RESEARCH PAPER

CBNAAT as a Diagnostic Utility for Detection of Tuberculosis and Rifampicin Resistance among Suspected Patients Attending a Tertiary Care Centre in Jharkhand

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Abstract

Background

Tuberculosis (TB) remains a major global public health problem, with delayed diagnosis and drug resistance contributing substantially to morbidity, mortality and transmission. Ziehl–Neelsen (ZN) smear microscopy is widely used for TB diagnosis but has limited sensitivity, particularly in patients with low bacillary loads. Cartridge-based nucleic acid amplification testing (CBNAAT) provides rapid molecular detection of *Mycobacterium tuberculosis* and simultaneously identifies rifampicin resistance. The present study was undertaken to evaluate the diagnostic utility of CBNAAT in comparison with conventional ZN smear microscopy among patients clinically suspected of tuberculosis.

Materials and Methods

A laboratory-based observational study was conducted at DumkaSadar Hospital, Jharkhand, from March 2025 to March 2026. A total of 2965 clinical samples obtained from patients suspected of tuberculosis on the basis of symptoms such as prolonged cough, fever, weight loss, weakness and bone pain were included. Samples were examined by ZN smear microscopy and CBNAAT for detection of *M. tuberculosis*. Rifampicin resistance was recorded from the CBNAAT results. The original study also reported isoniazid resistance; however, the method used for its determination was not specified and therefore cannot be attributed to conventional CBNAAT.

Results

Among the 2965 samples tested, ZN smear microscopy detected acid-fast bacilli in 128 (4.32%) samples, while 2837 (95.68%) were negative. CBNAAT detected *M. tuberculosis* in 504 (17.00%) samples and was negative in 2461 (83.00%). Thus, CBNAAT detected 376 more positive samples than ZN smear microscopy. Rifampicin resistance was reported in 103 samples (3.47% of the total study samples). And 100 isoniazid-resistant cases; however, the methodology for establishing isoniazid resistance was not available in the supplied study material.

Conclusion

CBNAAT demonstrated a substantially higher TB detection yield than ZN smear microscopy among clinically suspected patients. Its ability to rapidly detect *M. tuberculosis* and rifampicin resistance makes it a valuable diagnostic tool for early diagnosis and timely identification of patients requiring evaluation for drug-resistant TB.

Additional molecular or phenotypic drug-susceptibility testing is required for assessment of isoniazid resistance and other drug resistances.

Keywords

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INTRODUCTION

Tuberculosis (TB) remains one of the most important infectious diseases worldwide and continues to pose a major challenge to healthcare systems, particularly in countries with a high burden of disease. TB is caused primarily by *Mycobacterium tuberculosis*, an organism capable of producing pulmonary as well as extrapulmonary disease. Although TB is preventable and curable, delayed diagnosis, inadequate treatment, treatment interruption and the emergence of drug-resistant strains continue to contribute substantially to morbidity, mortality and ongoing transmission.

The global burden of TB remains considerable. Recent estimates indicate that approximately 10.7 million people developed TB globally in 2024, including 5.8 million men, 3.7 million women and 1.2 million children. TB continues to be among the leading causes of death from a single infectious agent and remains a major cause of mortality among people living with HIV [1]. The persistence of this burden emphasizes the need for early diagnosis, prompt treatment and effective surveillance for drug resistance.

India is among the countries contributing substantially to the global TB burden. The epidemiological situation is complicated by population density, socioeconomic inequalities, delayed healthcare-seeking behaviour, comorbidities and the presence of drug-resistant TB. Consequently, strengthening bacteriological diagnosis and ensuring rapid identification of drug resistance are essential components of tuberculosis-control strategies [2,3].

Early and accurate laboratory diagnosis is particularly important because patients with undiagnosed infectious TB may continue to transmit the organism to household members, healthcare workers and the community. Delays in microbiological confirmation may also result in inappropriate empirical treatment and delayed initiation of appropriate therapy for drug-resistant disease [4].

