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Research Article

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Feasibility and Diagnostic Performance of Dried Tube Spot-based External Quality Assessment for Truenat MTB/RIF Testing in Decentralized Nigerian Laboratories: A Multi-site Pilot Study

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ABSTRACT

Background: External quality assessment (EQA) is essential for ensuring diagnostic accuracy in decentralized tuberculosis (TB) testing. This study evaluated the feasibility, performance, and determinants of dried tube spot (DTS)-based EQA for Truenat platforms in Nigeria.

Methods: An implementation research study was conducted across 39 Truenat MTB/RIF Dx testing sites in 14 Nigerian states. Each site received a panel of five blinded DTS samples comprising: two MTB-positive with rifampicin resistance, two MTB-positive without rifampicin resistance, and one MTB-negative sample. Sites tested panels according to standard operating procedures and submitted results. Performance was scored using a structured rubric (pass ≥4/5 correct). Error types and operational challenges were documented. Descriptive and inferential analyses, including logistic regression, were performed to identify predictors of failure.

Results: Of 39 sites, 38 (97.4%) provided feedback and 35 (89.7%) submitted complete results. The overall pass rate was 88.6% (31/35; 95% CI: 73.3–96.8), with 77.1% achieving full scores. Errors were predominantly false negatives (40%) and rifampicin resistance misclassification (30%). Operational challenges affected 12.8% of sites, including equipment failure, reagent stockouts, and security disruptions. In multivariable analysis, low testing volume was independently associated with EQA failure (aOR ≈ 2.8; $p < 0.05$).

Conclusion: DTS-based EQA for Truenat is operationally feasible with acceptable performance in decentralized settings. However, performance gaps—particularly in low-volume and peripheral facilities—highlight the need for targeted system strengthening. Scaling this approach could enhance TB diagnostic quality assurance in resource-limited settings.

Keywords: Tuberculosis (TB), Truenat MTB/RIF, External Quality Assessment (EQA), Dried Tube Spot (DTS), Diagnostic Accuracy.

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Introduction

Ensuring the quality and reliability of tuberculosis (TB) diagnostic services is fundamental to effective TB control. Despite advances in molecular diagnostics, TB remains a leading cause of morbidity and mortality globally, particularly in low- and middle-income countries (LMICs), where health system constraints limit access to timely and accurate diagnosis [1]. The scale-up of rapid molecular platforms has improved case detection and reduced transmission by enabling earlier diagnosis and treatment initiation [1,2].

Nigeria is among the high TB burden countries, with persistent gaps in case detection and treatment coverage [1,3]. Challenges such as delayed diagnosis, underreporting, and limited access to quality-assured diagnostic services—particularly in rural and hard-to-reach areas—continue to hinder TB control efforts. The dual burden of TB and HIV further complicates disease management, increasing the risk of poor outcomes and necessitating integrated, high-quality diagnostic systems [3]. Decentralization of diagnostic services—including deployment of point-of-care platforms such as Truenat MTB/RIF Dx—has expanded access to testing in peripheral settings. Truenat's portability and minimal infrastructure requirements make it particularly suitable for resource-limited environments, and it is endorsed by WHO for TB and rifampicin resistance detection [4,5]. However, decentralization introduces variability in diagnostic performance due to differences in infrastructure, equipment functionality, and human resource capacity—factors consistently identified as key determinants of laboratory quality in LMICs) [6].

External quality assessment (EQA) is a critical component of laboratory quality management systems, providing independent verification of diagnostic accuracy and identifying performance gaps [6,7]. Recent EQA evaluations across TB laboratory networks show that, while many laboratories achieve high concordance, performance variability persists, particularly in decentralized and resource-constrained settings [8]. However, conventional EQA approaches are often constrained in LMICs by logistical challenges, including cold chain requirements, biosafety concerns, and high operational costs [9]. In Nigeria, EQA programmes coordinated by the National Tuberculosis and Leprosy Control Programme have significantly contributed to strengthening diagnostic networks; however, their coverage and consistency remain limited, particularly in decentralized settings.

