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Research Article

Survey on the outcome of self-assessment of laboratory quality at medical facilities from 2019 to 2024

Encuesta sobre los resultados de la autoevaluación de la calidad de los laboratorios en centros médicos, de 2019 a 2024

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ABSTRACT

Introduction: Clinical laboratory quality underpins accurate diagnosis and effective treatment. In Vietnam, self-assessment tools support continuous quality improvement.

Objective: To evaluate laboratory quality self-assessment results (2019–2024) and identify influencing factors.


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Methods: A cross-sectional study. Laboratories in the Central Coast, Central Highlands, and Southeast regions were included. ANOVA, Chi-square assessed score differences by year, region, facility type, and administrative level.

Results: 502 laboratories were evaluated, average quality score increase from 208.36 (2019) to 219.76 (2024). The proportion of laboratories not getting one Star criteria decreased from 56.8% (2021) to 35.1% (2024), while those not getting 3 Star criteria were below 25% in each year. Process control consistently scored highest, while information management, purchasing & inventory, continuous improvement, and client management all markedly increased their scores. Laboratories in the Southeast, private units, hospitals, and central-level institutions had higher scores, $p < 0.05$.

Conclusions: Rising quality scores reflect ongoing laboratory efforts aligned with national quality improvement trends. Regional, facility-type, and administrative disparities highlight the need for context-specific supports.

Keywords: laboratories; quality assurance, health care; quality improvement; self-assessment.

RESUMEN

Introducción: La calidad de los laboratorios clínicos sustenta un diagnóstico preciso y un tratamiento eficaz. En Vietnam, las herramientas de autoevaluación apoyan la mejora continua de la calidad.

Objetivo: Evaluar los resultados de la autoevaluación de la calidad de los laboratorios (2019-2024) e identificar los factores influyentes.

Métodos: Estudio transversal. Se incluyeron laboratorios de las regiones de la Costa Central, las Tierras Altas Centrales y el Sudeste. Mediante ANOVA y *ji* cuadrado se evaluaron las diferencias de puntuación por año, región, tipo de centro y nivel administrativo.

Resultados: Se evaluaron 502 laboratorios, la puntuación media de calidad aumentó de 208,36 (2019) a 219,76 (2024). La proporción de laboratorios que no obtuvieron el criterio de una estrella disminuyó del 56,8 % (2021) al 35,1 % (2024), mientras que la de los que no obtuvieron el criterio de 3 estrellas se situó por debajo del 25 % cada año. Mientras que la gestión de la información, las


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compras e inventarios, la mejora continua y la gestión de clientes aumentaron notablemente sus puntuaciones. Los laboratorios del sureste, las unidades privadas, los hospitales y las instituciones de nivel central obtuvieron puntuaciones más altas ($p< 0,05$).

Conclusiones: El aumento de las puntuaciones de calidad refleja los esfuerzos continuos de los laboratorios, alineados con las tendencias nacionales de mejora de la calidad. Las disparidades regionales, por tipo de centro y administrativas resaltan la necesidad de apoyos específicos para cada contexto.

Palabras clave: autoevaluación; control de calidad; garantía de la calidad de atención; laboratorios.

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INTRODUCTION

Clinical laboratory testing plays a vital role in healthcare and evidence-based medicine.[1,2] Laboratory results provide essential data to support clinical decisions in screening, diagnosis, and treatment.[3] Approximately 70–75% of medical diagnoses rely on clinical laboratory reports, making the quality of laboratory services directly impact the quality of healthcare.[4,5] Strengthening the quality of medical laboratories is a key component in building global health capacity. Any errors or deficiencies in laboratory practices can compromise patient care and increase healthcare costs. Therefore, laboratory quality is a high priority in many health systems.[6,7] In low- and middle-income countries, insufficient quality management systems in laboratories remain a challenge and barrier to providing reliable testing services in resource-limited settings. Achieving tangible improvements in laboratory quality depends on staff readiness for change, availability of resources, and effective project management.[8]


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Laboratory quality management is a continuous improvement process focused on measuring performance from the customer satisfaction perspective. Implementing comprehensive quality management in clinical laboratories requires the integration of quality planning and improvement with quality assurance to establish a complete quality management system.[9,10]

