

Establishing Zambia's First National Malaria RDT Proficiency Testing Programme: A Model for Strengthening Sustainable Diagnostic Capacity through South-to-South Collaboration

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Abstract

Background

Ensuring the quality of malaria rapid diagnostic testing (mRDT) remains a challenge in many resource-limited settings due to limited capacity to implement External Quality Assessment (EQA) programmes. With support from the East, Central and Southern Africa Health Community (ECSA-HC) as the regional coordinating body, Zambia established its first national malaria RDT proficiency testing (PT) programme through a South–South peer-learning partnership with Uganda’s National Reference Laboratory.

Methods

A descriptive implementation study was conducted across two PT cycles in 2025 using dried tube specimen (DTS)-based PT panels. Through a structured South–South collaboration facilitated by ECSA-HC, Zambia adapted Uganda’s established malaria EQA framework to its local context.

Results

Across the two implementation cycles, participation remained high (98% and 94%), with very satisfactory performance maintained above 94% during the expansion of the program. The diagnostic error rates remained low, with community-level testers reporting a higher rate (2.83%) than at the health facility level (0.98%). The median response and shipping turnaround time were 5 days and 13 days, respectively. The programme developed an ISO 17043-aligned quality management framework, standardised documentation and built technical capacity through a cascade Training of Trainers model, creating in-country capacity for malaria diagnostic quality assurance.

Conclusions

Zambia’s first national Malaria RDT PT programme demonstrates the value of South-South collaboration as a mechanism to accelerate diagnostic capacity strengthening. The partnership enabled the rapid transfer of technical expertise, quality practices, and operational experience within a shared regional context. Collectively, these findings demonstrate that South-South learning models are feasible, scalable, and capable of supporting the development of resilient laboratory systems consistent with the principles of the Africa CDC New Public Health Order.

Background

The Coronavirus disease 2019 (COVID-19) pandemic exposed deep inequalities and systemic flaws in the world’s collective response to infectious diseases [1, 2]. Governments must therefore prioritise universal health coverage to ensure that all its people, regardless of location and income, have access to

essential health services with minimal financial burden [3, 4]. This involves making serious investments in workforce training and health infrastructure that is sustainable. It is worth noting that a new approach to global health is gradually emerging, focusing on health system resilience, equitable access to medical countermeasures, and robust country-led public health institutions. [5, 6]. At the heart of this vision is the Africa Centre for Disease Control and Prevention (Africa CDC)'s call for a New Public Health Order for the continent — a framework that promotes regional self-sufficiency, enhances national public health institutes, and encourages local manufacturing of diagnostics, vaccines, and therapeutics [6, 7]. In the new Africa CDC order, diagnostics play a vital role. Accurate and prompt testing is the bedrock of effective disease monitoring, effective outbreak management and resilient pandemic preparedness [8, 9]. It is the first line of defence in detecting infectious organisms, guiding case management, and mounting effective public health responses. A country's ability to conduct reliable diagnostic testing is a key component of the International Health Regulations (IHR 2005) and an essential indicator of its role in global health security [10–12]. While global attention focuses on preparing for future pandemics, endemic diseases with high burdens like malaria continue to strain healthcare systems and claim hundreds of thousands of lives each year [13, 14]. Malaria remains a significant public health challenge in Africa and in Zambia, with an estimated 20,000 cases and approximately four deaths reported daily [15]. Zambia ranks among the top 20 globally in malaria incidence and mortality, and the fight against malaria is critical to broader health security [15, 16]. A health system capable of providing accurate malaria diagnosis is more resilient and better equipped to handle other infectious disease threats. Furthermore, eradicating malaria is a specific goal (SDG 3.3) within the Sustainable Development Goals (SDGs), and progress depends heavily on the quality of diagnostic testing methods [17]. Despite the widespread availability of mRDTs as a major tool used for malaria diagnosis, maintaining their quality and ensuring end-user competence remain major challenges [18]. External Quality Assessment (EQA) programmes are the gold standard for monitoring and improving diagnostic performance. However, many resource-limited countries, including Zambia, have struggled to establish them due to a lack of local expertise and resources [19, 20].

This paper argues that developing a national mRDT proficiency testing programme in Zambia, in partnership with Uganda, through a peer-to-peer learning approach, demonstrates the application of the New Public Health Order principles. The program was implemented under the Strengthening Laboratory Capacity through Twinning, Learning and Exchange for Accelerated Results project, with support from the Global Fund, with the East, Central and Southern Health Community (ECSA-HC) serving as a regional facilitator and coordinator of the peer-learning program. The project demonstrated that countries can leverage South-South cooperation as an economically viable and sustainable way to build essential diagnostic capacity that supports both disease-specific control measures and the broader global health security framework. This initiative extends beyond enhancing malaria diagnosis; it aims to develop resilient, self-reliant health systems that are strong enough to meet the challenges of the 21st century.

Methods

Programme design and peer-to-peer learning framework

The Zambian mRDT EQA programme was established through a structured peer-to-peer learning initiative. A technical team from the Zambian National Malaria Elimination Centre and the Churches Health Association of Zambia conducted a benchmarking visit to the Ugandan National Reference Laboratory. This hands-on experience covered key operational components of the EQA programme implementation, including aspects such as (i) programme design and preparation of proficiency testing panels with dried tube specimens (DTS), a stable and cost-effective method suitable for low-resource settings [21]; (ii) sample validation, packaging, and distribution; (iii) managing data systems; and (iv) Developing feedback and reporting protocols. This practical exchange of knowledge and operational tools provided an opportunity for contextual adaptation to the Zambian context, demonstrating the effectiveness and benefits of utilizing South-South cooperation. [21].

Study design and analytical approach

This was a descriptive implementation study that evaluated the performance and operationalisation of Zambia's first malaria rapid diagnostic test proficiency testing program across two implementation cycles in 2025 (Cycle 1 and Cycle 2). The primary unit of analysis was the participating testing site, with additional stratified analyses conducted by tester cadre.

Participant enrolment and representation strategy

In this study, participants were enrolled using a purposive phased implementation approach by provincial and district health authorities. In Zambia, malaria rapid diagnostic testing is decentralised and performed at point of care testing outside conventional laboratory testing. Enrolment was therefore designed around routine testers rather than laboratory infrastructure alone. The aim of this selection strategy was to ensure national representation across all ten provinces with diverse testing content, including community, primary healthcare, hospital-based services and the private sector. Priority was given to sites that routinely performed malaria RDT testing as part of existing malaria surveillance and supervisory systems.

Table 1
Showing participant enrolment criteria and Site Selection

Domain	Enrolment approach/criteria
Geographic representation	All 10 provinces were included to ensure equitable national representation of malaria quality assurance activities.
Enrolment model	A tester-based enrolment approach reflecting routine malaria RDT practice at point-of-care testing sites.
Site selection approach	High malaria-burden testing sites, including outpatient departments (OPDs) at rural health centres (RHCs), health facilities, and community testing sites.
Eligible participants	Health workers who routinely perform malaria RDT testing, including community health workers, nurses, laboratory personnel, and other trained healthcare staff.
Programme linkage requirement	Participating sites were required to be linked to a health facility or district health office for supervision and reporting.
Diagnostic platforms	Sites using HRP2 and/or pLDH malaria RDT kits were eligible for enrolment.

