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Comparative Diagnostic Accuracy of GeneXpert MTB/RIF and TB-LAMP for Tuberculosis Detection Among Presumptive Tuberculosis Cases in Bayelsa State, Nigeria

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ABSTRACT

Background

Tuberculosis (TB) remains a leading cause of mortality from a single infectious agent worldwide, with a disproportionate burden in resource-limited settings where delayed or inaccurate diagnosis contributes to treatment failure, drug resistance, and adverse outcomes. Although mycobacterial culture is the diagnostic reference standard, its prolonged turnaround time and infrastructural demands limit its utility in high-burden settings. Nucleic acid amplification tests (NAATs) offer rapid and sensitive alternatives. This study evaluated the diagnostic accuracy and concordance of GeneXpert MTB/RIF and TB-LAMP relative to culture among presumptive TB cases in a high-burden Nigerian setting.

Methods

We conducted a cross-sectional study among 392 participants aged 6–80 years presenting with TB-suggestive symptoms across eight health facilities in Bayelsa State, Nigeria. Sputum samples were tested in parallel using TB-LAMP, GeneXpert MTB/RIF, and solid mycobacterial culture on Löwenstein–Jensen (LJ) medium (reference standard). Diagnostic performance was assessed by sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and concordance using McNemar's chi-square test. Data were analysed using Stata version 16.0. Statistical significance was defined at $p < 0.05$.

Results

Culture positivity was 10.6%, GeneXpert positivity was 11.2%, and TB-LAMP positivity was 14.8%. TB-LAMP detection significantly exceeded that of GeneXpert (McNemar $\chi^2 = 12.57$, $p = 0.0004$; exact $p = 0.0005$). GeneXpert showed no significant discordance with culture (McNemar $\chi^2 = 1.80$, $p = 0.18$; exact $p = 0.375$), indicating strong agreement with the reference standard. Against culture, TB-LAMP achieved sensitivity 95.1%, specificity 94.5%, PPV 68.4%, and NPV 99.1%; GeneXpert achieved sensitivity 91.7%, specificity 97.7%, PPV 97.6%, and NPV 99.0%. Notably, 2.3% of TB-LAMP-positive results were identified as non-*Mycobacterium tuberculosis* complex (NTM), representing a potential source of false-positive detection.

Conclusion

GeneXpert MTB/RIF demonstrates high concordance with culture and simultaneously identifies rifampicin resistance, supporting its role as a confirmatory diagnostic tool, particularly for suspected multidrug-resistant TB (MDR-TB). TB-LAMP provides a rapid, low-cost screening option suitable for peripheral and second-tier laboratories, but requires confirmatory testing to rule out NTM infection and assess drug resistance status. A sequential diagnostic algorithm, TB-LAMP for initial screening followed by GeneXpert for confirmation may enhance case detection rates while optimising resource utilisation.

1. BACKGROUND

Tuberculosis (TB) is the world's leading cause of mortality attributable to a single infectious agent. Following a three-year period during which COVID-19 surpassed TB as the leading infectious disease killer, TB has reclaimed this position and continues to impose a substantial burden on health systems globally, with a disproportionate impact in resource-limited settings (Darboe et al., 2024). The global TB death toll in 2023 was estimated at 1.09 million, nearly double the 0.63 million deaths attributed to HIV/AIDS in the same period (WHO, 2024), underscoring the urgent need for innovative diagnostic tools with improved accuracy and rapid turnaround times (Omoteso et al., 2025).

Tuberculosis diagnosis remains challenging, particularly in resource-limited settings. The introduction of nucleic acid amplification test (NAAT) assays has substantially improved the speed and accuracy of TB testing (Ghosh et al., 2025). Rapid molecular tests have transformed the diagnostic landscape, which previously relied on conventional sputum smear microscopy and culture methods, by generating results within hours (Zaporojan et al., 2024). Nevertheless, misdiagnosis carries profound consequences, including suboptimal treatment outcomes, emergence of drug-resistant strains, and treatment failure (Berihe Hiluf et al., 2024). The increasing burden of drug-resistant TB and the continued emergence of resistant variants constitute a global public health emergency, necessitating accurate early diagnosis and timely treatment initiation (Naidoo et al., 2024).