In Vietnam, nearly all hospitals and healthcare facilities at the district level and above are equipped with clinical laboratories. The Ministry of Health has issued various policy documents to strengthen laboratory quality systems. On June 12, 2017, the Ministry promulgated the Criteria for Assessment of Medical Laboratory Quality issued under Decision No. 2429/QĐ-BYT (the 2429 criteria set). This set of criteria serves as a tool for healthcare facilities to conduct self-assessments of their laboratory quality systems, enabling competent authorities to inspect, evaluate, and report on laboratory quality levels. These evaluations provide the basis for recognizing results and ensuring interoperability between facilities.

The Quality Control Center for Medical Laboratory (QCC) has been assigned the responsibility of guiding and supporting laboratories in conducting quality self-assessments based on the 2429 criteria set. Since 2019, the QCC has actively implemented this task across three key regions of Vietnam including the Central Coast, Central Highlands, and Southeast. Through training programs, technical support, and regular monitoring, the Center has played a pivotal role in helping laboratories understand, apply, and continuously improve upon the standards outlined in the quality assessment framework.

This study aims to survey the results of self-assessment of laboratory quality at medical facilities from 2019 to 2024 and the associated factors influencing these outcomes.

METHODS

Study design

This is a cross-sectional study. Data collection is retrospective, with data from 2019 to 2023 (except 2022 due to COVID-19); and prospective with data from 2024.


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Subjects

The study subjects included laboratories at public and private medical facilities in the Central Coast, Central Highlands, and Southeast regions managed by the Quality Control Center for Medical Laboratory - University of Medicine and Pharmacy at Ho Chi Minh City from 2019 to 2024.

Inclusion criteria: Laboratories located in the 19 provinces and cities under the management of the Quality Control Center for Medical Laboratory.

Exclusion criteria: Laboratories that completed less than 50% of the assessment content; Laboratories that could not be contacted after more than three attempts.

Data Collection

The research data from 2019 to 2023 were collected secondarily from the archived database of the Center. However, in 2022, due to the impact of the COVID-19 pandemic, the Center prioritized epidemic prevention and control activities. As a result, the implementation of the self-assessment at medical units was not carried out in 2022. Therefore, the available secondary data from the Center's archives include the years 2019, 2020, 2021, 2023 and prospective with data from 2024.

Variables

The primary variable was the total self-assessment laboratories quality score, a continuous variable representing the overall score obtained by medical laboratories through self-assessment based on 12 essentials of quality management in laboratories. These aspects reflect the core components of laboratory quality management systems and include: (1) organization and management, (2) documentation, (3) personnel, (4) client management, (5) equipment, (6) internal audit, (7) purchasing and inventory, (8) process control, (9) information management, (10) corrective action, (11) continuous improvement, and (12) facilities and safety.

In the criteria set, certain core criteria are designated criteria 1-star (15 contents) and 3-star (18 contents). If only one 1-star or 3-star content is not met, it is considered as not meeting the 1-star and 3-star criteria. Star level 1 and Star level 3 are the proportion of laboratories that do not meet the 1-star, 3-star criteria. Star level 1 and Star level 3 are the proportion of laboratories that meet the 1-star, 3-star criteria.


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The independent variables included in the analysis were the region of the laboratory (Central Coast, Central Highlands, or Southeast), the type of unit (public or private), and the type of healthcare facility (hospital, health center, or others). Additionally, the managing agency was classified as the Ministry of Health, the Department of Health, or other ministries or sectors. For laboratories under public management, the administrative level was further categorized into central, provincial, or district levels.

Data analysis

Initial data cleaning and organization were performed in Excel, and statistical analysis was conducted using R version 4.3.1 software. Descriptive statistics (frequencies, proportions, means, and standard deviations), were used to summarize laboratory characteristics and score distributions across the years. Continuous variables (total scores and aspect-specific scores) were assessed for normality using the Shapiro-Wilk test.