Participant enrolment was geographically distributed equally across all ten provinces and aligned with the distribution of malaria burden, ensuring representation of both high- and low-transmission settings, as well as decentralised testing environments. The pilot cohort, comprising 10 sites from each of the 10 provinces in Zambia, was geographically distributed and represented diverse service-delivery contexts, including community health worker testing points, public health facilities, hospitals, and private facilities operating within diverse geographic and service-delivery contexts, including urban, peri-urban, rural, remote, and hard-to-reach settings. These 100 sites also served as the foundation for subsequent programme expansion (25 from each province) and acted as supervisory hubs for community-based malaria testing activities. Each facility oversaw community health workers (CHWs) who conducted malaria RDTs at the community level under routine programme supervision. The pilot cohort represented not only facility-based testing but also an entry point for decentralised malaria diagnosis. The program expanded and evolved from a facility- focused pilot into a nationally representative network encompassing both centralised and decentralised malaria testing platforms. Figure 1 illustrates the national distribution of these sites, demonstrating deliberate geographic representation across the country compared with the national malaria disease burden

Representation of decentralised testing within the participant cohort

Following the pilot phase, the programme was scaled to include an additional 150 testing sites, bringing the total number of enrolled sites to 250. The program expansion incorporated community health workers, hospitals, private facilities and other testing sites such as pharmacies and point of care testing at health facilities broadening the coverage across both facility-based and community- level malaria diagnostic services. Despite the fact that community health workers were included in the program, they

operated with autonomy at the community level, while remaining programmatically linked to supervising health facilities. Their inclusion is in line with routine malaria diagnostic practice in Zambia, where mRDTs are mainly performed by non- laboratory staff outside laboratory settings. By integrating community health workers into the broader participant cohort rather than analysing them as a separate programme, the PT scheme captured the malaria diagnostic performance across the full continuum of care. This approach ensured that the participant population reflected real-world testing conditions and service delivery models. Enrolled sites were further grouped by institution type and typical testing cadre to describe the composition of the participant cohort and the range of testing platforms included in the programme.

Table 2
Representation of enrolled sites by institution type.

Type of institution	Number of sites	Proportion of total (%)
Community-based testing sites	100	40.0
PH facilities (health centres/posts, clinics)	100	40.0
Private facilities	29	11.6
Hospitals	21	8.4
Total	250	100

As shown in Table 2, the participant cohort comprised a balanced mix of decentralised and facility-based testing platforms, with community health worker sites and public health facilities together accounting for the majority of enrolled sites.

Community Health worker sites are designated and decentralised testing points where malaria rapid diagnostic tests are conducted at the community level under the routine supervision of affiliated health facilities. On the other hand, public health facilities which comprise health posts and health centres, serve as the primary facility-based malaria diagnostic centres within the public centres. while public health facilities, comprising health centres and health posts, serve as the primary facility-based malaria diagnostic platforms within the public sector. In this study, private facilities accounted for 11.6% of participating sites, ensuring representation of malaria diagnostic services delivered outside the public sector and capturing testing activity within the mixed health system context. Hospitals, accounting for 8.4% of sites, are higher-level care settings where mRDTs are routinely used alongside other diagnostic modalities. The testing cadres varied by institutional level, ranging from community health workers at decentralised sites to nurses, clinical officers, laboratory technicians, and biomedical scientists in facility-based settings. This distribution reflects routine malaria diagnostic practice in Zambia and confirms that the PT programme spanned multiple levels of the health system. The range of participant types provided a comprehensive foundation for subsequent analyses of participation, data completeness, and diagnostic performance across testing contexts.

Stakeholder engagement: a foundational strategy for programme success

The successful implementation of the Zambia mRDT EQA scheme depended on a strong stakeholder engagement strategy developed following a technical benchmarking visit to Uganda. This approach aligns well with established best practices that emphasise the need for early and continuous involvement of all key stakeholders for the success of public health initiatives, especially in quality assurance programmes [22, 23]. The stakeholder engagement process was designed to foster buy-in and national ownership, ensure institutional alignment, and create a robust collaborative framework for the programme's long-term sustainability.

The Ministry of Health held a national stakeholder sensitisation meeting from November 14–15, 2024, marking the official introduction of the mRDT EQA scheme to a diverse group of over 50 participants. Participants included health directors and senior leaders from the provincial and district health offices, key implementing partners, clinical and laboratory staff at facilities, and other critical players in malaria diagnosis and quality assurance. This inclusive approach was intentionally chosen to ensure that the proficiency testing programme was not only technically sound but also well integrated into the country's existing health infrastructure, a key principle for managing health systems in resource-limited settings such as Zambia [24]. The stakeholder engagement also presented an opportunity to clearly define the roles and responsibilities of each stakeholder group. This process was participatory and covered the entire EQA workflow, from sample collection and transportation logistics to data management, test-event coordination, and prompt submission of results. The team also focused on aligning the mRDT PT scheme with existing national malaria control and laboratory policies. The alignment was key to ensuring the programme's technical feasibility and its smooth integration into the national health policy framework, thus preventing the creation of parallel or redundant systems [25]. The meeting also served as a key platform for building consensus and securing institutional commitment, and provided participants with an opportunity to provide valuable input on the feasibility of the proposed implementation tools and frameworks. This collaborative approach, a hallmark of effective stakeholder engagement, helped refine the operational plan and ensured it was practical and appropriate to the context [26]. The stakeholder meeting was also essential in guiding the selection and enrolment of participating sites. By engaging participants in detailed discussions, the programme leveraged their regional insights and local knowledge to develop a more strategic and representative site identification and sampling plan. This participatory approach to programme design has been shown to enhance the relevance and effectiveness of quality improvement initiatives [27]. By grounding the mRDT EQA initiative in early stakeholder engagement and collaborative learning from a successful regional model, Zambia has built strong national ownership and widespread support for the programme. This approach used in this project has been proven to be a key factor in the successful deployment and ongoing success of the national mRDT EQA scheme, demonstrating the significant impact of a well-implemented, participatory approach to public health programme execution.

Data collection and analysis

Data was gathered using both digital and paper forms and entered into a central Excel database for analysis. Performance was scored by comparing reported results to the known status of the PT samples. Data quality was ensured through the implementation of ISO 17043-aligned Standard Operating Procedures (SOPs) and quality control procedures. PT results submitted were checked for completeness and consistency before analysis. Descriptive statistical analysis was performed using Microsoft Excel. The acceptable performance threshold was set at 80%, consistent with performance classification approaches commonly used in malaria diagnostic quality assurance and proficiency testing programmes [38]. In addition to diagnostic accuracy data on result turnaround time (TAT), data on the frequency and types of documentation errors were collected to identify operational bottlenecks and areas for quality improvement, reflecting a comprehensive approach to implementation research [28].

Results were gathered using both digital and paper forms and entered into a central Excel database for analysis. Performance was scored by comparing reported results to the known status of the PT samples. Data quality was ensured through the implementation of ISO 17043-aligned Standard Operating Procedures (SOPs) and quality control procedures. Submitted results were verified for completeness and consistency before analysis. Descriptive statistical analysis was performed using Microsoft Excel. The acceptable performance threshold was set at 80%, consistent with performance classification approaches commonly used in malaria diagnostic quality assurance and proficiency testing programmes [38]. In addition to diagnostic accuracy, data on result turnaround time (TAT) and the frequency and types of documentation errors were collected to identify operational bottlenecks and areas for quality improvement, reflecting a comprehensive approach to implementation research [28].

Results

Replicable model for sustainable capacity building

Zambia's in-country mRDT PT scheme produced tremendous measurable capacity-transfer outputs consistent with a structured South–South peer-learning model. During the regional benchmarking mission to Uganda (August–September 2024), the Zambian implementation team was able to directly observe an operational malaria PT provider model, including panel production workflows, quality documentation systems, and approaches to stakeholder and participant engagement. This peer- peer exchange guided the contextual adaptation of Zambia's implementation roadmap within the country's existing laboratory and malaria programme structures. Rather than directly replicating Uganda's model, the benchmarking process enabled the adaptation of key operational approaches to align with Zambia's existing laboratory governance, malaria control, and supervisory systems. The capacity transfer process further evolved from observational learning during benchmarking to independent national implementation and local PT panel production.

