45%	SFBC (1999): 5.32%	
TRF	N1	g/l	1.74	0.025	1.42%	SFBC (1999): 7.27%	Compliant
	N2		2.44	0.029	1.17%	SFBC (1999): 5.45%	
	N3		3.44	0.036	1.05%	SFBC (1999): 4.54%	
PEPC	N1	pmol/l	0.89	0.028	3.15%	SFBC (1999): 13.63%	Compliant
	N2		3.58	0.059	1.65%	SFBC (1999): 7.27%	
	N3		7.64	0.119	1.55%	SFBC (1999): 7.27%	
TSH	N1	mUI/l	0.04	0.001	2.17%	SFBC (1999): 18.02%	Compliant
	N2		4.06	0.062	1.54%	SFBC (1999): 6.24%	
	N3		20.68	0.392	1.90%	SFBC (1999): 4.64%	
PTH	N1	pg/ml	5.67	0.223	3.93%	SFBC (1999): 13.63%	Compliant
	N2		52.23	1.448	2.77%	SFBC (1999): 7.27%	
	N3		210.43	5.383	2.56%	SFBC (1999): 7.27%	
FT3	N1	pmol/l	5.39	1.102	1.90%	SFBC (1999): 9.91%	Compliant
	N2		7.67	0.103	1.35%	SFBC (1999): 7.21%	
	N3		14.22	0.396	2.79%	SFBC (1999): 7.21%	
UG	N1	g/l	0.3	0.005	1.70%	SFBC (1999): 5.45%	Compliant
	N2		3.56	0.06	1.68%	SFBC (1999): 4.54%	
LAMBDA	N1	g/l	63.3	0.297	0.47%	SFBC (1999): 4.54%	Compliant
	N2		242.09	1.187	0.49%	SFBC (1999): 4.54%	

3.2. Results of Reproducibility

The results of the reproducibility study are expressed as coefficients of variation (CV), with values obtained for each analyte demonstrating the degree of variability under reproducibility conditions (Table 2).

Table 2. Reproducibility results (Coefficients of Variation, CV%).

Analytes	Concentration levels	Units	Mean	Standard Deviation	Coefficient of variation	Coefficient of variation of SFBC	Conclusion
	N1		4.07	0.473	11.63%	SFBC (1999): 17.22%	
β-hCG	N2	mIU/mL	25.02	1.769	7.07%	SFBC (1999): 11.85%	Compliant
	N3		463.26	23.96	5.17%	SFBC (1999): 11.88%	
	N1		23.7	1.244	5.25%	SFBC (1999): 6.89%	
ALAT	N2	UI/l	96.16	2.632	2.74%	SFBC (1999): 6.89%	Compliant
	N3		208.53	3.551	1.70%	SFBC (1999): 5.74%	
	N1		35.61	0.974	2.73%	SFBC (1999): 7.13%	
ASAT	N2	UI/l	133.3	4.343	3.26%	SFBC (1999): 7.45%	Compliant
	N3		229.85	10.982	4.78%	SFBC (1999): 5.99%	
	N1		1.02	0.012	1.20%	SFBC (1999): 4.88%	
CHOLT	N2	g/l	1.59	0.035	2.17%	SFBC (1999): 4.88%	Compliant
	N3		2.63	0.076	2.90%	SFBC (1999): 4.93%	
	N1		85.07	1.507	1.77%	SFBC (1999): 1.94%	
Cl	N2	mmol/l	94.83	1.262	1.33%	SFBC (1999): 1.94%	Compliant
	N3		105.87	1.814	1.71%	SFBC (1999): 1.94%	
	N1		3.14	0.084	2.67%	SFBC (1999): 13.78%	
CRP	N2	mg/l	9.21	0.849	9.22%	SFBC (1999): 6.89%	Compliant
	N3		27.3	0.858	3.14%	SFBC (1999): 5.74%	
	N1		0.371	0.018	4.84%	SFBC (1999): 6.89%	Compliant
HDL	N2	g/l	0.56	0.043	7.76%	SFBC (1999): 6.89%	Non Compliant
	N3		0.72	0.026	3.60%	SFBC (1999): 6.89%	Compliant
	N1		2.56	0.071	2.77%	SFBC (1999): 2.42%	
K	N2	g/l	3.79	0.077	2.03%	SFBC (1999): 1.93%	Compliant
	N3		6.54	0.131	2.00%	SFBC (1999): 1.93%	
	N1		111.09	7.073	6.37%	SFBC (1999): 7.21%	Compliant
LDH	N2	UI/l	222.3	34.267	15.41%	SFBC (1999): 7.21%	Non Compliant
	N3		439.16	19.153	4.36%	SFBC (1999): 4.52%	Compliant
	N1		8.9	0.239	2.69%	SFBC (1999): 4.84%	
MG	N2	mg/l	23.52	0.567	2.41%	SFBC (1999): 3.88%	Compliant
	N3		41.12	0.85	2.07%	SFBC (1999): 3.88%	
	N1		122.65	1.286	1.05%	SFBC (1999): 1.49%	Compliant
NA	N2	mmol/l	142.73	3.347	2.35%	SFBC (1999): 1.32%	Non compliant
	N3		161.84	1.22	0.75%	SFBC (1999): 1.07%	Compliant