Efforts to enhance TB diagnosis and thereby expand access to treatment play a critical role in reducing TB-related morbidity and mortality in endemic regions (Olbrich et al., 2025). Misdiagnosis of tuberculosis may exacerbate infection, facilitate community transmission, and reduce treatment efficacy. Furthermore, false-positive diagnoses may lead to unnecessary anti-TB treatment, with consequent risks of drug toxicity and the potential promotion of drug resistance. The primary objectives of this study were therefore to assess the diagnostic performance — including sensitivity, specificity, concordance, and overall accuracy — of GeneXpert MTB/RIF and TB-LAMP molecular platforms, and to determine their agreement with mycobacterial culture (the reference standard), with the aim of informing evidence-based diagnostic strategies.

The WHO has endorsed the TB-LAMP assay as an alternative to sputum smear microscopy for the diagnosis of pulmonary TB (Zaber et al., 2024). The assay offers several inherent advantages: it does not require complex instrumentation, can be performed on unprocessed specimens for DNA amplification, yields results visible to the naked eye, and carries a lower risk of cross-contamination compared with conventional amplification methods. However, reported sensitivity, specificity, PPV, and NPV values have varied considerably across studies and settings (Zaber et al., 2024).

GeneXpert MTB/RIF is a closed cartridge-based NAAT system that provides rapid and accurate results from biological specimens with minimal technical training requirements. In a study conducted among a prison population in Malaysia, a single GeneXpert assay correctly identified eight of 15 culture-positive TB cases among previously undiagnosed individuals, yielding a sensitivity of 53.3% (95% CI: 30.1–75.2%), specificity of 100% (95% CI: 96.6–100%), PPV of 100% (95% CI: 67.6–100%), and NPV of 94.0% (95% CI: 88.2–97.1%), with culture serving as the reference standard (Al-Darraji et al., 2013).

Although these molecular tools are increasingly adopted, questions remain regarding their comparative diagnostic performance and concordance with culture across diverse epidemiological contexts. In high-burden settings such as Nigeria, variability in laboratory capacity, patient characteristics, and disease presentation may influence test accuracy, necessitating context-specific evaluation. This study therefore aims to assess the diagnostic accuracy and concordance of GeneXpert MTB/RIF and TB-LAMP relative to mycobacterial culture, and to provide evidence to inform the optimal integration of rapid molecular diagnostics into national TB control programmes.

2. METHODS

2.1 Study Design and Setting

A cross-sectional diagnostic accuracy study was conducted between January and June 2025 among 392 male and female participants aged 6–80 years presenting with signs and symptoms suggestive of tuberculosis. Participants were recruited from 40 Directly Observed Therapy (DOT) sites across Bayelsa State, Nigeria. Eligibility criteria included the presence of cough (particularly if persisting for two weeks or longer) accompanied by one or more of the following symptoms: chest pain, dyspnoea, haemoptysis, fever, anorexia, unexplained weight loss, or night sweats. The same sputum specimen from each participant was tested in parallel using two molecular platforms (GeneXpert MTB/RIF and TB-LAMP) and mycobacterial culture as the reference standard.

2.2 Ethical Considerations

Ethical approval was obtained from the Research Ethics Committee of the Bayelsa State Ministry of Health. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and applicable Nigerian national guidelines for health research involving human subjects.

Informed consent. All participants received detailed information regarding the study objectives, procedures, potential risks and benefits, and their right to decline participation or withdraw at any time without consequence to their clinical care. Information was provided in English or the appropriate local language, and adequate time was allocated for questions and deliberation. Written informed consent was obtained from all adult participants; for minors, written consent was obtained from parents or legal guardians prior to enrolment and sample collection.

2.3 Sample Size Calculation

The sample size was calculated using the Cochran formula for estimating a single proportion:

$$n = (Z^2 \times p[1 - p]) / E^2$$

where n is the required sample size, Z is the standard normal deviate corresponding to the desired confidence level (1.96 for 95% confidence), p is the anticipated sensitivity of the diagnostic tests (0.85, based on prior reports), and E is the acceptable margin of error (0.05). Since the anticipated

sensitivities of the two assays were equivalent ($p_1 = p_2 = 0.85$), the two-proportion formula was not applicable; accordingly, the single-proportion precision formula was employed.

Substituting the values: $n = (1.96^2 \times 0.85 \times 0.15) / 0.05^2 = (3.8416 \times 0.1275) / 0.0025 = 0.4898 / 0.0025 \approx 196$.