Traditionally, diagnosis of pulmonary TB has relied heavily on sputum smear microscopy. Ziehl–Neelsen (ZN) staining is inexpensive, technically relatively simple and remains widely used, particularly in resource-limited settings [5]. However, microscopy has important limitations. A relatively high bacillary load is required for detection, and sensitivity may be reduced in paucibacillary disease, early disease, children, immunocompromised individuals and patients with smear-negative pulmonary TB [5,6].Another major limitation of smear microscopy is its inability to determine antimicrobial susceptibility. A positive acid-fast smear indicates the presence of acid-fast bacilli but does not reliably establish whether the organism is *M. tuberculosis* or determine whether it is resistant to rifampicin, isoniazid or other antitubercular drugs. Therefore, additional microbiological or molecular testing is required for species identification and resistance detection.

Mycobacterial culture has traditionally been considered an important reference method for confirming TB. Culture is considerably more sensitive than direct smear microscopy and allows subsequent phenotypic drug-susceptibility testing. However, culture-based methods require specialized infrastructure, trained personnel and prolonged incubation periods before results become available [6]. The time required for culture and conventional drug-susceptibility testing can contribute to delays in treatment decisions.

The development of nucleic acid amplification tests has significantly improved the speed of TB diagnosis. Cartridge-based nucleic acid amplification testing (CBNAAT), particularly the GeneXpert MTB/RIF platform, allows rapid molecular detection of *M. tuberculosis* complex directly from clinical specimens and simultaneously detects mutations associated with rifampicin resistance [7,8].

CBNAAT uses automated molecular amplification and detection technology, thereby reducing the need for extensive manual processing. One of its major advantages is the rapid availability of results

compared with conventional culture. The ability to detect MTB and assess rifampicin resistance using the same test makes CBNAAT particularly useful in settings where rapid identification of drug-resistant TB is clinically important.The Xpert MTB/RIF assay targets DNA sequences specific to the *M. tuberculosis* complex and simultaneously interrogates the rifampicin-resistance determining region of the *rpoB* gene. Detection of mutations in this region provides an indication of rifampicin resistance [7]. Rifampicin resistance is clinically important because it is frequently associated with multidrug-resistant TB and therefore requires prompt evaluation and appropriate management.WHO has recommended Xpert MTB/RIF as an initial diagnostic test for TB and rifampicin resistance in patients with symptoms suggestive of pulmonary TB. Current WHO guidance supports the use of rapid molecular testing rather than relying solely on conventional smear microscopy for initial diagnosis in appropriate clinical settings [9].

The diagnostic superiority of molecular testing over smear microscopy has been demonstrated in several studies. Boehme et al. evaluated Xpert MTB/RIF in multiple countries and found that the assay detected 90.3% of culture-confirmed TB cases compared with 67.1% detected by microscopy. Importantly, Xpert detected a substantial proportion of smear-negative, culture-positive cases [10].

A systematic review and meta-analysis also demonstrated the high diagnostic performance of Xpert MTB/RIF. Steingart et al. reported pooled sensitivity of approximately 89% and specificity of 99% when Xpert was used as an initial diagnostic test for pulmonary TB. The review also demonstrated greater TB detection compared with smear microscopy [11].

The ability to detect rifampicin resistance rapidly is another major advantage of CBNAAT. In the multicentre study by Boehme et al., Xpert MTB/RIF demonstrated high sensitivity and specificity for detection of rifampicin resistance [10]. CBNAAT has also demonstrated usefulness in extrapulmonary TB. Vadwai et al. evaluated Xpert MTB/RIF among patients with suspected extrapulmonary TB and reported high specificity and useful sensitivity compared with a composite reference standard [12]. The study further demonstrated that performance varies according to specimen type, emphasizing the importance of appropriate specimen selection and clinical interpretation.

