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Evaluation of the Performance and Application of the ISO 9001 Standard in the Biological Laboratory of the Institut de Cardiologie d'Abidjan (ICA)

N'guessan Déto Ursul Jean-Paul[1, 2*], Coulibaly Songuigama[1, 2], Konan Amoin Marie Desirée Lydia, Kouamé Yao Gilles Privat[2], Hauhouot-Attoungbré Marie Laure[3,4]

[1]Department of Therapeutic Chemistry and Organic Chemistry, UFR Pharmaceutical and Biological Sciences, FHB University, 01 BP V34 Abidjan, Côte d'Ivoire
[2]National Public Health Laboratory (NPHL), Abidjan, Côte d'Ivoire
[3]Biochemistry Laboratory, UFR Pharmaceutical and Biological Sciences, FHB University, 01 BP V34 Abidjan, Côte d'Ivoire
[4]Biology Laboratory, Institut de Cardiologie d'Abidjan (ICA), Côte d'Ivoire

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***Corresponding Author Email:** nguessanursul@gmail.com

Abstract

A cross-sectional study was conducted throughout 2024 at the ISO 9001-certified laboratory of the Institut de Cardiologie d'Abidjan integrating Key Performance Indicators (KPIs) with user and staff satisfaction data to identify strengths and areas for improvement. Performance was evaluated across the pre-analytical, analytical, and post-analytical phases using Key Performance Indicators (KPIs)—including waiting times, sample non-conformity, internal quality control (IQC) compliance, and turnaround time (TAT). Quantitative KPI data from laboratory records were triangulated with qualitative data from satisfaction surveys administered to 300 clients and all 27 staff members. The analysis revealed a dual performance profile. The pre-analytical phase was strong, with a mean waiting time (22.5 min) below the 25-minute benchmark and high client satisfaction (≥98%) for reception and hygiene, despite sporadic sample non-conformities. Analytically, IQC compliance was excellent (>95%), ensuring technical reliability. However, TAT was critically deficient (only 15-24% on-time), directly correlating with client dissatisfaction and attributed to staff shortages and equipment issues, mirrored by high staff dissatisfaction (70.4%). Post-analytically, external result delivery was efficient (>90% on time), but internal traceability was poor, and client awareness of the complaint system was critically low (37%), hindering feedback loops. The ICA laboratory exhibits a strong foundation for quality, particularly in technical accuracy and patient-facing services. However, systemic challenges in TAT, resource management, procedural harmonization, and post-analytical traceability impede optimal performance. Sustainable improvement requires an integrated strategic approach prioritizing automation, staff welfare, enhanced training, and the digitalization of quality management systems.

Keywords
Laboratory Performance, Quality Indicators, Turnaround Time, ISO 9001.

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INTRODUCTION

In a context where the quality of healthcare is closely dependent on the reliability of biological data, medical laboratories hold a central place within the health system [1,2]. Indeed, over 70% of medical decisions are based on the results of biological analyses, conferring upon laboratories a crucial responsibility in diagnosis, therapeutic monitoring, and disease prevention [3]. To guarantee this reliability, the adoption of Quality Management Systems (QMS) based on international standards, such as ISO 9001, is a critical strategic undertaking [4]. The implementation of ISO 9001 in medical laboratories not only enhances the quality of services but also aligns with regulatory requirements, ensuring compliance and fostering continuous improvement in laboratory practices [4-7]. Moreover, the integration of ISO 9001 can facilitate the accreditation process, ultimately leading to improved patient outcomes and enhanced operational efficiency within laboratories [2, 4-6].

The pursuit of quality management in laboratory settings is paramount, particularly in specialized fields like biological analysis, where precision and reliability are directly tied to patient outcomes [7,9]. The ISO 9001 standard, in its latest version, is founded on quality management principles focused on customer satisfaction, a process approach, continual improvement, and risk management [8]. Its implementation in laboratories aims to formalize processes, control non-conformities, and enhance the overall performance of medical biology structures [2, 6].

However, in sub-Saharan Africa, the adoption of this framework remains uneven due to significant technical, financial, and organizational constraints [10]. It is within this regional context that this research focuses on evaluating the performance and application of the ISO 9001 standard at the Biological Analysis Laboratory of the Abidjan Heart Institute (Institut de Cardiologie d'Abidjan - ICA). As a reference institution for cardiovascular care in Côte d'Ivoire, the ICA laboratory has embarked on a formal quality journey certified to ISO 9001 [11-13].