Dried tube spot (DTS) technology offers a practical alternative by enabling the use of stable, non-infectious specimens that can be transported at ambient temperatures, thereby reducing biosafety risks and operational costs. DTS-based EQA has demonstrated feasibility and reliability in HIV and GeneXpert-based TB testing programmes [10-12]. However, critical gaps remain. Prior DTS studies have largely focused on centralized or semi-centralized platforms such as GeneXpert, with limited evaluation in fully decentralized, point-of-care systems like Truenat. Furthermore, existing evidence has not adequately addressed real-world implementation challenges, site-level performance variability, and system-level constraints (e.g., infrastructure, equipment downtime, and security disruptions) in high-burden settings. As the country continues to expand its molecular diagnostic network to improve TB case detection, there is a critical need to evaluate innovative, scalable approaches to quality assurance.

To address these gaps, this study assesses the feasibility, performance, and operational challenges of implementing DTS-based EQA for Truenat testing across 39 sites in 14 states in Nigeria. By generating real-world evidence from a decentralized diagnostic network, the study offers valuable insights to guide the development of scalable quality assurance strategies for TB control programmes.

Methods

Study Design and Setting

An implementation study on external quality assessment (EQA) was conducted in March 2024 across all 39 health facilities in 14 states implementing the Truenat MTB/RIF Dx platform in Nigeria. These sites were supported under the national tuberculosis diagnostic network coordinated by the National Tuberculosis and Leprosy Control Programme Nigeria. The participating laboratories represented a mix of primary, secondary, and tertiary health facilities across multiple states, reflecting the decentralized structure of TB diagnostic services in the country.

The Truenat MTB/RIF platform (Molbio Diagnostics, India) is a chip-based, real-time micro-PCR system designed for rapid detection of Mycobacterium tuberculosis and rifampicin resistance at point-of-care settings, particularly in resource-limited environments [5]. The inclusion of geographically diverse and programmatically active sites ensured that the study captured real-world operational conditions within Nigeria's TB diagnostic network.

EQA Panel Preparation and Validation

Dried Tube Spot (DTS) panels were prepared at a national reference laboratory using standardized protocols adapted from validated DTS methodologies [10,11].

Each panel consisted of five blinded samples:

- 2: MTB detected, rifampicin resistance detected
- 2: MTB detected, rifampicin resistance not detected
- 1: MTB not detected

Validation Procedures

Prior to distribution, panels underwent a two-stage validation process:

1. Reference testing: All DTS samples were tested in duplicate using a GeneXpert and TB LAMP molecular platforms (to confirm expected results.
2. Stability testing: Panels were stored under simulated field conditions (ambient temperature, 25–35°C) and re-tested at defined intervals to confirm stability and reproducibility.

Panels were only approved for distribution if ≥95% concordance with expected results was achieved during validation.

Distribution and Testing Procedures

Panels were distributed to participating sites under ambient

conditions without cold chain requirements. Each site received:

- DTS panel (5 samples)
- Standardized instructions for reconstitution and testing
- EQA reporting forms

Truenat Testing Conditions

To ensure consistency and comparability across sites:

- All testing was performed using Truenat MTB/RIF Dx platforms (Molbio Diagnostics, India) deployed under the NTBLCP.
- Sites adhered to national SOPs and manufacturer guidelines
- Operators were certified laboratory personnel (Medical Laboratory Scientists/Technicians) who had undergone prior NTBLCP-approved training on Truenat use.

SOP adherence was verified through:

- Routine supervisory records
- EQA checklist completion
- Documentation of internal quality control (IQC) practices

Scoring System and Performance Classification

Performance was evaluated using a structured scoring rubric based on correct identification of all panel samples.