The country developed a comprehensive quality management framework, including two policy manuals, ten management system documents, five technical procedures, and forty-four standardised forms aligned with the requirements of ISO 17043. Concurrently, twelve national trainers were capacitated through a Training of Trainers model, followed by training for over 50 programme coordinators, provincial and district staff, and testers during the national roll-out. The country demonstrated operational maturity and capacity by producing – 445 PT panels across two cycles (125 in Cycle 1 and 320 in Cycle 2), demonstrating a rapid transition from pilot implementation to scalable routine production. The marked expansion between cycles suggests successful assimilation of technical workflows and progressive stabilisation of in-country PT operations. The Training of Trainers that was conducted created a multiplier effect by embedding technical expertise within national and provincial structures, strengthening institutional capacity beyond individual-level competency development. Similar laboratory strengthening initiatives have demonstrated that Training of Trainers models improve decentralised technical capacity and support long-term programme sustainability by retaining institutional knowledge [49, 50]. This approach has proven effective and reduces sustainability risks commonly associated with consultant-led or externally managed EQA schemes, where technical operations may remain dependent on external expertise [21, 22].

These outputs are illustrated in Fig. 2.

The findings of this study are consistent with broader laboratory- strengthening experiences in Africa, which have demonstrated that regional mentorship, peer-learning, and locally adapted implementation approaches have been associated with improved programme ownership, sustainability, and operational resilience [21–24]. Studies have revealed that South–South technical cooperation can facilitate capacity transfer through leveraging shared operational realities, existing regional expertise, and contextual problem-solving approaches [5, 6, 21]. The Zambian PT program extended beyond individual staff training to the establishment of robust functional systems for PT production, quality management, supervision, and continuous performance monitoring, strengthening institutional capacity - rather than solely individual capacity. This systems-oriented approach aligns with recommendations from the Africa CDC New Public Health Order framework, which encourages member states to develop resilient, self-reliant national public health institutions and sustainable diagnostic systems [6, 7]. The peer-to-peer learning model presented in this study provides a practical framework for other resource-limited settings seeking to establish sustainable diagnostic quality assurance systems while reducing dependency on externally driven technical assistance. The experience highlights the role of Africa’s regional coordinating institutions, such as ECSA-HC in facilitating South–South cooperation through technical coordination, mentorship linkages, and the translation of regional best practices into country-level implementation. The findings demonstrate how regionally coordinated peer-learning models can support the development of resilient, self-reliant laboratory systems consistent with the principles of the Africa CDC New Public Health Order [6, 7].

PT performance trends and scores

The Zambia malaria RDT proficiency testing scheme demonstrated high participation and sustained diagnostic performance across two implementation cycles. In the first cycle (Cycle 1), 100 facilities were enrolled, of which 98 (98%) participated. From the participating facilities, 96 (98%) achieved satisfactory performance ($\geq 80\%$), while 2 (2%) were graded unsatisfactory. In Cycle 2, enrolment increased substantially to 250 facilities, reflecting programme scale-up. Of these, 235 (94%) participated, and 229 (97.4% of participants; 94.9% of enrolled) achieved satisfactory scores, while 6 facilities (2.6% of participants; 5.1% of enrolled) were unsatisfactory. Despite the marked increase in the number of participating facilities, satisfactory performance remained consistently high, exceeding 94% across both cycles (Fig. 3). Over 90% of participating sites across both cycles were able to identify all DTS samples correctly within their PT panels, demonstrating a strong diagnostic accuracy and consistency across the expanded testing network.

The maintenance of high pass rates during expansion is particularly noteworthy. In most settings the rapid scale-up of EQA programmes in decentralised diagnostic settings has frequently been associated with declines in performance due to variability in staff competency, infrastructure capacity, and supervisory support [29]. However, performance observed in this programme was stable, suggesting that early investments in training that is well structured coupled with standardised documentation, and peer mentorship mitigate quality erosion during expansion. The high and consistent pass rates observed during programme growth further indicate that the South–South peer-learning approach supported not only technical capacity transfer but also operational resilience during scale-up. A number of regional laboratory strengthening initiatives have also shown that peer-to-peer mentorship, locally adapted implementation models, supported with continuous supportive supervision, contribute to sustained diagnostic performance and stronger institutional ownership [21, 22, 39, 40]. From a systems perspective, sustained participation above 90% across both cycles reflects strong stakeholder engagement and integration of PT into routine facility practice.

Diagnostic Quality as a pillar of health security and pandemic preparedness: diagnostic error rate monitoring as a PT performance indicator

Error rate analysis was conducted as an additional indicator of diagnostic accuracy across both PT cycles. The error rate was calculated using the formula:

$$\text{Overall Error Rate (\%)} = [(FP + FN) / N] \times 100$$

FP represents false positives, FN false negatives, and N the total number of panels tested. False positive and false negative proportions were similarly calculated using the 2×2 contingency table relative to the total panels tested, with the total number of panels tested as the denominator.

In Cycle 1, the false positive rate was 0.81%, the false negative rate was 0.20%, and the overall error rate was 1.01%. In Cycle 2, the false positive rate increased to 1.20%, the false negative rate increased to 0.40%, and the overall error rate increased to 1.61% (Fig. 4).

Figure 4. Trend in false positive, false negative, and overall error rates across PT cycles.

In addition to routine diagnostic performance monitoring, the consistently low error rates observed across implementation cycles have broader implications for health-system resilience and pandemic preparedness. A robust laboratory network that is capable of maintaining consistent malaria diagnostic performance across decentralised settings provides an operational foundation that can be leveraged during outbreaks and other public health emergencies. The systems, quality management structures, supply chains, and human resource capacity strengthened through the malaria PT programme contribute to broader national laboratory preparedness and align with the objectives of the Global Health Security Agenda (GHSa) and the WHO Pandemic Preparedness and Response (PPR) framework, both of which emphasise the importance of resilient national diagnostic systems [23, 30].

Cadre-specific diagnostic error rates as a PT performance indicator

To further characterise the observed error patterns, failures in Cycle 2 were disaggregated by tester type. Among 235 testers (1,175 total tests), community-based testers conducted 460 tests and recorded 13 errors (2.83%), while facility-based testers conducted 715 tests and recorded 7 errors (0.98%). All errors recorded among community-based testers were procedural and interpretation-related errors, with no evidence of complete test non-performance or panel rejection. The vertical line indicates the 3% reference threshold commonly used to assess acceptable malaria RDT performance under operational conditions (Fig. 5).

The error rate among community-level testers was higher than that observed at the facility level, but both remained below the 3% threshold commonly associated with acceptable operational performance for malaria RDTs, which demonstrate $\geq 97\%$ sensitivity and specificity in WHO product evaluations and field assessments. There are similar differential patterns between community- and facility-based testing cadres that have been reported in decentralised malaria diagnostic programmes, where variations in supervision frequency, testing exposure, environmental conditions, and adherence to testing procedures affect consistency of RDT interpretation [34, 35]. Some studies that conducted among community health workers in Zambia reported similar findings that most of the testing errors were related to deviations in procedures and result interpretation rather than complete test failure, with supportive supervision and refresher training identified as important interventions for improving testing consistency [35]. Similar findings were also reported by Harvey et al., who demonstrated that repeated mentorship, structured quality improvement interventions, and integrated supportive supervision significantly improved malaria diagnostic performance among peripheral and community-based testers across multiple African settings [40]. In this study, the fact that all the errors that were recorded among community-based testers were procedural and interpretation-related further suggests that competency gaps were largely correctable through continuous quality improvement mechanisms rather than fundamental testing incapacity. These findings therefore demonstrate the value of disaggregated error-rate analysis in strengthening PT surveillance and identifying cadre-specific performance trends that may require targeted supportive supervision, refresher training, or corrective interventions. Furthermore, the low absolute magnitude of error across both cadres indicates that diagnostic reliability was maintained

within the expanded PT network. The Integration of routine error surveillance within the PT framework further supports the rapid identification of performance gaps and continuous quality improvement within decentralised malaria diagnostic systems.

Turnaround time as an operational performance indicator

The Turnaround time (TAT) was closely monitored as a routine operational performance indicator across the two implementation cycles. Using only complete date records, the overall median shipping TAT was 13 days (interquartile range [IQR]: 7–20), while the median response TAT was 5 days (IQR: 1–8).

Distribution analysis demonstrated greater variability in shipping times than in response times, indicating that panel distribution contributed more substantially to overall delay than facility-level testing once panels were received (Fig. 6).