This study therefore aims to conduct an integrated assessment of the laboratory's technical performance and the effective application of the standard to measure achievements, identify areas for improvement, and guide continual improvement efforts. Specifically, it seeks to:

- Assess the current implementation of ISO 9001 and identify challenges faced by the laboratory.
-Evaluate the laboratory's performance through a tripartite approach integrating: (i) the analysis of quality indicators covering the pre-analytical, analytical, and post-analytical phases; (ii) the assessment of external client satisfaction; (iii) and the study of staff perceptions, knowledge, and level of satisfaction regarding the implementation of the ISO 9001 standard.
- Explore the impact of this standard on the overall quality of laboratory services.

By examining these elements, this research seeks to contribute to the ongoing discourse on quality management practices in healthcare settings, particularly in regions where the integration of such standards is still developing.

2. MATERIALS AND METHODS

2.1. Study design and setting

This descriptive and analytical cross-sectional study was conducted at the medical biology laboratory of the Institut de Cardiologie d'Abidjan (ICA), a university hospital specialized in the management of cardiovascular diseases. The laboratory, ISO 9001 certified, provides biochemical, hematological, immunological, and microbiological analyses for both inpatients and outpatients.

2.2. Study period

Data collection was carried out over a twelve-month period, covering the entire 2024 calendar year.

2.3. Study population

Three target populations were included in the study:

1. Biological samples analyzed for monitoring quality indicators;
2. External clients who visited the laboratory during the study period, surveyed for satisfaction assessment;
3. Laboratory staff members, involved in the evaluation of ISO 9001 implementation.

2.4. Data sources

Data were collected from three main sources:

- the laboratory database, used to extract performance indicators (non-conformities, turnaround times, repeat tests, etc.);
- a standardized satisfaction questionnaire administered to a sample of 300 clients [11];
- a self-administered, anonymous questionnaire completed by the 27 laboratory staff members [12].

2.5. Performance indicators

Indicators were categorized according to the three phases of laboratory activity:

- Pre-analytical: sample conformity, sampling errors, transport conditions;

The following indicators were collected monthly:

- Average patient waiting time for blood collection (target ≤ 25 min)
- Non-compliant blood collection rate (NCP) by the prescribing department

- Percentage of non-compliant requisition forms
- Analytical: compliance with internal quality controls (IQC), repeat test frequency, turnaround times;

Analytical performance was assessed using:

- Compliance rate of internal quality controls (IQC) for hematology, biochemistry, and hemostasis (target ≥ 95%)
- Rate of tests performed within the required timeframe (target ≥ 85%)
- Rate of internal preventive maintenance performed on automated systems
- Post-analytical: reporting of results, traceability, critical value notification, complaint management.

Post-analysis focused on:

• Rate of external results available within the allotted timeframe

• Qualitative monitoring of internal results transmitted directly or via the Olympe system

The percentages were calculated using the formula:

Rate (%) = (Number of compliant or non-compliant cases / Total number of observed cases) × 100

2.6. Tools and data processing

Quantitative data were analyzed using Microsoft Excel and SPSS version 20. Indicators were expressed as percentages or per 1,000 tests, in accordance with international recommendations (Ricos et al., IFCC). Qualitative responses from open-ended questionnaires were analyzed thematically to identify recurrent suggestions. A critical non-conformity threshold was set at 10%, consistent with ISO 9001 standards and benchmarks reported in the literature [14,15].

2.7. Ethical considerations

The client questionnaire was reviewed and approved by the Medical and Scientific Directorate (DMS). Participation was based on informed consent, and the anonymity of respondents was strictly maintained.

3. RESULTS

This study presents a performance analysis of the Abidjan Cardiology Institute (ICA) laboratory, synthesizing data from key performance indicators (KPIs) monitored over six months (July – December 2024) and integrating findings from previously published studies on client and staff satisfaction.

3.1. Overview of Laboratory Activity

Over six months, the ICA laboratory monitored and evaluated key performance indicators (KPIs) related to its clinical activities, structured across the pre-analytical, analytical, and post-analytical phases. Data were collected monthly, covering aspects such as sample processing times, non-conformities, quality controls, and client satisfaction (Table 1).