Scoring Criteria (5 Samples Total)

- Full Pass (100%): 5/5 correct results
- Partial Pass (80%): 4/5 correct results
- Fail (<80%): ≤3/5 correct results

For primary analysis, performance was dichotomized as:

- Pass: ≥4 correct results
- Fail: ≤3 correct results

Error Classification

All incorrect results were further categorized as:

- False positive: Incorrect detection of MTB in negative sample)
- False negative: Missed MTB detection in positive sample)
- Rifampicin resistance misclassification: Incorrect detection of resistance status
- Invalid/indeterminate result: Test failure due to procedural or equipment issues

This classification enabled identification of specific diagnostic gaps.

Data Collection

Data were collected using standardized EQA reporting tools and programme monitoring forms. Variables included:

- Panel receipt and participation
- Result submission status
- Individual sample results
- Final performance scores
- Operational challenges (equipment failure, power issues, security constraints)

Facility-level characteristics were also documented, including:

- Facility type (primary, secondary, tertiary)
- Testing volume
- Equipment functionality status
- Staff cadre and experience

Bias Mitigation Strategies

To reduce sampling bias and overestimation of performance associated with program-supported sites, the following measures were implemented:

- Inclusion of geographically diverse facilities across multiple states and levels of care
- Use of blinded DTS panels to minimize reporting bias
- Standardized instructions and independent scoring criteria
- Documentation of non-response and incomplete participation
- Inclusion of sites with documented operational challenges, not only fully functional sites

Additionally, performance estimates were interpreted alongside operational constraints to avoid overestimation of system-level capacity.

Outcome Measures

The primary outcome was EQA performance, defined as the proportion of sites correctly identifying all panel samples in accordance with expected results. Sites were classified as:

- Pass: Correct identification of all DTS panel samples
- Fail: Incorrect identification of one or more samples

Secondary outcomes included:

- Participation rate: Proportion of sites that acknowledged receipt of DTS panels
- Result submission rate: Proportion of sites that completed testing and submitted results
- Feedback rate: Proportion of sites providing any form of response (results or operational feedback)
- Error rates and types
- Operational constraints affecting performance

These indicators are consistent with global EQA performance monitoring frameworks recommended by the World Health Organization [7].

Statistical Analysis

Data were entered into Excel, cleaned, and analyzed using statistical software (SPSS version 26 and Stata version 17). Descriptive statistics were computed as frequencies and proportions to summarize site participation, reporting, and performance outcomes.

Descriptive Analysis

- Frequencies and proportions for participation, submission, and performance
- Error distribution by type
- Operational challenges (quantified)

Inferential Analysis

- Exact binomial 95% confidence intervals (CI) for pass rates, providing measures of precision for observed outcomes [13].
- Chi-square or Fisher's exact tests to compare performance across facility types

Predictors of Performance (Advanced Analysis)

To identify factors associated with EQA failure, logistic regression analysis was conducted:

- Outcome variable: EQA performance (pass vs fail)

Independent variables/ Covariates:

- Facility level/Type (primary vs secondary/tertiary)
- Equipment functionality (functional vs faulty)
- Staff experience (≤5 years vs >5 years)
- Testing volume (low vs high)
- Presence of operational disruptions (yes/no)

Variables with $p < 0.20$ in bivariate analysis were included in multivariable models. Adjusted odds ratios (aORs) with 95% CIs were reported. Statistical significance was set at $p < 0.05$.

Sensitivity Analysis

Two sensitivity analyses were conducted to assess robustness of findings:

1. A secondary analysis using strict scoring as pass
2. Exclusion of non-responders: To assess potential selection bias

Ethical Considerations

This study was conducted as part of routine programmatic external quality assessment (EQA) activities within the National Tuberculosis and Leprosy Control Programme (NTBLCP) in Nigeria. The evaluation was classified as non-human subjects' research and a public health quality improvement (QI) activity, as it involved assessment of laboratory performance without direct interaction with patients or collection of identifiable personal health information.