Continued

PAL	N1	UI/l	64.43	4.47	6.94%	SFBC (1999): 7.27%	Compliant
	N2		184.24	5.761	3.13%	SFBC (1999): 7.29%	
	N3		363.8	25.868	7.11%	SFBC (1999): 6.06%	Non compliant
PHOS	N1	mg/l	23.48	0.594	2.53%	SFBC (1999): 4.84%	Compliant
	N2		40.56	0.838	2.07%	SFBC (1999): 4%	
	N3		67.94	1.679	2.47%	SFBC (1999): 2.91%	
PROT	N1	g/l	44.35	0.662	1.49%	SFBC (1999): 3.88%	Compliant
	N2		59.13	1.316	2.23%	SFBC (1999): 2.91%	
	N3		85.03	2.046	2.41%	SFBC (1999): 2.91%	
TRIG	N1	g/l	0.59	0.021	3.56%	SFBC (1999): 6.43%	Compliant
	N2		1.41	0.105	7.46%	SFBC (1999): 5.51%	Non compliant
	N3		2.6	0.257	9.90%	SFBC (1999): 5.51%	Non compliant
UR	N1	g/l	1.27	0.021	1.66%	SFBC (1999): 7.1%	Compliant
	N2		0.85	0.023	2.70%	SFBC (1999): 4.73%	
	N3		0.146	0.01	6.95%	SFBC (1999): 3.03%	Non compliant
ALB	N1	g/l	28.85	0.508	1.76%	SFBC (1999): 7.21%	Compliant
	N2		39.37	0.731	1.86%	SFBC (1999): 5.98%	
	N3		54.37	0.718	1.32%	SFBC (1999): 4.85%	
B2M	N1	mg/l	0.99	0.032	3.23%	SFBC (1999): 8.80%	Compliant
	N2		1.21	0.072	5.94%	SFBC (1999): 7.70%	
	N3		1.73	0.084	4.84%	SFBC (1999): 7.73%	
PSAT	N1	ng/ml	0.66	0.024	3.69%	SFBC (1999): 24.16%	Compliant
	N2		3.25	0.139	4.29%	SFBC (1999): 8.48%	
	N3		21.32	0.902	4.23%	SFBC (1999): 8.48%	
UMALB	N1	mg/l	29.8	1.273	4.27%	SFBC (1999): 9.52%	Compliant
	N2		89.54	3.87	4.32%	SFBC (1999): 7.14%	
CPK	N1	UI/l	81.94	1.999	2.44%	SFBC (1999):7.25%	Compliant
	N2		179.47	9.155	5.10%	SFBC (1999):7.25%	
	N3		383.13	18.652	4.87%	SFBC (1999): 6.06%	
FER	N1	ug/dl	126.4	3.927	3.11%	SFBC (1999): 9.69%	Compliant
	N2		162.17	7.892	4.87%	SFBC (1999): 6.06%	
	N3		235	10.019	4.26%	SFBC (1999): 4.82%	
IGE	N1	UI/ml	63.28	4.735	7.48%	SFBC (1999): 14.54%	Compliant
	N2		384.57	19.943	5.19%	SFBC (1999): 9.69%	
IGG	N1	g/l	7.06	0.139	1.96%	SFBC (1999): 7.17%	Compliant