The relatively short median response TAT suggests that the participating sites were able to complete testing and reporting promptly as soon as they received the PT panels which demonstrated that the program had been effectively integrated within their routine diagnostic workflows. On the other - hand, the wider dispersion observed in the shipping TAT reveals the influence of logistical infrastructure, a commonly reported bottleneck in most of the decentralised EQA programmes in sub-Saharan Africa [29]. Similar malaria EQA initiatives have identified transportation and distribution systems as primary contributors to programmatic delay, particularly during early scale-up phases [36]. Within the context of this study, TAT monitoring does not serve as a comparative performance metric between cycles but rather as evidence of operationalisation. The ability to track distribution and reporting timelines systematically demonstrates that quality monitoring mechanisms have been institutionalised and that is a core component of sustainable proficiency testing systems [37]. These findings further demonstrate that the peer-to-peer South–South model facilitated not only the development of technical panel production capacity but also the integration of performance monitoring into routine programme governance structures.

Quality control performance of PT panels

Across both implementation cycles, 445 (PT) panels were produced (125 in Cycle 1 and 320 in Cycle 2). Quality control (QC) processes were incorporated at multiple stages of panel production, including specimen screening, malaria parasite characterisation, pooled sample validation, homogeneity testing, and stability assessments prior to distribution. Quality-controlled dedicated panels were reserved for homogeneity and stability verification in accordance with ISO 17043-aligned procedures. The QC results demonstrated 100% homogeneity and 100% stability across both cycles, with no variation detected between validation samples and no degradation observed over the entire testing and distribution period. There were no discrepancies in panel integrity identified during the evaluation of results. Facility performance remained high (Cycle 1: 96/98 satisfactory; Cycle 2: 229/235 satisfactory), indicating that participant outcomes reflected testing competency rather than material inconsistency. The findings of this study provide empirical validation of the PT methodology, especially the use of dried tube specimens (DTS) as the panel matrix. DTS are supposed to be stable, easy to transport and independent

of cold-chain requirements, and this makes them more suitable for decentralised EQA in resource-limited settings like Zambia. Published field evaluations have similarly shown the robustness and usability of DTS for malaria RDT quality assurance programmes [38]. Stability-testing studies conducted in Liberia and Benin, and results of these studies confirmed that well-prepared dried *Plasmodium falciparum* specimens can maintain stability and reproducibility under operational conditions [39]. The general wider EQA guidance also emphasises the necessity of validated and stable PT materials to ensure that participant performance accurately reflects diagnostic competence [19]. The combination of complete panel stability and consistently high participant pass rates gives confidence in both the technical reliability of the DTS-based PT system and the integrity of the performance assessment. The QC outcomes of this study therefore demonstrate that the South–South mentorship model successfully transferred not only production capacity but also rigorous quality-assurance practices, reinforcing the credibility and sustainability of the in-country PT scheme.

System strengthening outcomes

Beyond improvements in participation, proficiency scores, and diagnostic accuracy, the implementation of the in-country malaria RDT proficiency testing scheme has led to structural changes within the laboratory and surveillance ecosystem. The malaria RDT quality system strengthening was evaluated through evidence of institutionalisation, integration into routine governance structures, and the development of sustainable technical capacity. Unlike short-term training outcomes, these results reflect embedded functions that persist beyond individual PT cycles and reduce dependence on external technical assistance.

Institutionalisation of quality management systems

The Implementation of the mRDT PT scheme led to the formal establishment of a Quality Management System infrastructure for malaria quality assurance programmes, including the development of management and technical system documents aligned with ISO 17043 principles. The policy and technical documents operationalised effective document control, robust corrective action processes, effective non-conformance reporting, and strengthened internal quality control (IQC) tracking within the PT framework. The presence of standardised documentation enabled traceability of panel production, distribution, scoring, and follow-up on corrective actions. In addition to document production, these materials were adopted and integrated into the routine workflow, forming the basis for structured review meetings and audit-readiness processes. Institutionalisation of documented QMS structures is widely recognised as a prerequisite for durable laboratory strengthening and accreditation preparedness. By embedding these standardised management procedures within national systems, the PT programme transitioned from an externally supported implementation project to a locally governed quality infrastructure. This represents a measurable system-level outcome rather than a temporary project output that can be adopted by other countries that have no functional MRDT PT programs.

Integration of PT into routine surveillance and continuous quality improvement Mechanisms

The PT scheme was successfully incorporated into routine MOH supervisory and surveillance processes through structured monitoring of TATs, cadre-disaggregated error rates and documentation of formal corrective actions. The PT findings were integrated into provincial and district-level review meetings and informed targeted supportive supervision (TSS) visits and refresher training activities. The Error surveillance system was not limited to mere pass/fail grading but also included stratified analysis of false-positive and false-negative rates, enabling identification of cadre-specific variability.

Of the 235 participating sites in Cycle 2, misclassifications (1.60%) were identified, and after disintegrating the data, distinct error patterns between community and facility-based testers were revealed. This kind of integration of PT outputs into supervisory workflows aligns with evidence that embedding laboratory quality indicators within routine surveillance systems enhances the uptake of corrective actions and strengthens governance oversight. The shift from episodic PT participation to continuous performance monitoring reflects the maturation of quality oversight functions within the malaria diagnostic system.

Progressive monitoring of participation rates, proficiency performance, turnaround times, and diagnostic error patterns across implementation cycles enabled the PT programme to function as a continuous quality improvement (CQI) mechanism rather than solely as an external assessment exercise. The Trend analysis that was used facilitated identification of operational bottlenecks, recurrent testing errors, and cadre-specific performance gaps that required targeted intervention. The findings from subsequent PT reviews informed corrective actions, supportive supervision, refresher training, redistribution of reporting tools, and reinforced standard testing procedures at underperforming sites. Familiar approaches have been reported in malaria quality assurance programmes in neighbouring countries like Tanzania, where routine EQA findings were used to guide supervision, retraining, and targeted quality improvement interventions contributing to improved diagnostic performance over time [43]. Proficiency testing, supportive supervision, and corrective action systems as core components of continuous quality improvement frameworks for diagnostic services that are recognised by the World Health Organisation [44] and countries should ensure that they integrate these in the laboratory networks. The integration of longitudinal performance monitoring into routine programme oversight strengthened accountability and provided an opportunity for data-driven refinement of the implementation processes during programme scale-up. This programme findings demonstrate the value of PT systems not only for assessing diagnostic competency but also for supporting quality improvement within decentralised malaria diagnostic networks.

Development of in-country PT production and quality control capacity

A total of 445 DTS-based PT panels were produced locally across two cycles (125 in Cycle 1; 320 in Cycle 2), with embedded quality-control procedures including specimen screening, parasite characterisation, homogeneity testing, and stability verification. Internal QC recorded 100% homogeneity and stability across validation and distribution phases, ensuring material integrity throughout both cycles. The program was able to produce its own in-country DTS and this reduced dependence on external suppliers and shortened distribution timelines. The DTS in-country production also enabled iterative refinement of panel composition based on observed error patterns. Local production of DTS is a critical milestone towards technical self-reliance and sustainable EQA expansion in resource-limited settings and by coupling panel production with ISO-aligned QC processes, the programme demonstrated operational autonomy and technical competence consistent with advancing laboratory system maturity.

Operational challenges, lessons learned and best practices for programme scale-up

Implementation of the national mRDT PT programme revealed several operational challenges commonly encountered during pilot and scale-up of decentralised quality assurance systems. Variability in shipping turnaround times highlighted logistical challenges associated with transportation to remote and hard-to-reach districts, a commonly reported constraint in decentralised EQA programmes in sub-Saharan Africa [40, 41]. However, integration of PT distribution within existing national and district-level sample referral and transport systems substantially improved programme feasibility. The availability of established courier and sample transport networks reduced logistical burden and supported timely panel distribution across decentralised testing sites.