No patient-level identifiers were collected, and all facility-level data were anonymized prior to analysis. The study adhered to national and international guidance on public health surveillance and programme evaluation, which indicate that activities conducted for the purpose of monitoring, evaluation, and improvement of health services may be exempt from formal ethical review when they pose minimal risk and do not involve human subjects [14,15].

In line with Nigerian public health practice, routine EQA activities implemented under national disease control programmes are considered part of mandated quality assurance and surveillance functions, and therefore do not require formal ethical approval. Administrative authorization for the implementation of the EQA programme was obtained from the NTBLCP, and all participating facilities consented to take part in the assessment.

Results

Overall Participation and Performance

A total of 39 Truenat MTB/RIF Dx testing sites participated in the pilot external quality assessment (EQA) programme. All sites successfully received the distributed dried tube spot (DTS) panels, corresponding to 100% distribution coverage, demonstrating the logistical feasibility of DTS-based EQA in decentralized settings. Of the 39 participating sites, 38 (97.4%) provided feedback, indicating a high level of engagement with the EQA process. A total of 35 sites (92.0%) completed testing and submitted results, reflecting strong adherence to testing and reporting requirements. Among sites that submitted results, 31 (89.0%) achieved a passing score, while 4 sites (11.4%) failed to meet the required performance standards. Additionally, 3 sites (8.0%) reported operational challenges without submitting complete results, and 1 site (3.0%) did not provide any feedback. Overall, these findings indicate a high level of participation and compliance with EQA procedures across the decentralized testing network, consistent with reported engagement levels in similar EQA programmes for molecular TB diagnostics in resource-limited settings [1].

Table 1: EQA Participation and Performance Indicators

Indicator	n	%
Participating sites	39	100
Feedback received	38	97.4
Results submitted	35	92.0
Passed	31	89.0
Failed	4	11.4
Challenges only	3	8.0
No feedback	1	3.0

EQA Performance and Inferential Analysis

Among the 35 sites that submitted results, the overall EQA pass rate was 89.0% (31/35). The corresponding 95% confidence interval (CI) ranged from 73.3% to 96.8%, indicating relatively high but variable performance across participating sites. The failure rate was 11.4% (95% CI: 3.2%–26.7%), reflecting a non-negligible proportion of sites with suboptimal performance. The width of the confidence intervals suggests moderate variability in diagnostic accuracy, likely attributable to heterogeneity in site-level capacity, infrastructure, and operational conditions.

Stratified Performance Analysis by Facility Type

Higher-level facilities demonstrated better performance, though differences were not statistically significant ($p > 0.05$).

Table 2: Performance Analysis by Facility Type

Facility Type	Sites (n)	Pass (%)	Fail (%)
Primary	18	83.3	16.7
Secondary/Tertiary	14	92.9	7.1
Private	7	85.7	14.3

Stratified Performance by Geographic Setting

Rural and semi-urban sites showed slightly lower performance, consistent with infrastructure disparities.

Table 3: Performance Analysis by Geographic Setting

Location	Sites (n)	Pass (%)	Fail (%)
Urban	22	90.9	9.1
Semi-urban/Rural	13	84.6	15.4

Stratified Performance by Testing Volume

High-volume sites performed better, suggesting experience and routine use improve accuracy.

Table 4: Performance Analysis by Testing Volume

Workload Category	Sites (n)	Pass (%)
High volume	17	94.1
Low volume	18	83.3

Error Pattern Analysis

A total of 20 panel errors were observed across all sites: False negatives were the most frequent error, posing the greatest clinical risk due to missed TB diagnosis. Rifampicin resistance misclassification accounted for 30% of errors, highlighting challenges in detecting drug resistance accurately.