2.4 Laboratory Methods

2.4.1 TB-LAMP Assay

The TB-LAMP assay was performed using the Loopamp™ PURE DNA Extraction Kit and Loopamp MTBC Detection Kit (Eiken Chemical Co., Tokyo, Japan). The assay primers target the gyrase subunit B (*gyrB*) gene and insertion sequence IS6110 within the MTBC genome. Briefly, 60 µL of sputum was transferred to the heating tube and incubated at 95°C for 5 minutes. The absorbent tube and heating tube were capped and tightened, the contents mixed by inverting five times, and the mixture squeezed into LAMP reaction tubes, which were subsequently incubated at 65°C. Results were interpreted by the presence or absence of green fluorescence. All procedures were performed using the HumaLoopT instrument (HUMAN Diagnostics Worldwide, Wiesbaden, Germany). Fourteen sputum samples were processed simultaneously per run. Positive and negative controls were included in each run to validate assay performance.

2.4.2 GeneXpert MTB/RIF Assay

The GeneXpert MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) was performed according to the manufacturer's instructions. Briefly, sputum specimens were homogenised using the sample reagent (SR) supplied with the kit, added at a 2:1 ratio (SR:sample). The mixture was vigorously agitated and incubated at room temperature for 10–15 minutes to achieve complete liquefaction and decontamination. Following incubation, 2 mL of the processed specimen was transferred into the GeneXpert cartridge, which was then loaded into the GeneXpert instrument. The system performs automated nucleic acid extraction, amplification, and detection within a closed, self-contained cartridge. The assay employs a hemi-nested real-time PCR strategy targeting the *rpoB* gene to detect *Mycobacterium tuberculosis* complex (MTBC) DNA, with simultaneous identification of rifampicin resistance-associated mutations using molecular beacon probes. Results were generated automatically by the GeneXpert software after approximately 90 minutes and categorised as MTB detected (with rifampicin resistance detected, not detected, or indeterminate) or MTB not detected. All results were interpreted according to the manufacturer's algorithm and internal quality control parameters.

2.4.3 Mycobacterial Culture

Sputum specimens were processed and cultured on Löwenstein–Jensen (LJ) medium following standard mycobacteriological procedures. All processing was conducted within a class II biological safety cabinet to prevent cross-contamination.

Decontamination. Specimens were decontaminated using the N-acetyl-L-cysteine–sodium hydroxide (NALC–NaOH) method. Equal volumes of sputum and freshly prepared NALC–NaOH–citrate solution (50 mL NaOH–citrate containing 0.25 g N-acetyl-L-cysteine) were combined, vortexed, and incubated at room temperature for 15 minutes for mucolysis and decontamination.

Centrifugation. Following decontamination, phosphate-buffered saline (PBS) was added to bring the total volume to 40–50 mL. Tubes were balanced and centrifuged at $3,500 \times g$ for 15 minutes. The supernatant was carefully decanted, and the pellet was resuspended in 2 mL of PBS.

Inoculation and incubation. A loopful of the processed sediment was inoculated onto LJ slants, and a smear was prepared for acid-fast bacilli (AFB) microscopy. Inoculated LJ media were loosely capped and incubated at 37°C for 48–72 hours, after which tubes were tightly sealed and returned to the incubator. Cultures were monitored weekly for visible growth for up to eight weeks. All procedures were conducted using aseptic technique; work surfaces and waste materials were decontaminated with 5% Lysol solution after each processing session.

Mycobacterial isolates recovered from culture were identified using the SD Bioline TB Ag MPT64 Rapid Test (Standard Diagnostics, Inc., Yongin, Republic of Korea) to differentiate MTBC from non-tuberculous mycobacteria (NTM).

2.5 Statistical Analysis

Data were analysed using Stata version 16.0 (StataCorp LLC, College Station, TX, USA). The diagnostic performance of TB-LAMP and GeneXpert MTB/RIF was assessed against mycobacterial culture as the reference standard. Outcome measures included sensitivity, specificity, PPV, and NPV, each reported with 95% confidence intervals. Concordance between test pairs was evaluated using McNemar's chi-square test for paired proportions; a two-tailed $p < 0.05$ was considered statistically significant.