The usefulness of rapid molecular testing is particularly important in tertiary-care hospitals. Such centres receive patients with prolonged symptoms, complicated disease, previous treatment, immunocompromising conditions and suspected drug resistance. In these patients, reliance on smear microscopy alone may result in missed or delayed diagnosis.Another important advantage of CBNAAT is its relatively rapid turnaround time. Early availability of molecular results can allow clinicians to initiate appropriate therapy sooner and may facilitate infection-control measures and contact investigation. Rapid identification of rifampicin resistance also allows patients to be directed towards appropriate drug-resistant TB management pathways.

However, CBNAAT should not be regarded as a complete replacement for all microbiological investigations. Conventional Xpert MTB/RIF detects MTB and rifampicin resistance; it does not provide a complete drug-susceptibility profile. In particular, isoniazid resistance cannot be directly inferred from a conventional Xpert MTB/RIF result [8,9]. Additional molecular or phenotypic testing is therefore required when resistance to isoniazid or other antitubercular drugs needs to be established.The distinction is important because multidrug-resistant TB is defined by resistance to at least rifampicin and isoniazid. Therefore, identification of rifampicin resistance through CBNAAT should prompt appropriate further testing for additional drug resistance according to the applicable diagnostic algorithm [9].

The present study was undertaken in a tertiary-care hospital in Jharkhand to evaluate the diagnostic utility of CBNAAT among patients clinically suspected of tuberculosis. The study included 2,965 samples collected over one year from March 2025 to March 2026. All samples were subjected to ZN smear microscopy and CBNAAT for detection of tuberculosis, while the study also recorded reported resistance findings.

The primary purpose of the study was to compare the detection of TB by conventional microscopy and CBNAAT and to assess the contribution of rapid molecular testing in identifying cases that may not be detected by smear microscopy. The study also aimed to document rifampicin resistance among the tested population.

MATERIAL AND METHODS

Study design

A laboratory-based observational study was conducted to evaluate the diagnostic utility of CBNAAT in clinically suspected tuberculosis cases.

Study setting

The study was conducted at DumkaSadar Hospital, Jharkhand.

Study period

The study was conducted for one year, from March 2025 to March 2026.

Study population

The study population consisted of patients clinically suspected of tuberculosis who attended the hospital during the study period and from whom clinical specimens were submitted for TB investigation.

Sample size

A total of **2965 clinical samples** were included in the study.

Clinical suspicion

Patients were considered clinically suspected of TB on the basis of symptoms and clinical findings suggestive of tuberculosis. The symptoms documented in the source paper included:

- Prolonged cough
- Fever
- Weight loss
- Weakness
- Bone pain
- Other clinical features suggestive of tuberculosis

Inclusion criteria

Patients/specimens fulfilling the following criteria were included:

1. Patients clinically suspected of tuberculosis.
2. Patients presenting with symptoms suggestive of TB.
3. Patients from whom an appropriate clinical specimen was submitted for laboratory testing.
4. Specimens received during the study period.
5. Specimens adequate for laboratory processing.

Exclusion criteria

The following were excluded:

1. Specimens without adequate clinical information.
2. Unlabelled or incorrectly labelled specimens.
3. Grossly inadequate specimens.
4. Leaking or improperly transported specimens.
5. Duplicate specimens submitted without a clinical indication for repeat testing.
6. Specimens insufficient for the required laboratory investigations.
7. Specimens yielding invalid CBNAAT results when repeat testing was not possible.

Note: These exclusion criteria were not explicitly provided in the uploaded one-page manuscript and should therefore be verified against the actual laboratory protocol before submission.

Ziehl–Neelsen staining

Clinical specimens were subjected to ZN staining for detection of acid-fast bacilli. Smears were examined microscopically and categorized as positive or negative according to standard laboratory reporting procedures.

CBNAAT

CBNAAT was performed for molecular detection of *M. tuberculosis* and rifampicin resistance. The assay provides automated molecular detection and identifies mutations associated with rifampicin resistance.