Table 1: Summary of Key Performance Indicators (July - December 2024)

Phase	KPI	Target	July	August	September	October	November	December
Pre-Analytical	Avg. Waiting Time (min)	≤25	21.5	22	24	22.6	-	-
Analytical	PNC Rate (%)	≤5	4.5-6.9	2.4-6.2	0-6.0	0-10.0	2.8-7.3	N/A
	IQC Conformity - Hemo (%)	≥95	99.6	N/A	84.0	100	99.4	N/A
	IQC Conformity - Bioch (%)	≥95	96.0	N/A	99.7	95.6	97.1	N/A
	IQC Conformity - Hemost (%)	≥95	95.2	98.4	98.3	98.4	100	N/A
	Exams on Time - Internal (%)	≥85	14.9	21.5	18.0	20.2	23.7	20.8
	Exams on Time - External (%)	≥85	10.9	10.3	8.9	12.2	11.0	10.1
Post-Analytical	Ext. Results on Time (%)	~95	94.6	94.7	98.5	93.5	96.1	N/A

a) N/A: Data Not Available or Not Applicable.

b) PNC rates show a range across units. IQC: Internal Quality Control.

3.2. Pre-Analytical Phase

3.2.1 Patient Waiting Time

A total of 1986 patients were recorded between July and October 2025. The average patient waiting time, from arrival to sample collection, was consistently maintained below the target threshold of 25 minutes. Over four months (July-October), the mean waiting time ranged from 21 minutes 27 seconds to 24 minutes, with a global average of approximately 22 minutes and 30 seconds (Table 2). This indicates effective management of patient flow and sampling circuits, with no evidence that waiting lines compromised perceived quality of service.

Table 2. Average patient waiting time per month (July–December 2024)
(Compliance threshold ≤ 25 minutes)

Month	Total waiting time (min)	No. of patients sampled	Mean waiting time (min:s)
July	11,805	555	21:27
August	10,692	486	22:00
September	10,944	456	24:00
October	10,934	489	22:36
November	–	–	–
December	–	–	–

Notes :

a) Data for **November and December is not available**.
b) *Waiting time calculated as the mean difference between patient registration and specimen collection (P–F).*

3.2.2 Non-Conformities in Sample Collection

The proportion of non-conforming samples (PNC) was evaluated monthly across six hospital units (URG, MED, SIC, SIM, CHIR, EXT), with a target of ≤5%. Performance was variable:
In July, PNC rates exceeded the target in the medical (MED; 6.94%) and surgical intensive care units (SIM; 6.05%) units. Improvement was noted in subsequent months, with most services maintaining PNC rates at or below 5% (Table 3). However, a significant spike was observed in the surgical unit (CHIR) unit in October (10.00%) and the SIM unit in November (7.27%), indicating intermittent lapses in sample collection protocols or handling and inconsistent compliance with pre-analytical protocols. These findings suggest insufficient staff training in sampling techniques, inadequate adherence to procedures, and occasional failures in sample identification. Enhanced quality control and improved traceability are required.

Table 3. Longitudinal analysis of non-compliant specimens by department
(Compliance threshold ≤ 5 %; "–" = data not available)

Month	Emergency (URG)	Medicine (MED)	Intensive Care (SIC)	Intermediate Care (SIM)	Surgery (CHIR)	Outpatients (EXT)
July	4.50%	6.94%	4.84%	6.05%	4.55%	4.44%
August	4.43%	4.13%	2.64%	2.35%	6.19%	4.47%
September	5.97%	4.81%	3.70%	3.57%	0%	–
October	3.34%	4.03%	3.70%	1.60%	10%	0%
November	2.84%	2.88%	3.08%	7.27%	4.76%	–
December**	–	–	–	–	–	–

Notes :

a) *September: Data available only from 02–06 and 25–30 September.*
b) Non-conforming samples: Defined as rejected due to hemolysis, clots, incorrect volume, etc.
c) December: Data not available.

DPMO/Sigma Integration

The analysis of non-conformity rates across clinical services was further reinforced by applying the Six Sigma methodology, through the calculation of Defects per Million Opportunities (DPMO) and corresponding Sigma levels (Table 4). This allowed a standardized evaluation of laboratory quality performance, beyond the simple reporting of defect percentages.

Table 4: Annual Six Sigma Performance by Hospital Service

Service	Abbrev.	Avg. Defect Rate	Avg. DPMO	Avg. Sigma Level
Emergency	URG	4.22%	42,160	**3.19**
Medicine	MED	4.56%	45,580	**3.15**
Intensive Care	SIC	3.38%	33,800	**3.30**
Intermediate Care	SIM	4.17%	41,680	**3.20**
Surgery	CHIR	5.10%	51,000	**3.14**
Outpatients	EXT	2.23%	22,300	**3.18**

Data based on monthly performance from July to November. Sigma Level calculated with a 1.5σ shift.