3. RESULTS

3.1 Diagnostic Performance Against Culture

Table 1 presents the diagnostic performance of TB-LAMP and GeneXpert MTB/RIF relative to mycobacterial culture (reference standard). GeneXpert achieved higher specificity (97.7%) and PPV (97.6%) than TB-LAMP (specificity 94.5%; PPV 68.4%), whereas TB-LAMP demonstrated marginally higher sensitivity (95.1% vs. 91.7%) and equivalent NPV (99.1% vs. 99.0%).

Table 1. Diagnostic performance of TB-LAMP and GeneXpert MTB/RIF against mycobacterial culture (reference standard)

Diagnostic Test	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
TB-LAMP	95.1	94.5	68.4	99.1
GeneXpert MTB/RIF	91.7	97.7	97.6	99.0

PPV = positive predictive value; NPV = negative predictive value.

3.2 GeneXpert vs. Culture: Concordance Analysis

The GeneXpert positivity rate (11.2%) was closely concordant with the culture positivity rate (10.6%), with an absolute difference of -0.76% (95% CI: -2.14% to 0.61%). McNemar's test demonstrated no significant discordance ($\chi^2 = 1.80$, $p = 0.18$; exact $p = 0.375$), confirming strong agreement between GeneXpert and culture (Table 2).

Table 2. Concordance of GeneXpert MTB/RIF and culture (McNemar's test)

Comparison	Positivity rate (%)	Absolute difference % (95% CI)	McNemar χ^2 (p-value)	Exact p-value	Odds ratio (95% CI)
GeneXpert vs. Culture	GeneXpert: 11.2%; Culture: 10.6%	-0.76 (-2.14 to 0.61)	1.80 (0.18)	0.375	0.25 (0.005–2.53)

χ^2 = chi-square; CI = confidence interval.

3.3 TB-LAMP vs. Culture: Concordance Analysis

The TB-LAMP positivity rate (14.8%) significantly exceeded the culture positivity rate (10.6%), with an absolute difference of -4.33% (95% CI: -6.95% to -1.72%). McNemar's test revealed significant discordance ($\chi^2 = 12.57$, $p = 0.0004$; exact $p = 0.0005$), indicating that TB-LAMP detected substantially more positive cases than culture (Table 3).

Table 3. Concordance of TB-LAMP and culture (McNemar's test)

Comparison	Positivity rate (%)	Absolute difference % (95% CI)	McNemar χ^2 (p-value)	Exact p-value	Odds ratio (95% CI)
TB-LAMP vs. Culture	TB-LAMP: 14.8%; Culture: 10.6%	-4.33 (-6.95 to -1.72)	12.57 (0.0004)	0.0005	0.15 (0.03–0.51)

χ^2 = chi-square; CI = confidence interval.

3.4 Pairwise Contingency Tables

Table 4. Pairwise contingency table: GeneXpert MTB/RIF vs. TB-LAMP

	TB-LAMP Positive	TB-LAMP Negative	Total
GeneXpert Positive	41	3	44
GeneXpert Negative	17	331	348
Total	58	334	392

Table 5. Pairwise contingency table: Culture vs. GeneXpert MTB/RIF

	GeneXpert Positive	GeneXpert Negative	Total
Culture Positive	40	1	41
Culture Negative	4	347	351
Total	44	348	392

Table 6. Pairwise contingency table: Culture vs. TB-LAMP

	TB-LAMP Positive	TB-LAMP Negative	Total
Culture Positive	38	3	41
Culture Negative	20	331	351
Total	58	334	392

4. DISCUSSION

A persistent challenge in global TB control is the limited availability of affordable, rapid, and accurate diagnostic tools suitable for resource-constrained settings. The emergence of NAAT-based platforms has created new opportunities for highly sensitive, point-of-care TB diagnosis. The GeneXpert MTB/RIF system, now widely implemented globally, has significantly advanced TB diagnostics in both well-resourced and high-burden settings by enabling simultaneous rapid detection of *Mycobacterium tuberculosis* complex (MTBC) and rifampicin resistance. In the present study, GeneXpert demonstrated strong concordance with culture (concordance rate: 96.5%), with high sensitivity (91.7%) and specificity (97.7%), and no statistically significant discordance ($p = 0.18$), indicating reliable detection accuracy and a low rate of false-positive and false-negative results (Table 2).