The analysis focused on assessing changes in total self-assessment laboratories' quality scores and scores across the 12 essentials of quality management in laboratories in each year from 2019 to 2024. Using one-way ANOVA tests the difference in self-assessment scores between years. Additionally, significant differences in self-assessment scores across regions, types, healthcare facilities, managing agency, and level units by Chi-square test. Statistical significance was defined at $p < 0.05$.

Ethical considerations

The study adhered to the Declaration of Helsinki and was approved by the institutional review board of the University of Medicine and Pharmacy at Ho Chi Minh City (Approval Number: 215/2024/HĐ-ĐHYD, dated 22/8/2024).

RESULTS

From 2019 to 2024 (excluding 2022), the majority of laboratories participating in the quality self-assessment were located in the Southeast region, accounting for the highest proportion in most years, ranging from 35.0% to 46.8%.


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The Central Coast region maintained a relatively stable participation rate (37.8% - 40.4%), while the Central Highlands had a lower rate overall. In 2021, however, the Central Coast had the highest participation rate at 53.6%, whereas the Southeast accounted for only 14.3%. Most participating laboratories were affiliated with public healthcare facilities, although the proportion of non-public laboratories showed an increasing trend from 10.7% in 2021 to 43.9% in 2024. Hospitals represented the main type of facility (53.3% - 82.1%), followed by health centers and other types, with the "Others" category increasing noticeably from 2023. The majority of facilities were under the jurisdiction of provincial Departments of Health, with a consistently high rate above 75%.

In terms of classification, level III facilities had the highest participation rate, while central-level facilities consistently had the lowest. Overall, laboratories participating in the self-assessment were predominantly public, provincial, or district-level facilities managed by local health departments, with a geographical concentration in the Southeast and Central Coast regions (table 1).

The average quality scores showed a positive trend, increasing from 208.36 ± 43.92 in 2019 to 219.76 ± 28.09 in 2024. The proportion of laboratories not meeting Star Level 1 criteria remained relatively high in the early years (e.g., 78.6% in 2021), a marked decline was observed in 2024, dropping to 35.1%. The proportion of laboratories not meeting Star Level 1 criteria remained relatively high in the early years (e.g., 78.6% in 2021), a marked decline was observed in 2024, dropping to 35.0%. The proportion of not meeting Star Level 3 criteria remained consistently high, above 75% over the years. In 2019, 80.9% of the 47 participating laboratories did not reach the 3-star level. This rate was 80.0% in 2020, 85.7% in 2021, 76.1% in 2023, and 75.3% in 2024. This proportion shows a downward trend but is not significant (table 2).

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Table 1 – Description of laboratories participating in self-assessment of laboratory quality at medical facilities from 2019-2024

Characteristics, n (%)	2019	2020	2021	2023	2024
	n = 47	n = 45	n = 28	n = 285	n = 98
Regions					
Central Coast	18 (38.3)	17 (37.8)	15 (53.6)	115 (40.4)	36 (36.7)
Central Highlands	7 (14.9)	8 (17.8)	9 (32.1)	70 (24.6)	18 (18.4)
Southeast	22 (46.8)	20 (44.4)	4 (14.3)	100 (35.0)	44 (44.9)
Types					
Public units	37 (78.7)	33 (73.3)	25 (89.3)	13 (74.7)	55 (56.1)
Private units	10 (21.3)	12 (26.7)	3 (10.7)	72 (25.3)	43 (43.9)
Healthcare facilities					
Hospital	30 (63.8)	30 (66.7)	23 (82.1)	152 (53.3)	60 (61.9)
Health center	14 (29.8)	14 (31.1)	5 (17.9)	110 (38.6)	22 (22.7)
Others	3 (6.4)	1 (2.2)	0 (0.0)	23 (8.1)	15 (15.5)
Managing agency					
Other Ministries/Sectors	3 (6.3)	- (0.0)	2 (7.1)	7 (2.5)	2 (2.0)
Ministry of Health	6 (12.8)	4 (8.9)	5 (17.9)	13 (4.5)	6 (6.2)
Department of Health	38 (80.9)	41 (91.1)	21 (75.0)	65 (93.0)	90 (91.8)
Level units (n=354)					
Central	6 (17.2)	4 (12.1)	5 (20.8)	13 (6.3)	6 (11.1)
Provincial	20 (57.1)	13 (39.4)	13 (54.2)	97 (46.6)	30 (55.6)
District	9 (25.7)	16 (48.5)	6 (25.0)	98 (47.1)	18 (33.3)