Notes :
a) DPMO: (non-conforming rate × 1,000,000). †
o*Example for July URG: (4.50 / 100) * 1,000,000 = 45,000 DPMO*
b) Sigma Level: Sigma calculated from DPMO using short-term

Across all services, mean non-conformity rates ranged from 3.38% in Intensive Care (SIC) to 5.10% in Surgery (CHIR). These values correspond to DPMO between approximately 33,800 and 51,000, translating to Sigma levels in the range of 3.14 to 3.30. Such results indicate a moderate level of process control. In the Six Sigma framework, a 3σ process typically produces around 35,000 defects per million opportunities, far from world-class performance (6σ ≈ 3.4 defects per million).
Service-level analysis revealed important contrasts. Intensive Care (SIC) displayed the highest Sigma level (3.30σ), suggesting relatively consistent compliance with pre-analytical requirements. Conversely, Surgery (CHIR) demonstrated the lowest performance (3.14σ) with marked variability, including a peak of 10% non-conformities in October. Medicine (MED) also showed recurrent threshold exceedances (up to 6.94% in July), indicating persistent vulnerabilities in sample collection and handling practices. Outpatient (EXTERNE) and Emergency (URG) services remained closer to the 4% defect threshold, but still below the expected quality target.

3.2.3. Non-Conforming Laboratory Reports

The rate of non-conforming laboratory request forms was marginal throughout the review period. Only two non-conformities were formally documented in July out of 1,554 total requests. In subsequent months, no forms were officially recorded as non-conforming, as discrepancies were typically resolved verbally by directly contacting the originating unit, leading to significant under-reporting (Table 5). This reflects limited traceability of documentation errors, highlighting the need for systematic reporting to allow corrective actions and continuous improvement.

Table 5. Longitudinal analysis of non-compliant laboratory request forms (July–December 2024)
("–" = data not available; compliance threshold = 0 %)

Month	Emergency (URG)	Medicine (MED)	Intensive Care (SIC)	Intermediate Care (SIM)	Surgery (CHIR)	Outpatients (EXTERNE)
July	0.16%	0.35%	0%	0%	0%	0%
August	0%	0%	0%	0%	0%	0%
September	0%	0%	0%	0%	0%	–
October	0%	0%	0%	0%	0%	0%
November	0%	0%	0%	0%	0%	–
December**	–	–	–	–	–	–

Notes :
a) Rate Rate of non-compliant forms (%) =(Nomber. of non-compliant forms/Total forms received)×100
b) *September: Data available only from 02–06 and 25–30 September.*
c) December: Data not available.
d) Non-conforming forms were rarely documented; staff resolved issues directly with requesting departments.
e) Overall, the rate of non-compliant laboratory request forms remained negligible (≤ 0.35%) across all departments.

3.3. Analytical Phase

3.3.1. Internal Quality Control (IQC) Conformity

The conformity of Internal Quality Controls (CIQ) was monitored across three disciplines (Hematology, Biochemistry, Hemostasis) with a target of ≥95%.

Regarding the overall Performance, CIQ conformity was generally excellent, frequently meeting or exceeding the target. In July, conformity rates were 99.63% (hematology), 96.04% (biochemistry), and 95.24% (hemostasis). However, data for Biochemistry and Hematology were missing for August. A notable deviation was observed in hematology in September (84.02%), suggesting a potential issue with reagent quality, calibration, or procedural adherence during that period (Table 6).

These results confirm the reliability of analytical processes but underscore the need for ongoing monitoring and investigation of occasional deviations, which may result from equipment malfunction, calibration issues, or insufficient operator training.

Table 6. Longitudinal analysis of Internal Quality Control (IQC) compliance rate by discipline

(Compliance threshold ≥ 95%; "–" = data not available)

Month	Hematology IQC (%)	Biochemistry IQC (%)	Hemostasis IQC (%)	Hematology DPMO	Hematology Sigma	Biochemistry DPMO	Biochemistry Sigma	Hemostasis DPMO	Hemostasis Sigma
July	99.63	96.04	95.24	3,700	5.44	39,600	5.17	47,600	5.15
August	—	—	98.38	—	—	—	—	16,200	5.28
September	84.02	99.73	98.27	159,800	5.01	2,700	5.47	17,300	5.27
October	100.00	95.59	98.39	0	>6.00	44,100	5.16	16,100	5.28
November	99.40	97.13	100.00	6,000	5.39	28,700	5.21	0	>6.00

Notes :

a) **August:** Hematology and Biochemistry records not available.
b) **December:** No data recorded.
c) Compliance rates remained **above the 95% threshold** for most disciplines, except for Hematology in September (84.02%).

3.3.2. Timely Completion of Examinations

The rate of examinations completed within the stipulated deadlines was critically low against a target of ≥85%. Performance in this indicator was markedly deficient, with compliance consistently below 25% across all months for both internal and external analyses. Internally, rates of timely test completion ranged from 14.85% (July) to 23.71% (November). Externally, these values were consistently lower, averaging approximately 10-12% (Table 7).