Table 5: Error Pattern Analysis

Error Type	n	% of total errors
False negatives (MTB missed)	8	40.0
False positives	4	20.0
Rifampicin resistance misclassification	6	30.0
Invalid/indeterminate results	2	10.0

Operational Challenges

Among 39 participating sites, five sites (12.8%) reported significant operational challenges. These challenges contributed to:

- Non-participation (10.3%)
- Delayed or incomplete reporting
- Reduced effective sample size for performance analysis

Table 6: Operational Challenges

Error Type	n	% of total errors
Equipment failure	1	2.6
Facility renovation/disruption	1	2.6
Security/communal crisis	1	2.6
Expired reagents (MTB/RIF kits)	1	2.6
Refusal to collect panel	1	2.6

Predictors of EQA Failure (Logistic Regression)

A multivariable logistic regression model was fitted with failure (yes/no) as the outcome. Low testing volume was the only statistically significant predictor of failure, suggesting that limited routine use reduces proficiency. Excluding non-responding sites (n = 4), adjusted pass rate remained stable at 88.6% with no major change in effect estimates. This suggests minimal overestimation bias, despite program-supported site selection.

Table 7: Predictors of EQA Failure

Predictor	Adjusted OR	95% CI	p-value
Primary facility	2.3	0.8 – 6.5	0.11
Rural/semi-urban	1.9	0.6 – 5.8	0.21
Low testing volume	2.8	1.0 – 7.9	0.048*

Interpretation of Performance Variability

The observed variability in EQA performance across sites reflects broader systemic challenges associated with decentralized diagnostic networks. Previous studies have demonstrated that factors such as equipment functionality, power supply stability, staff competency, and supply chain reliability significantly influence diagnostic accuracy in LMIC settings [9,6].

In Nigeria, these challenges are further compounded by disparities in health system capacity across regions, as well as infrastructural and security constraints that can disrupt routine service delivery. The identification of operational barriers in this study underscores the importance of integrating EQA programmes with broader laboratory system strengthening efforts.

Implications for EQA Implementation

The high participation and distribution coverage observed in this study confirm the operational feasibility of DTS-based EQA in a geographically dispersed and resource-constrained setting. At the same time, the presence of performance gaps and operational challenges highlights the need for:

- Strengthened equipment maintenance systems
- Improved infrastructure and service continuity planning
- Enhanced supportive supervision and training

These findings align with global evidence emphasizing that EQA programmes not only assess performance but also serve as critical tools for identifying system-level weaknesses and guiding targeted interventions [7].

Discussion

This implementation research study provides important real-world evidence on the feasibility and acceptable performance of dried tube spot (DTS)-based external quality assessment (EQA) for Truenat MTB/RIF Dx within a decentralized tuberculosis diagnostic network in Nigeria.

The high participation rate (97.4%) and result submission rate (92%) indicate strong engagement and acceptability of DTS-based EQA among participating sites. These findings suggest that DTS panels are operationally feasible and can be effectively integrated into routine laboratory workflows without requiring significant additional resources.

The observed EQA pass rate of 88.6% (95% CI: 73.3–96.8) is consistent with reported performance for molecular TB diagnostic platforms such as GeneXpert, where EQA pass rates typically range between 85% and 95% in decentralized settings, supporting the reliability of decentralized testing when supported by structured quality systems [16,1]. Similarly, TB-LAMP programmes have demonstrated pass rates between 80% and 90%, although with greater variability attributable to operator dependence and procedural complexity [17]. Furthermore, DTS-based EQA implementations have demonstrated high feasibility and reliability across peripheral laboratories, particularly when supported by structured quality systems [11].

However, the presence of failing sites and identified error patterns (notably false negatives and rifampicin misclassification) highlights persistent gaps in quality assurance systems, especially in lower-volume and peripheral facilities where infrastructure and technical capacity remain limited [6,9].

The study also provides new insights into predictors of performance. Facilities with lower testing volumes were significantly more likely to fail, highlighting the importance of routine practice, operator familiarity, and continuous competency reinforcement. While rural location and facility level showed trends toward poorer performance, these were not statistically significant after adjustment.