Table 2 – Average score of laboratories participating in self assessment (2019–2024)

Year	Number Labs	Score quality	Star level 1	Star level 3
		Mean ± SD	n (%)	n (%)
2019	47	208.36 ± 43.92	18 (38.3)	9 (19.2)
2020	45	213.71 ± 38.68	13 (28.9)	9 (20.0)
2021	28	211.48 ± 33.87	6 (21.4)	4 (14.3)
2023	285	216.22 ± 35.17	162 (56.8)	68 (23.9)
2024	98	219.76 ± 28.09	63 (64.9)	24 (24.7)
p value	-	0.412[a]	< 0.001[b]	0.717[b]

[a]One-way ANOVA

[b]Chi-square test


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The essentials showed a marked increase: information management (2019: 7.62 points - 2024: 9.88 points (p = 0.004)), purchasing & inventory (2019: 18.05 points – 2024: 19.87 points (p = 0.017)), continuous improvement (2019: 13.96 to 2024:15.68 points (p > 0.05)), and client management (2019: 8.94 to 2024: 10.22 points (p = 0.002). Process control consistently held the highest average score (2019: 46.89 points; 2021: 42.45 points; 2024: 48.35 points (p = 0.007). Several essentials demonstrated high stability with minimal score variation, such as equipment (25–27 points), facilities and safety (around 27 points), personnel (17–18.7 points (p < 0.05)), and document (7.7–8.3 points). Organization and management showed a gradual increase from 17.51 ± 5.26 (2019) to 18.52 ± 4.09 (2024), p > 0.05. Some essentials initially improved and then plateaued, including internal audit, and corrective action, p > 0.05 (table 3).

Table 3 - Average score of laboratories participating in self assessment at 12 essentials of quality management in laboratories (2019–2024)

Variable	2019	2020	2021	2023	2024	p value
Organization and Management	17.51 ± 5.26	17.91 ± 4.8	18.32 ± 3.89	18.28 ± 4.03	18.52 ± 4.09	0.716
Document	7.72 ± 2.58	8.17 ± 1.98	8.36 ± 1.99	8.29 ± 1.78	8.23 ± 1.78	0.427
Personnel	17.43 ± 3.61	18.00 ± 3.67	17.43 ± 3.27	17.99 ± 2.66	18.75 ± 2.29	0.047
Client management	8.94 ± 3.85	9.78 ± 3.27	11.20 ± 2.69	10.73 ± 3.21	10.22 ± 2.65	0.002
Equipment	26.55 ± 3.69	26.79 ± 3.31	25.30 ± 3.29	26.51 ± 3.75	25.98 ± 3.92	0.348
Internal audit	7.87 ± 5.21	9.07 ± 4.74	9.32 ± 4.55	8.29 ± 4.57	8.74 ± 3.74	0.488
Purchasing & inventory	18.05 ± 3.77	19.00 ± 3.69	20.25 ± 2.76	19.44 ± 3.47	19.87 ± 2.48	0.017
Process control	46.89 ± 9.35	46.32 ± 8.22	42.45 ± 7.75	47.23 ± 7.27	48.35 ± 6.47	0.007
Information Management	7.62 ± 2.59	9.10 ± 2.38	8.80 ± 1.31	8.21 ± 1.99	8.99 ± 3.85	0.004
Corrective action	8.39 ± 4.67	8.17 ± 5.63	9.25 ± 4.36	8.75 ± 4.09	9.27 ± 3.93	0.569
Continuous improvement	13.96 ± 6.44	13.13 ± 6.8	14.05 ± 7.07	14.51 ± 6.45	15.68 ± 4.94	0.197
Facilities and Safety	27.43 ± 4.55	28.28 ± 3.75	26.75 ± 3.51	27.99 ± 3.73	27.17 ± 4.35	0.189