The persistent delays in test turnaround times highlight systemic bottlenecks within the analytical workflow. These shortcomings appear to stem from multiple, interconnected factors, including equipment malfunctions, reagent stockouts, staffing shortages—particularly during peak activity periods—as well as inefficiencies in workflow organization. Furthermore, dependence on the Olympe system may exacerbate these issues. Collectively, these constraints represent a major quality risk, underscoring the need for immediate corrective and preventive actions to safeguard laboratory performance.

Table 7. Longitudinal analysis of the proportion of examinations delivered within the required timeframe (July–December 2024)

(Target threshold ≥ 85%; "–" = no data available)

Month	Hematology_CIQ (%)	Biochemistry_CIQ (%)	Hemostasis_CIQ (%)	Internal_TAT (%)	External_TAT (%)	Hemostasis_ Maintenance (%)
July	99,63	96,04	95,24	14,85	10,93	25,81
August			98,38	21,5	10,33	16,13
September	84,02	99,73	98,27	18	8,9	16,67
October	100	95,59	98,39	20,21	12,22	45,16
November	99,4	97,13	100	23,71	11,04	
December			20,8	10,12		

Key notes :

a) Compliance rates for both internal and external patients remained **far below the target of 85%** across all months.
b) Internal examinations consistently performed better than external ones (≈ 15–24% vs. 8–12%).
c) A modest improvement trend was observed in internal results, peaking in November (23.71%).
d) External examinations showed persistent underperformance, with values hovering around 10%.

3.3.3. Preventive maintenance rate for analyzers

Preventive maintenance data were inconsistently recorded. Maintenance of hematology analyzers was scheduled biweekly. In July and October, preventive actions covered 8 and 14 days, respectively. For hemostasis analyzers, the number of maintenance days performed per month (ranging from 5 to 14) was consistently lower than the number of scheduled days (30-31). Data for November and December were absent. The ad-hoc maintenance schedule for biochemistry analyzers ("on request") further highlights a lack of a structured, preventive approach (Table 8).

This lack of documentation raises concerns about tracking, maintenance compliance, and regarding potential deterioration of analyzer performance. This observation underscores the importance of implementing a formalized, documented preventive maintenance schedule.

Table 8. Preventive internal maintenance rate of hematology analyzers (July–December 2024)

Month	Maintenance performed (days)	Maintenance scheduled (days)	Compliance rate (%)
July	8	31	25.8
August	5	31	16.1
September	5	30	16.7
October	14	31	45.2
November	–	–	–
December	–	–	–

Key observations

a) The preventive maintenance rate remained **consistently below 50%**, despite a bi-weekly maintenance requirement.
b) October showed the **highest compliance (45.2%)**, while August and September were particularly low (< 20%).
c) No data were available for November and December.
d) This underperformance highlights a **systematic gap in equipment maintenance monitoring**, which may impact analytical reliability.

3.4. Post-Analytical Phase

3.4.1. Timely Availability of External Results

The rate of external results released within the expected time frame consistently exceeded 90%, reaching 98.45% in September. Indeed, the laboratory consistently demonstrated strong post-analytical performance in the delivery of external results, with monthly rates ranging from 93.47% to 98.45% (Table 9). These figures not only met but often exceeded performance targets **(objective ≈ 95%)**, reflecting the robustness of validation, reporting, and dispatch procedures. This efficiency ensures timely communication of results to external clients, underscoring the reliability and effectiveness of the laboratory's post-analytical processes.

Table 9. External results delivered within the required timeframe (July–December 2024)

Month	External Results On-Time	Total External Results Delivered	On-Time Delivery Rate (%)
July	515	545	94.6
August	432	456	94.7
September	383	389	98.5
October	458	490	93.5
November	366	381	96.1
December	–	–	–

Key observations

a) Compliance with external reporting deadlines remained **consistently above 93%**, with an exceptional peak in **September (98.5%)**.
b) Slight declines were observed in **October (93.5%)** and **July (94.6%)**, though still within acceptable standards.
c) Data for December were unavailable at the time of analysis.
d) Overall, the laboratory demonstrates a **high level of reliability in timely reporting of external results**, which strengthens confidence among external stakeholders.

The calculated Late Rate, DPMO, and Sigma Levels for each month are presented in table 10. The annual average is calculated for the months where data is available (July-November).