WHO recommends Xpert MTB/RIF as an initial diagnostic test for TB and rifampicin resistance in appropriate patients with suspected pulmonary TB.

Assessment of drug resistance

Rifampicin resistance was assessed using the CBNAAT result. The original paper additionally reports 100 isoniazid-resistant cases. However, the

supplied methodology does not specify the assay used for detection of isoniazid resistance.

Therefore, in the final manuscript, isoniazid resistance should be reported only after specifying the actual method used, such as line-probe assay, Xpert MTB/XDR, phenotypic drug-susceptibility testing or another validated molecular method.

Data analysis

Data were summarized using frequencies and percentages. The diagnostic positivity rates were calculated using the total number of tested samples as the denominator.

Because culture or another validated reference standard was not provided in the supplied dataset, diagnostic sensitivity and specificity were not calculated.

RESULTS

A total of **2965 samples** obtained from patients suspected of tuberculosis were investigated during the study period. All samples underwent ZN smear microscopy and CBNAAT. The original study reported 128 smear-positive samples and 504 CBNAAT-positive samples.

Table 1. Distribution of study samples

Parameter	Number	Percentage
Total samples tested	2965	100.00%

A total of 2965 samples were collected and investigated over the one-year study period. The large sample size provides substantial routine laboratory data for assessing the additional diagnostic yield obtained through CBNAAT.

Table 2. ZN smear microscopy results

ZN smear result	Number	Percentage
Positive	128	4.32%
Negative	2837	95.68%
Total	2965	100.00%

ZN smear microscopy detected acid-fast bacilli in 128 samples, corresponding to 4.32% of the total samples. The remaining 2837 samples (95.68%) were smear negative. Thus, the majority of clinically suspected cases did not demonstrate acid-fast bacilli by conventional microscopy.

Graph 1: ZN smear microscopy results

Table 3. CBNAAT results

CBNAAT result	Number	Percentage
MTB detected	504	17.00%
MTB not detected	2461	83.00%
Total	2965	100.00%

CBNAAT detected MTB in 504 of the 2965 samples, giving a positivity rate of 17.00%. MTB was not detected in 2461 samples (83.00%). The molecular detection rate was therefore substantially higher than the positivity rate obtained by ZN microscopy.

Table 4. Comparison between ZN microscopy and CBNAAT

Diagnostic method	Positive	Negative	Positivity rate
ZN microscopy	128	2837	4.32%
CBNAAT	504	2461	17.00%

CBNAAT detected 504 positive cases compared with 128 positive cases detected by ZN microscopy. Thus, there were **376 more positive detections by CBNAAT** than by smear microscopy. This demonstrates the substantially greater detection yield of molecular testing in the studied population.However, because the individual-level cross-tabulation between smear and CBNAAT results was not supplied, it is not possible to state exactly

how many of the 504 CBNAAT-positive cases were smear negative.

Table 5. Reported rifampicin-resistance findings

Parameter	Number	Percentage of total samples
Rifampicin resistant	103	3.47%
Total samples	2965	100.00%

Rifampicin resistance was reported in 103 samples, representing 3.47% of the total 2965 samples. Since CBNAAT/Xpert MTB/RIF specifically detects rifampicin resistance, this finding is directly relevant to the molecular diagnostic component of the study.

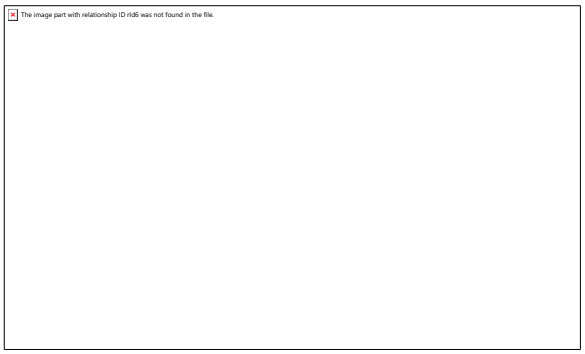
Table 6. Reported isoniazid-resistance findings

Parameter	Number	Percentage of total samples
Isoniazid resistant reported	100	3.37%
Total samples	2965	100.00%

The original study reports 100 isoniazid-resistant cases. However, the method used to establish isoniazid resistance is not described in the supplied manuscript. Therefore, these cases should be retained in the final paper only after the additional diagnostic method is confirmed. They should **not be described as isoniazid resistance detected by conventional CBNAAT/Xpert MTB/RIF**.