Continued

	N2		9.79	0.17	1.73%	SFBC (1999): 6.01%	
	N3		13.73	0.336	2.45%	SFBC (1999): 4.85%	
	N1		0.07	0.002	3.34%	SFBC (1999): 18.17%	
MTX	N2	umol/l	0.43	0.02	4.74%	SFBC (1999): 12.01%	Compliant
	N3		0.96	0.044	4.57%	SFBC (1999): 12.11%	
	N1		2.11	0.16	7.57%	SFBC (1999): 18.17%	
ACE	N2	ng/ml	17.13	0.747	4.36%	SFBC (1999): 9.64%	Compliant
	N3		46.53	2.258	4.85%	SFBC (1999): 9.64%	
	N1		4.36	0.224	5.14%	SFBC (1999): 18.17%	
AFP	N2	ng/ml	73.83	2.541	3.44%	SFBC (1999): 9.69%	Compliant
	N3		208.28	6.939	3.33%	SFBC (1999): 9.69%	
	N1		0.9	0.047	5.27%	SFBC (1999): 9.48%	
C3	N2	g/l	1.39	0.044	3.13%	SFBC (1999): 7.19%	Compliant
	N3		2.01	0.058	2.90%	SFBC (1999): 5.98%	
	N1		0.16	0.007	4.41%	SFBC (1999): 9.50%	
C4	N2	g/l	0.24	0.01	4.05%	SFBC (1999): 7.16%	Compliant
	N3		0.34	0.01	3.02%	SFBC (1999): 5.95%	
	N1		19.15	0.512	2.68%	SFBC (1999): 10.90%	
CA125	N2	UI/ml	46.56	0.754	1.62%	SFBC (1999): 8.48%	Compliant
	N3		77.35	1.634	2.11%	SFBC (1999): 8.48%	
	N1		9.41	0.327	3.47%	SFBC (1999): 10.90%	
CA153	N2	UI/ml	39.91	1.566	3.92%	SFBC (1999): 8.48%	Compliant
	N3		73.86	2.593	3.51%	SFBC (1999): 8.48%	
	N1		36.68	1.459	3.98%	SFBC (1999): 14.54%	
CA199	N2	UI/ml	71.03	2.248	3.16%	SFBC (1999): 12.11%	Compliant
	N3		173.2	6.25	3.61%	SFBC (1999): 12.11%	
	N1		3.89	0.399	10.25%	SFBC (1999): 12.15%	
FOLAT	N2	ng/ml	5.37	0.46	8.58%	SFBC (1999): 9.69%	Compliant
	N3		13.09	1.196	9.13%	SFBC (1999): 9.69%	
	N1		0.66	0.037	5.61%	SFBC (1999): 7.08%	
IGM	N2	g/l	0.88	0.052	5.96%	SFBC (1999): 5.79%	Compliant
	N3		1.24	0.048	3.86%	SFBC (1999): 4.95%	
	N1		12.69	0.402	3.16%	SFBC (1999): 12.11%	
INSU	N2	uU/ml	55.57	3.214	5.78%	SFBC (1999): 9.69%	Compliant
	N3		110.16	3.17	2.88%	SFBC (1999): 9.69%	

Continued

PROG	N1	ng/ml	0.91	0.146	16.11%	SFBC (1999): 30.28%	Compliant
	N2		11.88	0.394	3.32%	SFBC (1999): 12.05%	
	N3		24.85	1.396	5.62%	SFBC (1999): 12.08%	
UUR	N1	g/l	8.93	0.357	4.00%	SFBC (1999): 7.27%	Compliant
	N2		21.37	0.745	3.49%	SFBC (1999): 7.27%	
IGA	N1	g/l	1.62	0.056	3.49%	SFBC (1999): 7.19%	Compliant
	N2		2.15	0.057	2.67%	SFBC (1999): 6.02%	
	N3		3.03	0.092	3.04%	SFBC (1999): 4.95%	
TRF	N1	g/l	1.78	0.045	2.53%	SFBC (1999): 9.59%	Compliant
	N2		2.49	0.174	6.97%	SFBC (1999): 7.21%	
	N3		3.58	0.123	3.45%	SFBC (1999): 6.09%	
UG	N1	g/l	0.30	0.011	3.66%	SFBC (1999): 7.27%	Compliant
	N2		3.65	0.057	1.55%	SFBC (1999): 6.06%	
PEPC	N1	pmol/l	0.88	0.022	2.52%	SFBC (1999): 18.17%	Compliant
	N2		3.73	0.138	3.70%	SFBC (1999): 9.69%	
	N3		7.45	0.326	4.37%	SFBC (1999): 9.69%	
TSH	N1	mUI/l	0.04	0.002	5.38%	SFBC (1999): 24.09%	Compliant
	N2		3.89	0.162	4.16%	SFBC (1999): 8.41%	
	N3		22.24	1.292	5.81%	SFBC (1999): 6.02%	
PTH	N1	pg/ml	7.5	0.906	12.08%	SFBC (1999): 18.17%	Compliant
	N2		60.34	3.601	5.97%	SFBC (1999): 9.69%	
	N3		227.71	10.116	4.44%	SFBC (1999): 9.69%	
AU	N1	mg/l	24.62	0.141	0.57%	SFBC (1999): 4.36%	Compliant
	N2		52.96	0.527	1.00%	SFBC (1999): 3.88%	
	N3		78.63	0.703	0.89%	SFBC (1999): 3.39%	
FT3	N1	pmol/l	3.98	0.162	4.08%	SFBC (1999): 13.22%	Compliant
	N2		10.61	0.714	6.73%	SFBC (1999): 9.61%	
	N3		19.79	1.098	5.55%	SFBC (1999): 9.61%	
APO A	N1	g/l	1.01	0.028	2.78%	SFBC (1999): 9.69%	Compliant
	N2		1.42	0.044	3.08%	SFBC (1999): 7.27%	
	N3		2.15	0.052	2.40%	SFBC (1999): 6.06%	
GLY	N1	g/l	0.51	0.008	1.49%	SFBC (1999): 3.88%	Compliant
	N2		1.31	0.021	1.63%	SFBC (1999): 2.91%	
	N3		2.99	0.055	1.84%	SFBC (1999): 1.94%	
HAPTO	N1	g/l	0.7	0.012	1.79%	SFBC (1999): 7.16%	Compliant