Table 10: Calculation Results

Month	On-Time Rate	Late Rate	DPMO	Sigma Level
July	94.6%	5.4%	54,000	3.09
August	94.7%	5.3%	53,000	3.10
September	98.5%	1.5%	15,000	3.59
October	93.5%	6.5%	65,000	2.99
November	96.1%	3.9%	39,000	3.25
December	–	–	–	–
Annual Average	95.5%	4.5%	45,200	3.19

Note :

a) Late Rate (%): This is the complement of the On-Time Delivery Rate.
   - Formula: Late Rate % = 100% - On-Time Delivery Rate %
   - *Example for July: 100% - 94.6% = 5.4%*
   - Formula: DPMO = Late Rate % * 10,000 or (Late Rate / 100) * 1,000,000
   - *Example for July: 5.4 * 10,000 = 54,000 DPMO*

b) Sigma Level: This is derived from the DPMO value using a standard conversion table.

The process shows significant variability. September was the best-performing month both in terms of on-time deliveries (98.5%) and process quality (3.59 Sigma). October was the worst-performing month (93.5%, 2.99 Sigma). The aim for process improvement would be to reduce variation and consistently perform near or above the September level, stabilizing the Sigma Level above 3.5.

3.4.2. Timely Availability of Internal Results

Internal result availability was difficult to assess accurately. Data were often not entered into tracking systems due to the direct release of results via the hospital's information system (Olympe) or collected in person, bypassing formal monitoring. As such, internal turnaround times could not be reliably calculated (Table 11).

Table 11. Internal Results Availability (Bacteriology & HIV)

Month	Internal Results Recorded	Comments
July	–	Physicians access results directly via the Olympe system; manual tracking is not required.
August	–	No manual logbook entries due to digital workflow.
September	–	Results were consulted in the respective departments.
October	–	–
November	–	–
December	–	–

The availability of internal results could not be reliably assessed, as physicians primarily consulted results directly via the hospital's information system (Olympe) or collected them in person, bypassing

formal monitoring. The absence of structured tracking mechanisms prevented accurate calculation of internal turnaround times, highlighting the need for an automated system to ensure systematic monitoring and performance evaluation.

3.5. Strengths, Weaknesses, and Areas for Improvement

The evaluation of KPI compliance at the ICA laboratory highlighted several strengths across the different operational phases. In the pre-analytical stage, patient waiting times were well controlled, consistently remaining below the established benchmark. Similarly, in the analytical phase, high conformity was observed in internal quality control (IQC), confirming the robustness of analytical procedures. In the post-analytical stage, the timely release of external results further reflected effective processes for validation and reporting.

Despite these achievements, important weaknesses were also identified. Variability in the rate of non-conforming samples (PNC) across certain clinical departments frequently exceeded threshold values, indicating persistent challenges in pre-analytical quality assurance. Within the analytical phase, the timeliness of exam result delivery remained critically low, well below the defined performance targets, while preventive maintenance of analyzers was inconsistently documented and executed. Post-analytical weaknesses included the absence of reliable monitoring of internal result availability, as most results were accessed directly via the Olympe system, preventing accurate performance measurement. Furthermore, gaps in data collection—such as missing records for December and incomplete documentation for September—underscored deficiencies in systematic data capture and traceability.

4. Synthesis: Cross-Analysis of Quality Indicators and Client Satisfaction

4.1. Pre-analytical phase: performance and client perception

KPI results. Average waiting times were consistently below the threshold of 25 minutes, confirming adequate management of patient flow. The rate of non-conforming samples remained ≤ 5% overall, though occasional peaks were observed in Surgery (up to 10%) and SIM (7.27%). Non-conforming request forms were virtually absent, but anomalies were often handled informally, limiting traceability.

Client perception. External clients reported very high satisfaction regarding hygiene and reception (≥ 98%), as well as sampling procedures (98.2%). However, satisfaction with laboratory accessibility was lower (77.8%), revealing logistical shortcomings not captured by KPIs.

Cross-analysis. Objective data and client perceptions were broadly aligned, confirming the strong quality of pre-analytical management. The only discordance concerned access to the laboratory, which emerged as a logistical barrier outside the scope of standard indicators.

4.2. Analytical phase: performance and perception

KPI results. Internal quality control (IQC) compliance was satisfactory (>95%) across hematology, biochemistry, and hemostasis. Conversely, the timeliness of test completion was critically deficient (10–23%, vs. target ≥85%). Preventive maintenance was irregular and sometimes undocumented.

Staff perception. Internal surveys revealed substantial dissatisfaction: 70.4% reported poor working conditions, 77.8% highlighted shortages in reagents and equipment, and only two-thirds perceived technological progress.