The Programme expansion also exposed limitations associated with manual PT panel production processes. Although local production of DTS panels proved feasible and effective during early implementation, increasing enrolment volumes substantially increased demands on specimen preparation, aliquoting, drying, packaging, documentation, and distribution workflows. Similar scalability challenges have been described in DTS-based PT programmes implemented in other resource-limited settings [45, 46]. To mitigate these constraints, the programme adopted phased expansion and standardised production workflows aligned with ISO 17043 quality management principles. Technical procedures, standardised forms, and dedicated quality control processes were developed and these improved production consistency and traceability. However, long-term national expansion may require investment in semi-automated production systems and strengthened logistics infrastructure to support larger-scale PT operations efficiently and sustainably.

Sustainable financing remains an important consideration for the long-term continuity of national PT programmes. Similar EQA initiatives in resource-limited settings have identified recurrent operational costs, transportation, training, supervision, and technical support requirements as major barriers to programme sustainability [47]. In the present programme, implementation through a South–South peer-learning framework provided a cost-effective alternative to conventional externally led technical assistance by leveraging regional expertise, existing infrastructure, and practical operational experience.

Integration of PT activities within existing malaria surveillance, laboratory quality assurance, and supervisory systems further reduced implementation costs and minimised resource duplication. The use of locally produced DTS panels also reduced dependence on external PT providers and international shipment costs.

Implementation experience additionally highlighted the importance of establishing a structured long-term sustainability and financing strategy early during programme development. Although the initial implementation was supported through Global Fund financing under the STELLAR Project framework, long-term operationalisation of national PT programmes requires sustainable domestic planning mechanisms to support recurring production, distribution, supervision, quality control, and training costs. The development of a SMART business and sustainability plan during early implementation phases may therefore help guide resource mobilisation, operational forecasting, integration into national budgets, and long-term programme continuity. Similar recommendations have been emphasised in laboratory strengthening and quality assurance programmes aimed at reducing dependency on short-term external funding [48, 49]. These findings reinforce the importance of integrating PT activities within existing national health systems and regional networks to strengthen sustainability and country ownership of diagnostic quality assurance programmes.

Collectively, these experiences demonstrate that successful implementation of decentralised national PT programmes requires more than technical panel production capacity alone. The best practices that were identified through this programme include phased implementation, early stakeholder engagement, integration into existing supervisory and sample referral systems, continuous performance monitoring through CQI frameworks, and adoption of a cost-effective South–South peer-learning model. These findings highlight the importance of embedding sustainability planning, operational adaptability, and country ownership mechanisms from programme inception to support long-term continuity and scalable expansion of national diagnostic quality assurance systems. Future programme priorities include expansion of participant coverage, progressive automation of PT production workflows, strengthening of digital reporting systems, and integration of the PT framework into additional disease programmes and decentralised diagnostic platforms.

Discussion

The programme successfully established Zambia's first national malaria RDT PT scheme, strengthening in-country PT production capacity. It further developed an ISO 17043-aligned quality management framework, trained national and sub-national personnel, and maintained high diagnostic performance during expansion from 100 to 250 testing sites. These outcomes collectively demonstrate not only successful technical capacity transfer but also the establishment of functional systems for quality assurance, performance monitoring, and continuous quality improvement within the national malaria diagnostic network.

The New Public Health Order for Africa calls for a transition from dependency on external technical assistance towards greater regional self-reliance and country-led capacity development [40]. The findings from this study demonstrate how a structured South–South peer-learning model can operationalise these principles within national laboratory systems. Through collaboration with Uganda’s National Reference Laboratory, Zambia adapted an established malaria PT framework to its local context, accelerating programme implementation while strengthening national ownership and technical capacity [5]. The Zambia–Uganda partnership represents one of several peer-learning initiatives for regional laboratory strengthening programmes, where countries have exchanged expertise in laboratory quality management systems, laboratory information systems, proficiency testing, equipment maintenance, and broader laboratory system strengthening. These experiences illustrate the value of regional platforms in facilitating transfer of proven practices between countries facing similar operational realities and public health challenges. The benchmarking process played a critical role in informing programme design, including panel production, quality management systems, stakeholder engagement, and data management processes. The study findings demonstrate that South–South collaboration can serve as a practical mechanism for building sustainable diagnostic capacity while advancing the objectives of the New Public Health Order.

This paper presents a case study of the first two PT cycles and, as such, has limitations. The data represent only two single time points and do not yet show trends in performance over time. The study was not designed as a controlled trial, so the impact of the peer-to-peer learning model cannot be quantitatively separated from other contributing factors. However, as a descriptive analysis of a real-world implementation, it offers valuable, actionable insights for other national programmes.

Achieving SDG 3.3 – ending the epidemics of AIDS, tuberculosis, and malaria – is impossible without reliable diagnostics. Misdiagnosis of malaria leads to improper treatment, contributes to the development of drug resistance, and wastes valuable resources. By establishing a mechanism for continuous quality improvement, this programme directly improves the accuracy of malaria diagnosis, which in turn supports more effective case management and surveillance. This is a crucial step toward reaching the ambitious malaria elimination targets set by the WHO. Furthermore, by enhancing the quality of services at the primary healthcare level, this programme advances the broader goal of Universal Health Coverage (UHC), which depends on access to quality essential health services for all [42]. The launch of Zambia’s first national mRDT proficiency testing programme was successful. The success of the programme was more than just a programmatic milestone. It clearly demonstrates how investments in diagnostic quality can create ripple effects that strengthen health system resilience and enhance global health security.

Conclusions

The establishment of a national mRDT EQA programme in Zambia is a significant achievement with implications that go well beyond malaria control. It is a strong demonstration of the effectiveness of peer-to-peer learning and South-South cooperation as strategic approaches for building resilient, self-

reliant health systems needed in the post-COVID era. This initiative provides a practical, clear and replicable blueprint on how countries can implement the principles of the New Public Health Order, enhance their roles in global health security, and accelerate progress toward the Sustainable Development Goals. The Zambia experience is more than just a successful national programme; it is a global public health asset, offering a straightforward and cost-effective pathway for expansion to other disease programmes, integration into national health budgets, and replication in other ECSA-HC member states and beyond.

Abbreviations

Africa CDC: Africa Centres for Disease Control and Prevention

CHW: Community health worker

CHAZ: Churches Health Association of Zambia

COVID-19: Coronavirus Disease 2019

CQI: Continuous quality improvement

DTS: Dried tube specimen

ECSA-HC: East, Central and Southern Africa Health Community

EQA: External Quality Assessment

GFATM: Global Fund to Fight AIDS, Tuberculosis and Malaria

GHSA: Global Health Security Agenda

HMIS: Health Management Information System

HRP2: Histidine-rich protein 2

IHR: International Health Regulations

IQC: Internal quality control

IQR: Interquartile range

ISO: International Organization for Standardization

MOH: Ministry of Health

mRDT: Malaria rapid diagnostic test

OPD: Outpatient department

pLDH: Plasmodium lactate dehydrogenase

PPR: Pandemic Preparedness and Response

PT: Proficiency testing

QC: Quality control

QMS: Quality management system

RDT: Rapid diagnostic test

RHC: Rural health centre

SDG: Sustainable Development Goal

SOP: Standard operating procedure

STELLAR: Strengthening Laboratory Capacity through Twinning, Learning and Exchange for Accelerated Results

TAT: Turnaround time

TSS: Targeted supportive supervision

UHC: Universal Health Coverage

WHO: World Health Organisation

Declarations

Ethics approval and consent to participate

Not applicable. This descriptive implementation study utilised aggregated programmatic data from the National Malaria Programme and did not involve human participants, patient-level data, or identifiable personal information. Consequently, informed consent was not required, and formal ethical approval was not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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N/A

Authors' contributions

DMS and CK conceived and designed the study. DMS, CK, MH, MM, JC, AM, and MC contributed to programme implementation, data acquisition, validation activities, and interpretation of findings. CK and MC conducted the statistical analysis. DMS and CK drafted the manuscript. JC, AM, MC, PA, and LN provided technical input and contributed to programme implementation and data interpretation. MH, MM, AM, MK, PA, AS, LN, NS, FJ, and SN critically reviewed the manuscript and provided important intellectual and technical contributions. All authors read and approved the final manuscript.