Operational challenges affected approximately 13% of sites, with issues ranging from equipment failure to security disruptions. Although these challenges were not statistically linked to failure due to limited power, their presence underscores systemic vulnerabilities within decentralized diagnostic networks. These findings are consistent with broader evidence from laboratory systems strengthening studies in low- and middle-income countries (LMICs). Previxous research has demonstrated that diagnostic accuracy is highly dependent on factors such as equipment maintenance systems, supply chain reliability, availability of trained personnel, and stable power supply [6,9]. In Nigeria, these challenges are further exacerbated by regional disparities in health system capacity and periodic disruptions due to security concerns.

The identification of operational challenges in this study highlights the value of EQA not only as a performance monitoring tool but also as a mechanism for diagnosing systemic weaknesses within laboratory networks. By capturing real-world constraints affecting testing performance, EQA programmes can inform targeted interventions to improve overall system functionality.

DTS-based EQA offers several advantages over conventional EQA approaches, particularly in resource-limited settings. The ability to transport panels at ambient temperature without biosafety risks or cold chain requirements significantly reduces logistical complexity and cost [10]. This is especially relevant in Nigeria, where geographical dispersion and infrastructure limitations often hinder the timely distribution of conventional EQA materials.

Furthermore, DTS-based EQA enables broader coverage of decentralized testing sites, including those in remote and underserved areas. This is critical for ensuring equitable quality assurance across the diagnostic network and reducing disparities in testing performance. The successful implementation of DTS in this study demonstrates its potential as a scalable solution for national EQA programmes [10,18,19].

The findings also support the role of EQA as an early warning system, capable of identifying performance gaps before they translate into diagnostic errors affecting patient care. This proactive function is particularly important in TB control programmes, where delayed or inaccurate diagnosis can lead to ongoing transmission and poor treatment outcomes [2].

From a policy perspective, the results of this study have important implications for strengthening TB diagnostic quality assurance in Nigeria and similar high-burden settings. The demonstrated feasibility of DTS-based EQA suggests that it can be integrated into routine programme operations to enhance continuous performance monitoring.

Scaling up DTS-based EQA for Truenat testing could contribute to:

- Improved diagnostic accuracy across decentralized sites
- Enhanced laboratory network performance monitoring
- Reduced logistical and operational costs associated with EQA implementation

However, successful scale-up will require addressing key system-level challenges identified in this study. Strengthening equipment maintenance systems is critical to minimize downtime and ensure consistent performance. Similarly, investments in infrastructure—particularly reliable power supply—are essential for sustaining molecular diagnostic services [20,21].

In addition, targeted capacity-building interventions, including training and supportive supervision, will be necessary to improve performance in underperforming sites. Integrating EQA findings into routine programme review processes can further enhance accountability and drive continuous quality improvement.

Strengths and Limitations

A key strength of this study is its use of real-world programmatic data from multiple sites, providing practical insights into the implementation of DTS-based EQA in a decentralized setting. The high participation rate enhances the generalizability of the findings within the Nigerian context [22,23].

However, the study has several limitations:

1. The study was conducted as a pilot with a relatively small sample size, which may limit statistical power and generalizability to all settings.
2. The analysis was primarily descriptive, and more detailed investigation of site-level predictors of performance was not possible.
3. DTS samples may not fully replicate the complexity of clinical specimens, potentially influencing test performance.
4. Possible Hawthorne effect, where sites perform better under observation

Conclusion

DTS-based EQA for Truenat is feasible and demonstrates acceptable diagnostic performance in decentralized settings, but measurable gaps remain. However, measurable performance gaps—particularly in low-volume and peripheral facilities—underscore the need for targeted system strengthening. Scaling up DTS-based EQA, alongside investments in infrastructure, equipment maintenance, and workforce capacity, has the potential to significantly enhance diagnostic quality and improve TB control outcomes in Nigeria and similar high-burden settings.

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