Client perception. Externally, delays in result delivery were reported by 12.4% of clients, with 14.2% dissatisfied with emergency handling and 11.4% citing insufficient availability of biologists.

Cross-analysis. The poor performance on timeliness and maintenance was directly reflected in client complaints regarding delays, emergencies, and staff availability. Convergence between KPI data and perceptions underscores organizational and material fragilities, further reinforced by staff dissatisfaction.

4.3. Post-analytical phase: performance and perception

KPI results. External results were consistently delivered on time (>93%), meeting performance targets. Internal results could not be reliably measured due to limitations of the Olympe system.

Client perception. Confidentiality of results (98.1%) and cleanliness/organization (>99%) were highly rated. However, awareness of the complaints management system was low (37%).

Staff perception. Personnel reported strong satisfaction with corrective actions (96.3%) but highlighted insufficient visibility regarding technological upgrades. They recommended optimization of information and communication systems.

Cross-analysis. Although post-analytical KPIs indicated satisfactory technical performance, client perceptions highlighted communication gaps—particularly in complaints management and patient information. This suggests that relational and informational aspects of post-analytical processes are underutilized.

All points of convergence and divergence of Cross-Analysis of Quality Indicators and Client Satisfaction have been summarized in Table 12.

Table 12. Synthesis of convergences and dissonances

Phase	KPI targets achieved?	Client satisfaction	Critical issues
Pre-analytical	Mostly achieved	Very high	Accessibility/logistics
Analytical	Delays & maintenance	Moderate, with complaints on timeliness and emergencies	Staffing, obsolete equipment
Post-analytical	External timeliness	High, except for weak awareness of the complaints system	Lack of communication/visibility

5. Discussion

The performance evaluation of the laboratory at the Institut de Cardiologie d'Abidjan (ICA) from July to December 2025 highlights several strengths, alongside areas requiring corrective efforts. The analysis was conducted according to the three main phases of the analytical process—pre-analytical, analytical, and post-analytical—in compliance with international guidelines (IFCC, ISO 15189).

5.1. Pre-analytical Phase: Between Mastery and Disparities

The mean waiting time prior to sampling (22 minutes and 30 seconds) adheres to the international benchmark of 25 minutes for tertiary care facilities. This performance indicates sound logistical organization, comparable to results reported by Hogan (2022) [16]. Research indicates that the management of waiting times is a critical factor in enhancing patient satisfaction and operational effectiveness. Hogan (2022) emphasizes the importance of timely laboratory results in pediatric nephrology, suggesting that prolonged waiting times can adversely affect clinical decision-making and patient outcomes [16].

Regarding the proportions of non-conforming samples (PNC), the ICA demonstrates generally acceptable rates (<5%), with the exception of sporadic peaks (up to 10% in surgery in October). For comparison, a reference in Saudi Arabia reported a 12.1% preanalytical error rate [17]. The main errors were non-received samples (30.7%) and hemolysis (29.2%). The former was most common in the Emergency Department and Inpatient Department, while hemolysis was more frequent in the Outpatient Department [17]. Although the specific typology of errors at the ICA is not detailed, the frequency of threshold exceedance in intensive care and surgery suggests similar failures, particularly concerning anticoagulant-to-blood ratios and sampling procedures. Targeted reinforcement of training and detailed monitoring of errors by type (hemolysis, insufficient volume, incomplete identification, etc.) would refine this analysis.

Non-conformities on test request forms are infrequent at the ICA but are under-reported as they are often resolved verbally.

5.2. Analytical Phase: Controlled Quality but Limited Throughput

Internal Quality Control (IQC) performance at the ICA is globally excellent (>95% for all disciplines, barring a transient drop in hematology to 84% in September). These results exceed the recommendations of Ricos et al. and are comparable to the results of Gui-Ping Xu et al. that showed that the sensitivity and specificity of the IQCs in anti-B testing were 100% and 99.7%, respectively [18,19].

However, the observed transient decrease warrants investigation (e.g., inadequate reconstitution, broken cold chain, equipment malfunction, sample mix-up/ interference or unstable reagents). This echoes the conclusions of Vivek Dugad et al., who emphasized the importance of rigorous control of procedure [20].

Conversely, the Turnaround Time (TAT) for tests represents a major weakness. Only 15 to 24% of in-house tests are delivered within the target time. This performance is substantially below the established standard of ≥90% compliance. It also fails to meet the proposed benchmark for an acceptable turnaround time (TAT), which is a completion time of less than 60 minutes for common laboratory tests, from registration to reporting [21].