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Figures

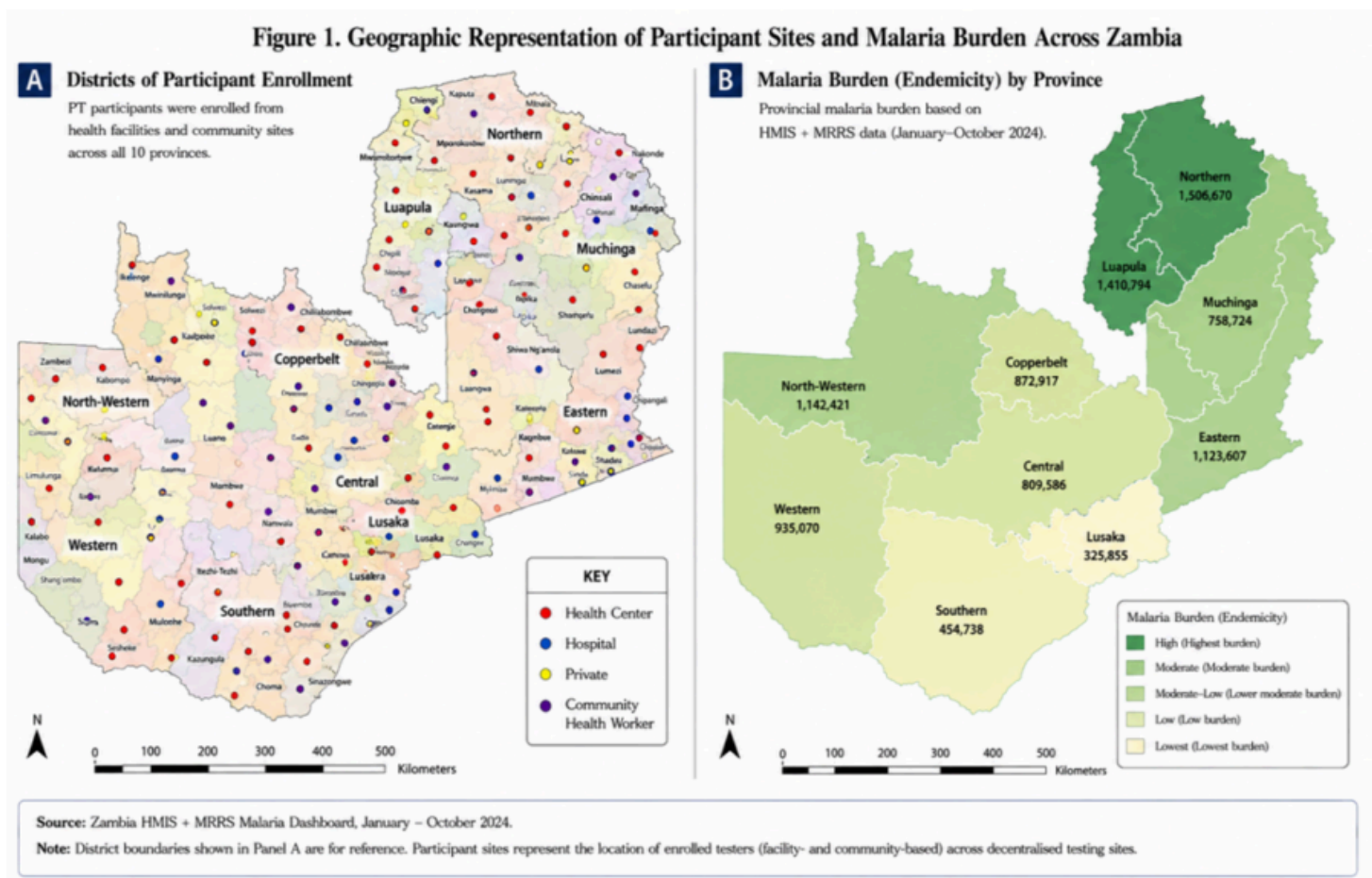


Figure 1

(a & b). Geographic distribution of enrolled participant sites and malaria burden representation across Zambia. Figure 1(a) illustrates the distribution of enrolled proficiency testing participant sites across the districts included in the programme. Figure 1(b) illustrates provincial malaria burden categories derived from national malaria surveillance data, demonstrating representation of both high- and low-transmission settings within the participant cohort.

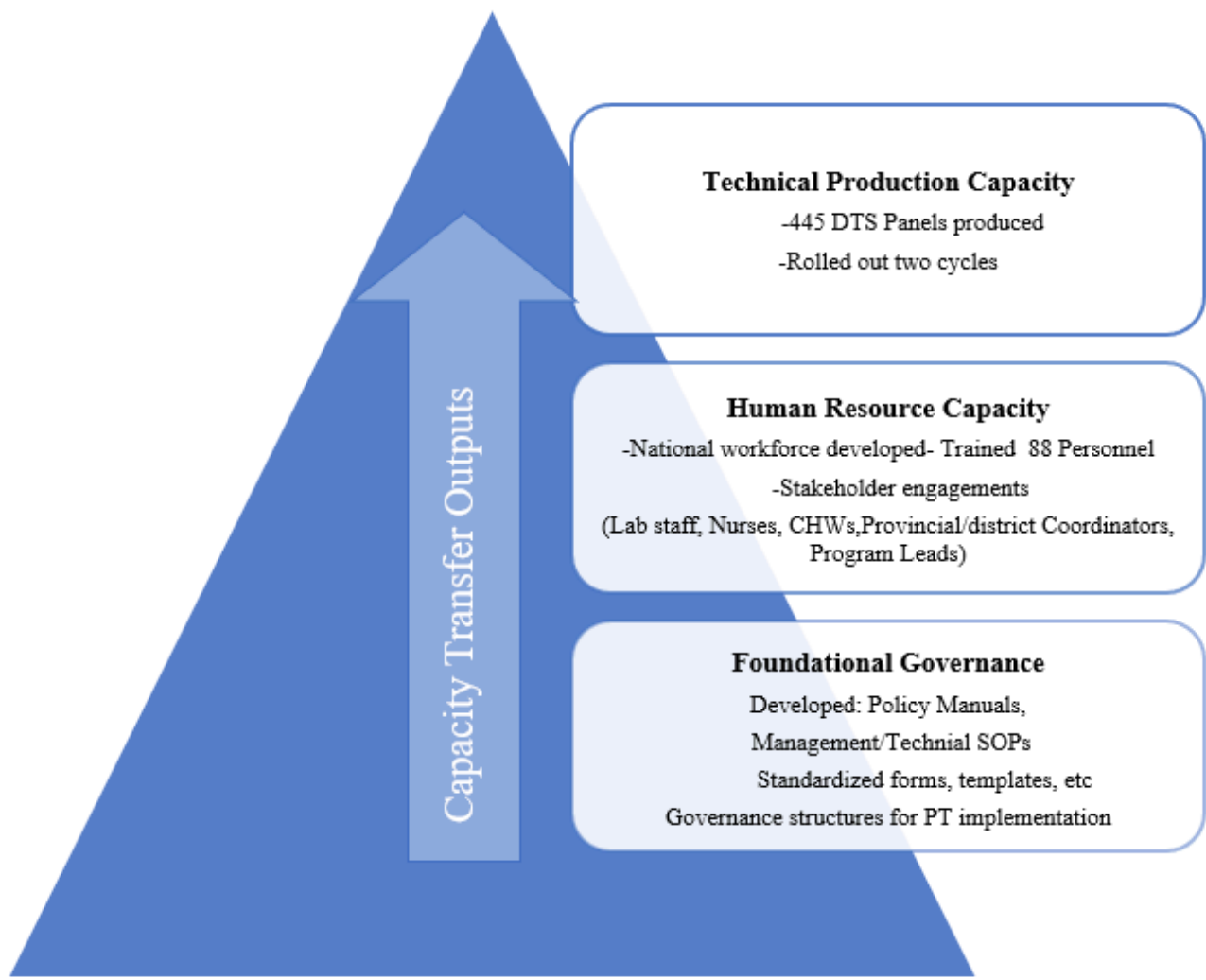


Figure 2

Multi-level capacity transfer outputs achieved through the implementation of in-country malaria RDT proficiency testing.