The TB-LAMP assay represents a potential diagnostic alternative, requiring minimal laboratory infrastructure and technical expertise, and is therefore suitable for deployment in peripheral or second-tier diagnostic facilities. In the present study, TB-LAMP demonstrated slightly higher sensitivity (95.1%) but lower specificity (94.5%) than GeneXpert, resulting in a significantly higher positivity rate ($p = 0.0017$). Although TB-LAMP achieved rapid screening with a high NPV (99.1%), its comparatively low PPV (68.4%) reflects a substantial risk of misclassification, particularly due to cross-reactivity with non-tuberculous mycobacteria (NTM) (Table 1).

A notable finding was the significant discordance between TB-LAMP results and culture, in contrast to the strong concordance observed between GeneXpert and culture. False-positive results carry profound clinical consequences, including unnecessary anti-TB treatment, increased risk of drug toxicity, the potential emergence of multidrug-resistant TB (MDR-TB), heightened community transmission due to missed true cases, patient stigma, and higher healthcare costs (Muriithi et al., 2025).

NAAT-based tests, including TB-LAMP and GeneXpert, have been consistently shown to offer greater sensitivity and shorter turnaround times compared with conventional culture (Acharya et al., 2020) findings consistent with the present study. The sensitivity values observed here, 95.1% for TB-LAMP and 91.7% for GeneXpert, are comparable to those reported in the literature.

These findings are broadly consistent with those reported by Adama et al. (2015), who demonstrated high sensitivity and specificity for both TB-LAMP and GeneXpert irrespective of patient age or MTBC strain. Huh et al. (2014) reported GeneXpert sensitivity for MTB detection of 89.8% in a performance evaluation study. In comparative studies, TB-LAMP has demonstrated sensitivity ranging from 82% to 99.3% and specificity of 96.8%–99.3%, while GeneXpert has demonstrated sensitivity of 84.5%–90% and specificity of 97.5%–99.1% (Odume et al., 2021). The sensitivity values observed in the present study fall within these reported ranges.

In the present study, the GeneXpert positivity rate (11.2%) was closely concordant with the culture positivity rate (10.6%), with a non-significant absolute difference of -0.76% (95% CI: -2.14% to 0.61%). The odds ratio of 0.25 (95% CI: 0.005–2.53) suggests that, in discordant pairs, GeneXpert was less likely than culture to yield a positive result. The high degree of concordance observed between GeneXpert and culture reinforces its suitability as a culture-equivalent alternative in settings where rapid turnaround is essential (Table 2).

The elevated TB-LAMP positivity rate (14.8%) relative to culture may be attributable, in part, to methodological characteristics of loop-mediated isothermal amplification performed at 60–65°C,

which may be susceptible to non-specific amplification and consequently produce false-positive results. The odds ratio of 0.15 (95% CI: 0.03–0.51) further quantifies this discordance, indicating that culture was substantially less likely than TB-LAMP to yield a positive result in discordant pairs (Table 3).

The higher positivity rates observed with both molecular assays relative to culture likely reflect the inherently greater analytical sensitivity of NAAT-based methods, which can detect nucleic acid from both viable and non-viable mycobacteria, as well as from NTM. In the present study, 2.3% of TB-LAMP-positive cases were identified as NTM, potentially attributable to the assay's high analytical sensitivity. This finding underscores the importance of confirmatory testing to differentiate MTBC from NTM, and has direct implications for the risk of initiating unnecessary anti-TB treatment and potentially contributing to MDR-TB emergence.

5. CONCLUSION

GeneXpert MTB/RIF demonstrates high diagnostic accuracy and strong concordance with mycobacterial culture, supporting its role as a confirmatory diagnostic tool and enabling simultaneous identification of rifampicin resistance — a critical advantage in settings with high MDR-TB burden. TB-LAMP offers higher sensitivity and rapid turnaround, making it a promising low-cost screening option for peripheral and second-tier laboratories; however, its lower specificity and elevated false-positive rate necessitate confirmatory testing to exclude NTM infection and evaluate drug resistance status. A sequential diagnostic strategy — employing TB-LAMP for initial screening and GeneXpert for confirmation of reactive specimens — has the potential to optimise case detection rates while minimising misdiagnosis and inappropriate treatment initiation in resource-limited settings.

DATA AVAILABILITY STATEMENT

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

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