Mean ± SD. SD - Standard Deviation

One-way ANOVA

Over the course of five years, 502 laboratories participated in the quality self-assessment. Significant differences in average scores were observed across regions, facility types, managing agencies, and administrative levels. The Southeast region had the highest regional score


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(220.07 ± 33.14), while the Central Highlands had the lowest (202.59 ± 40.80; p = 0.006). The average score of private units (221.48 ± 31.17) was significantly higher than that of public units (213.46 ± 36.30, p = 0.036). Laboratories based in hospitals achieved the highest average score (221.51 ± 31.92), followed closely by those in other types of facilities (220.95 ± 32.39). In contrast, laboratories in health centers had the lowest average score (203.92 ± 38.32), p = 0.024. Laboratories under the Ministry of Health had the highest scores (231.75 ± 22.90), p = 0.008. Central-level laboratories outperformed those at the provincial and district levels (p = 0.007) (table 4).

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Table 4 - Average score of laboratories participating in self assessment by region, type, healthcare facilities, managing agency, and level units (2019–2024)

Characteristics, mean ± SD	Total 5 year n=502	2019 n=47	2020 n=45	2021 n=28	2023 n=285	2024 n=98
Regions						
Central Coast	218.84 ± 31.73	212.00 ± 48.18	216.09 ± 38.48	224.03 ± 21.65	219.13 ± 30.74	220.47 ± 25.32
Central Highlands	202.59 ± 40.80	196.14 ± 42.77	213.81 ± 41.14	192.83 ± 45.05	198.09 ± 41.82	222.50 ± 29.02
Southeast	220.07 ± 33.14	209.27 ± 41.98	211.60 ± 39.80	206.37 ± 29.20	225.55 ± 30.19	218.03 ± 30.35
p value	0.006	0.832	0.977	0.069	0.003	0.539
Types						
Public units	213.46 ± 36.30	209.07 ± 47.35	216.12 ± 36.82	210.00 ± 34.33	212.11 ± 36.32	221.6 ± 27.09
Private units	221.48 ± 31.17	205.75 ± 29.70	207.08 ± 44.43	223.67 ± 33.01	228.37 ± 28.45	217.36 ± 29.50
p value	0.036	0.115	0.442	0.945	0.016	0.562
Healthcare facilities						
Hospital	221.51 ± 31.92	217.70 ± 39.49	213.52 ± 40.53	214.17 ± 30.39	223.07 ± 31.45	226.27 ± 23.19
Health center	203.92 ± 38.32	185.43 ± 49.62	219.79 ± 29.60	199.10 ± 49.29	202.90 ± 37.91	211.75 ± 31.78
Others	220.95 ± 32.39	222.00 ± 21.98	134.50	N/A	234.63 ± 22.26	205.53 ± 33.58
p value	0.024	0.374	0.210	0.180	0.006	0.076
Managing agency						
Other Ministries/Sectors	186.82 ± 41.68	167.83 ± 58.88	N/A	196.70 ± 30.76	180.86 ± 39.27	226.25 ± 28.64
Ministry of Health	231.75 ± 22.90	240.67 ± 20.71	230.50 ± 18.01	217.60 ± 29.02	237.73 ± 19.76	222.50 ± 27.09
Department of Health	215.37 ± 35.07	206.46 ± 42.97	212.07 ± 39.88	211.43 ± 36.07	216.10 ± 34.96	219.44 ± 28.42
p value	0.008	0.174	0.790	0.878	0.067	0.991
Level units (n=354)						
Central	231.75 ± 22.90	240.67 ± 20.71	230.00 ± 18.01	217.00 ± 29.02	237.73 ± 19.76	222.50 ± 27.09
Provincial	217.67 ± 35.96	206.97 ± 55.32	211.04 ± 47.57	206.35 ± 41.50	220.36 ± 31.74	223.88 ± 21.52
District	205.80 ± 36.52	194.89 ± 37.49	216.66 ± 30.65	210.20 ± 27.27	202.86 ± 37.81	216.11 ± 35.32
p value	0.007	0.059	0.735	0.500	0.017	0.072