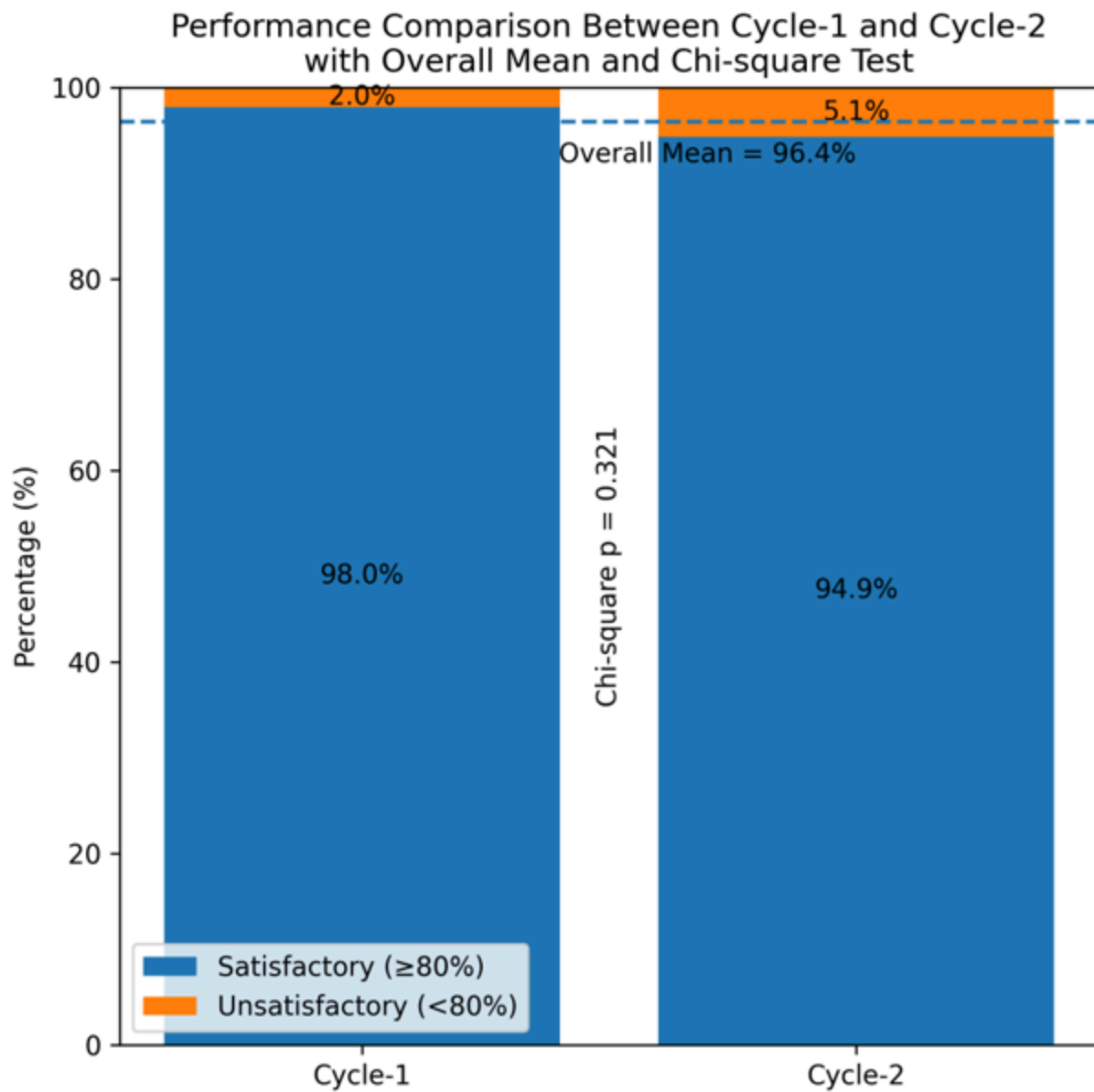


Figure 3

Performance comparison between Cycle 1 and Cycle 2, showing satisfactory pass rates in both cycles.

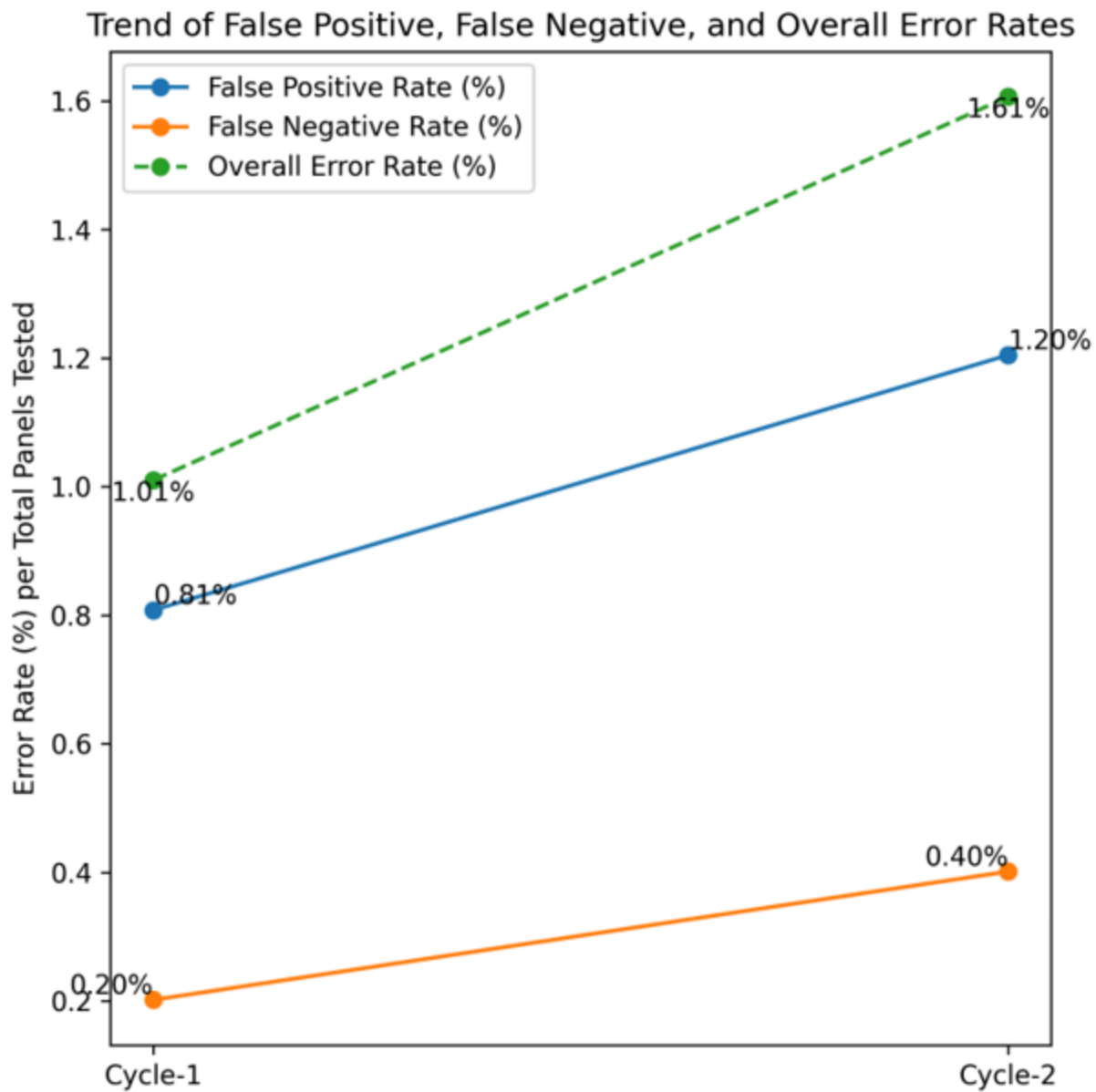


Figure 4

Trend in false positive, false negative, and overall error rates across PT cycles.