Continued

	N2		1.02	0.072	7.05%	SFBC (1999): 6.01%	Non compliant
	N3		1.44	0.023	1.62	SFBC (1999): 4.81%	Compliant
LAMBDA	N1	g/l	64.12	0.546	0.85%	SFBC (1999): 6.06%	Compliant
	N2		242.96	0.528	0.22%	SFBC (1999): 6.06%	

4. Discussion

The verification of analytical methods demonstrated high compliance with established performance criteria, confirming the reliability of these systems for routine laboratory use. The repeatability assessment showed near-total compliance across all analytes, indicating high precision in the tested methods. The only exception was observed in the third level of Lactate Dehydrogenase (LDH), where the laboratory's coefficient of variation (CV) exceeded the threshold set by the SFCB. Reproducibility results also demonstrated a high level of compliance, with some exceptions. Deviations were noted in the following cases: Haptoglobin (Level 2), Urea (Level 3), Triglycerides (Levels 2 and 3), Alkaline Phosphatase (Level 3), Lactate Dehydrogenase (Level 2) and High-Density Lipoprotein (Level 2).

Targeted improvements are necessary for specific parameters to ensure full compliance with established guidelines and enhance analytical reliability. One key corrective action involves calibration adjustments, which play a crucial role in maintaining assay accuracy. Calibration errors, drift, and reagent variability can introduce deviations in measurement, particularly in analytes where inconsistencies were observed. To address these issues, laboratories should optimize calibration frequency, especially for affected analytes, and implement multi-point calibration for assays with non-linear response curves. Continuous monitoring of calibration drift over time is also essential to detect performance shifts and make timely adjustments [11] [12]. Additionally, quality control (QC) enhancements should be prioritized to strengthen the detection of analytical variations before they impact patient results. Implementing stricter QC protocols, using third-party control materials for independent verification, and establishing real-time QC monitoring can significantly improve assay reliability. Routine evaluation of QC data using statistical tools such as Levey-Jennings charts and Westgard rules will help identify deviations and allow for immediate corrective actions [13] [14]. These improvements will not only optimize precision but also reinforce the laboratory's adherence to international performance standards.

Beyond calibration and QC measures, methodological refinements are crucial for addressing inconsistencies in reproducibility and repeatability. Standardizing sample handling procedures, including transport, storage, and processing conditions, can minimize preanalytical variability that may contribute to observed deviations [15]. Additionally, assessing reagent stability and monitoring lot-to-lot variability through parallel testing will help mitigate inconsistencies caused by reagent changes [16]. Instrument maintenance schedules should also be optimized to ensure sustained precision, as mechanical wear or optical misalignments could lead to fluctuations in assay performance. Furthermore, participating in inter-laboratory comparisons and external quality assessment programs can provide valuable benchmarking data and highlight areas for improvement [17]. Future studies should focus on identifying the root causes of these variations, exploring alternative reagents or analytical methodologies, and implementing advanced monitoring tools, such as machine learning or AI-driven predictive maintenance, to detect performance shifts early. AI algorithms could enable early detection of analytical drifts by analyzing QC data trends, allowing for timely corrections before impacting patient results. Calibration optimization could also be achieved through machine learning models that dynamically adjust calibration frequency based on instrument performance. Additionally, predicting instrument failures using AI-powered sensors and alert systems would help laboratories anticipate technical issues and optimize maintenance schedules. Lastly, AI tools could improve result interpretation by identifying statistical anomalies and reducing human errors in data analysis, ultimately ensuring higher accuracy and reliability in clinical diagnostics. By continuously refining these processes, laboratories can ensure the long-term accuracy and precision of the Alinity ci Series and Architect ci 8200, ultimately strengthening their role in delivering reliable clinical biochemistry results.

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Conflicts of Interest

The authors declare no conflicts of interest.

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