Table 7. Overall summary of findings

Parameter	Finding
Total samples	2965
ZN-positive samples	128 (4.32%)
CBNAAT-positive samples	504 (17.00%)
Additional positive detections by CBNAAT compared with ZN	376
Rifampicin-resistant samples reported	103
Isoniazid-resistant samples reported	100*



Graph 2: Overall summary of findings

The overall results demonstrate that CBNAAT produced a considerably greater TB detection yield than ZN smear microscopy. Rifampicin resistance was identified in 103 samples. The additional 100 isoniazid-resistant cases reported in the original dataset require clarification regarding the method of detection.

DISCUSSION

The present study evaluated the diagnostic utility of CBNAAT among 2965 patients suspected of tuberculosis at a tertiary-care hospital in Jharkhand. The major finding was that CBNAAT detected MTB in 504 samples (17.00%), whereas ZN smear microscopy detected only 128 samples (4.32%). Thus, molecular testing identified 376 more positive samples than smear microscopy.

The findings are consistent with the established limitations of conventional smear microscopy. Although ZN microscopy remains an important and inexpensive diagnostic technique, its sensitivity is limited, particularly in paucibacillary disease. Patients with relatively low bacillary loads may therefore have negative smear results despite having microbiologically detectable TB [5,6].

The considerably higher positivity obtained through CBNAAT in the present study supports the use of molecular testing for improving case detection. Boehme et al. reported that Xpert MTB/RIF detected 90.3% of culture-confirmed TB cases compared with 67.1% detected by microscopy [10]. They also demonstrated that Xpert detected a substantial proportion of smear-negative, culture-positive cases.

The systematic review by Steingart et al. similarly demonstrated high diagnostic accuracy of Xpert MTB/RIF, with pooled sensitivity of approximately 89% and specificity of 99% when used as an initial test [11]. The review also found that Xpert increased TB detection compared with smear microscopy.

The present study cannot provide sensitivity and specificity estimates because culture or another validated reference standard was not included in the supplied data. Therefore, the observed 17.00% CBNAAT positivity should be interpreted as a **positivity rate and not as sensitivity**. Similarly, the 4.32% smear positivity rate should not be interpreted as smear sensitivity.

The additional diagnostic yield of molecular testing is clinically important. Of the 2965 samples, only 128 were smear positive, while 504 were CBNAAT positive. This indicates that a substantial number of patients with suspected TB would not have been microbiologically identified if diagnosis had relied exclusively on smear microscopy. Patients referred to such centres may have prolonged disease, previous treatment, low bacillary loads or complex clinical presentations. Rapid molecular testing can therefore complement conventional microscopy and improve laboratory confirmation.Another important finding was the identification of rifampicin resistance in 103 samples. Rifampicin resistance is an important marker of drug-resistant TB and requires timely evaluation. The Xpert MTB/RIF platform was specifically developed to detect MTB and rifampicin resistance simultaneously [7,8].

In the multicentre study by Boehme et al., Xpert MTB/RIF demonstrated 94.4% sensitivity and 98.3% specificity for rifampicin-resistance detection [10]. These findings support the clinical value of rapid molecular resistance screening.The importance of rapid rifampicin-resistance detection is also reflected in current WHO recommendations. Xpert MTB/RIF is recommended as an initial diagnostic test for TB and rifampicin resistance in appropriate patients with suspected pulmonary TB [9].