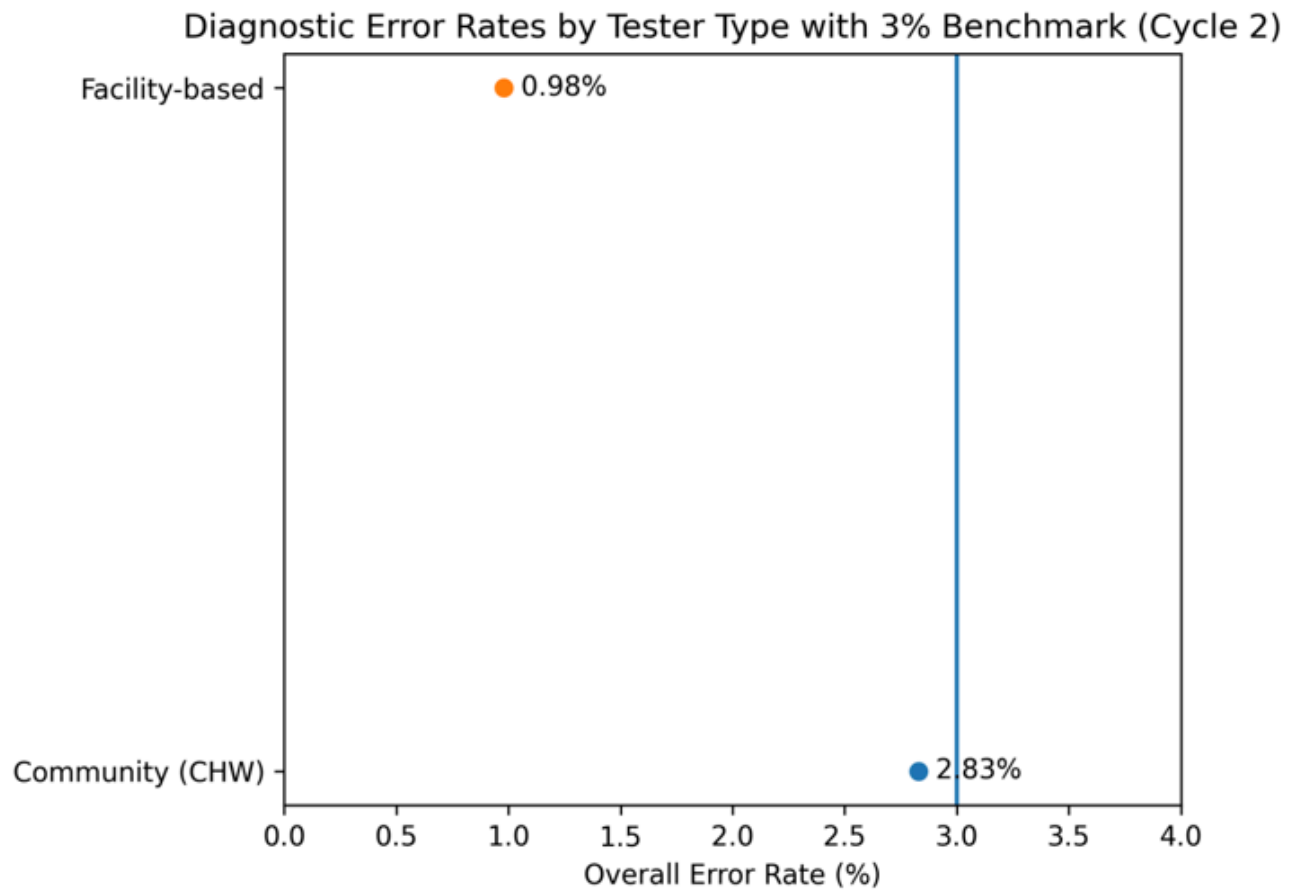


Figure 5

Diagnostic error rates by tester type with 3% performance benchmark (Cycle 2).

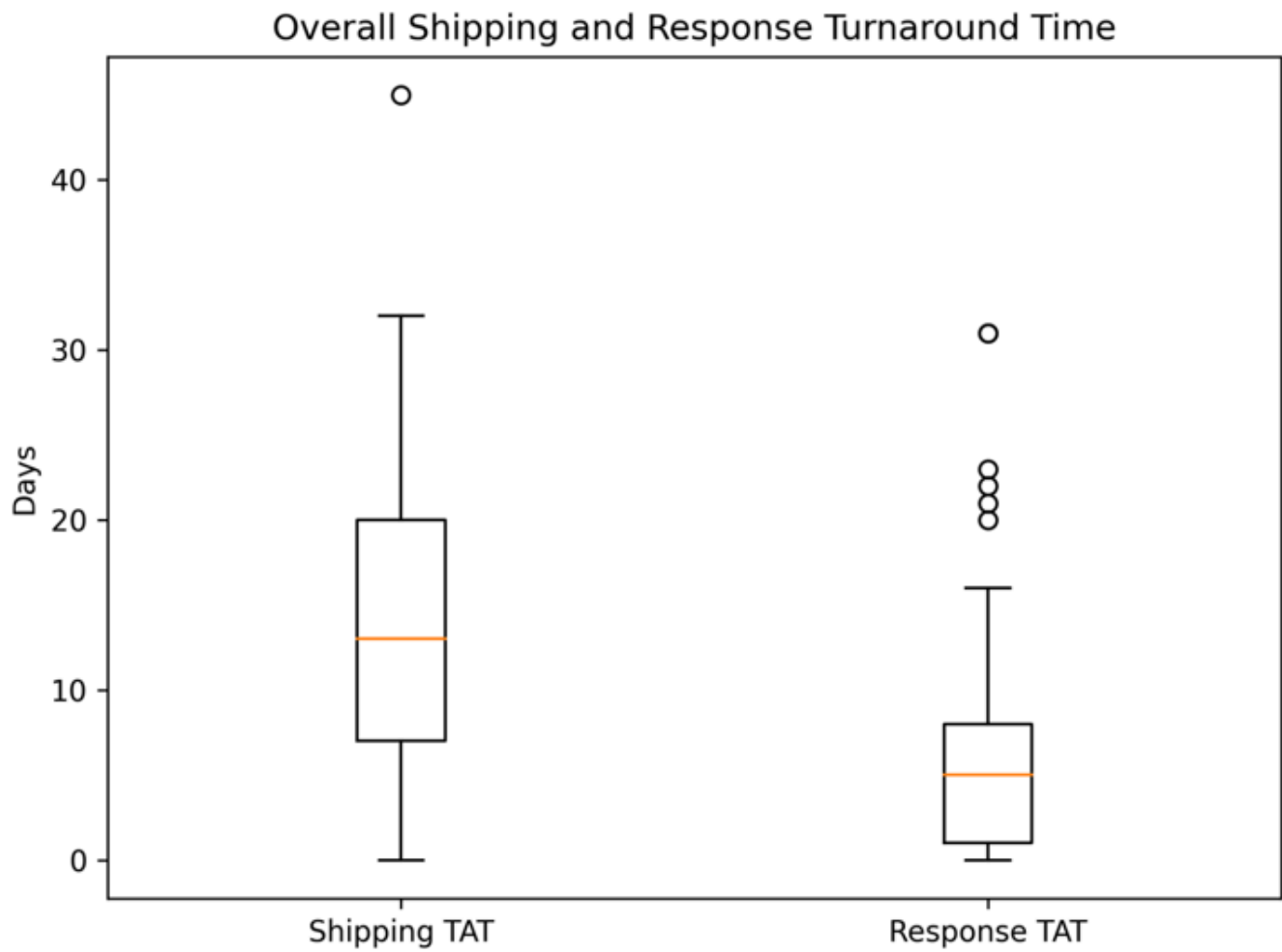


Figure 6

Distribution of shipping TAT and response TAT across implementation cycles.