Mean ± SD. SD - Standard Deviation

One-way ANOVA


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DISCUSSION

This study surveys the results of self-assessment of laboratory quality at medical facilities in the Central Coast, Central Highlands, and Southeast regions of Vietnam from 2019 to 2024 (excluding 2022 due to COVID-19). The findings revealed a modest but consistent improvement in overall quality scores over the five-year period, with the average score increasing from 208.36 ± 43.92 in 2019 to 219.76 ± 28.09 in 2024. Notably, the proportion of laboratories failing to meet the minimum Star Level 1 standard decreased significantly, from 56.8% in 2021 to 35.0% in 2024, suggesting an encouraging trend in compliance and performance. However, the proportion of laboratories not meeting the 3-star level remained at less than 25% achieving this benchmark each year, indicating ongoing challenges in achieving advanced levels of quality management.

These findings align with outcomes reported in other developing settings. In Ethiopia, the study by *Sisay A* et al.[11] evaluated the results of strengthening laboratory management towards accreditation program (SLMTA) in Addis Ababa showed a significant improvement in the overall average score (141.4; range 65-196, 95% CI: 86.275-115.5, p = 0.000) and increased the number of laboratories achieving 2- and 3-star levels. Crucially, those getting adequate and timely manner mentorship were found 2.5 times more likely to get success in the final score (AOR= 2.501, 95% CI= 1.109-4.602) than those who did not get it. A systematic review of low- and middle-income countries underscores that success in quality management system implementation depends on leadership engagement, sufficient funding, continuous training, and mentorship factors.[12]

Current study outcome indicated improvements in the laboratory quality score of 12 essentials, such as information management, client management, and purchasing and inventory, demonstrating clear progress and reflecting increased attention to operational systems and workflow efficiency. Process control consistently stood out as the strongest performing domain. Other essentials, including equipment management, facilities and safety, personnel, and documentation, remained relatively stable over time. In contrast, internal audit and corrective action, though initially showing some improvement, appeared to level off, suggesting ongoing challenges in sustaining gains in these more complex, system-based quality functions. This result is similar to a review of 126 laboratories implementing strengthening laboratory management


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toward accreditation in 12 nations showed purchasing & inventory and facilities and safety showed strong improvements (average 58–74%), while internal audit and corrective action lagged, with average scores of 32–50%. This pattern underscores a common challenge: laboratories excel initially in tangible, operational components but struggle with systems and sustainability.[13]

In other regions, such as Africa, studies from Kenya reported internal audits and corrective actions to face implementation challenges.[14] At the global, literature on quality management system such as ISO 15189 supports the critical role of internal audits and management reviews in continual improvement, while other domains maintain stability.[15]

Significant disparities in laboratory quality self-assessment scores were observed across regions, facility types, managing agencies, and administrative levels over a five-year period. Laboratories located in the Southeast region, affiliated with the Ministry of Health, hospital-based, and operating at the central administrative level consistently demonstrated higher self-assessment scores. In contrast, lower scores were reported among laboratories in the Central Highlands, health centers, publicly managed units, and those at subnational levels. These findings highlight the influence of resource availability, institutional support, and organizational capacity on laboratory quality performance.

Current study findings reinforce this pattern and highlight the need for targeted policy interventions to reduce performance gaps. Strengthening the quality systems in underperforming units particularly health centers and district-level laboratories will require investments in capacity building, technical mentorship, and stronger governance. By narrowing these gaps, Vietnam can promote more equitable quality assurance across all levels of the health system while aligning with global trends in laboratory system strengthening.

This study has limitations. Self-assessment data may be affected by self-reporting bias and performance overestimation. Sample sizes were inconsistent across years, limiting comparability. Moreover, voluntary participation prevented balanced representation across regions, facility types, and administrative levels, potentially affecting the generalizability of the results.


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Rising quality scores reflect ongoing laboratory efforts aligned with national quality improvement trends. Regional, facility-type, and administrative disparities highlight the need for context-specific supports.

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Conflicts of interest

None of conflicts of interest in relation to the work.


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Data availibility

Raw data is stored in Excel files and is available from the corresponding author upon reasonable request. Email: huevan@ump.edu.vn