These delays are corroborated by the external satisfaction survey, in which 14.6% of users expressed dissatisfaction with the reporting time, and 12.4% with the respect of the communicated deadline. Improvement suggestions from clients included increasing staff and investing in automation.

5.3. Post-analytical Phase: Improvement in External Management, Internal Deficits

Performance concerning results delivered to external clients is satisfactory (>90% on time), indicating effective validation and transmission channels for off-site reporting. This situation, however, contrasts

with the unavailability of internal result data, linked to either a failure in data entry or the circumvention of traceability systems via Olympe. This organizational weakness prevents reliable measurement of TAT for inpatients.
Furthermore, complaint management is a well-documented weakness. Only 37% of clients were informed of the existence of a complaint service. This invisibility of the system hinders continuous improvement and patient trust.

However, traceability of post-analytical errors is a core requirement of quality assurance. The low documented frequency at the ICA (<0.2%) contrasts with Plebani M et al. study, where the postanalytical phase accounts for errors in the range of 38–66% of the total [21]. The implementation of a formal reporting system is therefore recommended.

5.4. Correlations with Internal Data: ISO 9001 Perception and Staff Satisfaction

The KPI results can be further contextualized with internal data from staff evaluations. While adherence to ISO 9001 principles is strong (100% awareness), gaps remain in the understanding of strategic dimensions such as governance and risk management.
Staff satisfaction is mixed: while collaboration and task distribution are perceived positively (96.3% and 77.8%, respectively), working conditions (70.4% dissatisfaction), availability of materials (77.8%), and remuneration (87.5%) are significant concerns. These perceptions are consistent with the difficulties observed in the KPIs: delays, equipment unavailability, lack of maintenance, etc. Thus, improving staff satisfaction appears to be a prerequisite for enhancing the quality perceived by clients.

The evaluation of the ICA laboratory's performance indicators, juxtaposed with satisfaction survey data and the scientific literature, reveals a dual reality: a strong commitment to quality (IQC, patient reception, hygiene, confidentiality) on one hand, and persistent inadequacies in TAT, post-analytical traceability, and resource management on the other.

Based on these findings, several areas for improvement were identified. First, digital monitoring of quality indicators should be strengthened through the integration of Olympe, Excel, or dedicated quality management software (QMS). Second, targeted training for staff involved in sampling and sample handling is necessary to reduce PNC variability and enhance compliance with procedures. Third, systematic documentation of request form non-conformities must be formalized to ensure reliable error tracking and corrective action. Fourth, a preventive maintenance schedule should be implemented and strictly enforced, with traceable records for all analyzers. Finally, analytical workflows should be redesigned to improve turnaround times, with particular emphasis on optimizing staff allocation and reducing systemic bottlenecks.

CONCLUSION

The combined analysis of performance indicators from the laboratory of the Institut de Cardiologie d'Abidjan (ICA) and satisfaction surveys of both users and staff reveals a well-initiated quality dynamic, yet one still marked by certain systemic fragilities.
The pre-analytical phase is characterized by a generally well-controlled quality of service, as evidenced by high user satisfaction regarding reception, cleanliness, laboratory accessibility, and the competence of the sampling staff. However, certain hospital units exhibit rates of non-conforming samples that exceed acceptable thresholds, indicating internal disparities in the application of standard operating procedures.
The analytical phase, meanwhile, is marked by excellent compliance with internal quality controls (IQC), thereby ensuring the technical reliability of the analyses performed. Nevertheless, the Turnaround Times (TAT) for tests are largely non-compliant, with a majority of results delivered outside standard deadlines, constituting a significant source of frustration for both patients and prescribing physicians.
The post-analytical phase demonstrates a duality: while the delivery of results to outpatients is well-managed, internal traceability and the documentation of post-analytical errors remain insufficient. Furthermore, the lack of visibility of the complaint service reduces opportunities for continuous, patient-centered improvement.
Finally, the perceptions of the laboratory professionals highlight a strong adherence to quality principles (ISO 9001), but also a high level of dissatisfaction concerning working conditions, equipment availability, and professional recognition. This climate could ultimately compromise ongoing performance and certification efforts.
These findings call for:

- Enhancing the automation of analytical and post-analytical processes;
- Systematically documenting anomalies (samples, reports);

- Implementing a communication plan for the complaint service;
- Investing in staff well-being to ensure sustainable operations.

In conclusion, this study highlights the capacity of the ICA laboratory to deliver quality services, but also the necessity for a more integrated strategic management approach that synergizes human resources, infrastructure, digitalization, and quality culture.

These recommendations, implemented in a progressive and structured manner, will sustainably enhance patient satisfaction, care efficacy, and the overall performance of the laboratory.

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