The present study therefore demonstrates two important advantages of CBNAAT: increased MTB detection compared with smear microscopy and rapid detection of rifampicin resistance.The study's findings also have implications for infection-control practices. Earlier microbiological confirmation allows healthcare providers to recognize infectious TB more rapidly and may reduce unnecessary delays in isolation and treatment. Earlier identification of rifampicin-resistant disease also facilitates referral to appropriate drug-resistant TB management pathways.The original manuscript reports 100 isoniazid-resistant cases in addition to the 103 rifampicin-resistant cases. This observation is potentially important but requires methodological clarification. Conventional Xpert MTB/RIF is designed to detect MTB and rifampicin resistance; it does not directly determine isoniazid susceptibility. WHO guidance recommends additional drug-susceptibility testing when information about resistance to isoniazid and other drugs is required.Consequently, the manuscript should identify the actual test used to establish isoniazid resistance. If line-probe assay, Xpert MTB/XDR, phenotypic DST or sequencing was performed, that methodology should be added to the Methods section and the results should be presented separately from the CBNAAT results.

If no additional test was performed, the 100 isoniazid-resistant cases should be removed from the resistance analysis rather than being attributed to CBNAAT. This correction is important to maintain the scientific validity of the manuscript.

The denominator used for resistance reporting should also be clarified. In the present manuscript, 103 rifampicin-resistant samples represent 3.47% of all 2965 tested samples. However, for clinical interpretation, resistance is generally more informative when reported as a proportion of confirmed TB cases. Since the supplied data do not explicitly provide the relationship between the 103 resistant cases and the 504 CBNAAT-positive cases, the percentage among confirmed TB cases should not be calculated without verifying the original dataset.

Similarly, the proportion of isoniazid resistance among confirmed TB cases cannot be established from the supplied manuscript.

Another limitation is the absence of specimen-wise information. The diagnostic performance of molecular testing can vary depending on whether the specimen is sputum, gastric aspirate, lymph-node aspirate, pleural fluid, CSF or another clinical material. Vadwai et al. demonstrated variation in Xpert performance across extrapulmonary specimen types [12].The present study would therefore be strengthened by reporting the type and number of specimens tested. If the original laboratory database contains this information, it should be incorporated into the final manuscript.The absence of a smear/CBNAAT cross-tabulation is another

limitation. Although the study demonstrates that CBNAAT detected 504 cases and microscopy detected 128, it cannot determine from the aggregate numbers how many cases were simultaneously positive by both methods and how many were exclusively CBNAAT positive. Individual-level paired results would permit more meaningful analysis.Despite these limitations, the large number of specimens and the routine tertiary-care setting provide useful real-world information regarding the diagnostic yield of molecular TB testing. The substantial difference between smear and CBNAAT positivity supports the continued integration of rapid molecular diagnostics into TB-control programmes.

Overall, the findings are consistent with published evidence demonstrating that Xpert MTB/RIF can improve TB detection compared with microscopy and provide rapid information regarding rifampicin resistance [10,11]. Molecular testing should therefore form an important component of modern TB diagnostic algorithms, while conventional culture and appropriate drug-susceptibility testing remain important where indicated.

CONCLUSION

1. **CBNAAT demonstrated a substantially higher TB detection yield than ZN smear microscopy**, identifying 504 (17.00%) MTB-positive samples compared with 128 (4.32%) smear-positive samples among 2965 suspected cases.
2. **CBNAAT provides rapid detection of MTB together with rifampicin resistance**, making it valuable for early diagnosis and identification of patients requiring evaluation for drug-resistant TB.
3. **Additional drug-susceptibility testing remains necessary for resistance to drugs not assessed by conventional Xpert MTB/RIF**, particularly isoniazid. The 100 isoniazid-resistant cases reported in the original dataset should therefore be linked to and described according to the specific additional test used.

Declarations
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Ethical Approval: Not applicable (review article).

Consent for publication: There is consent for the publication of this paper.
Authors' contributions: All authors contributed equally.

LIMITATIONS

1. A culture or other validated reference standard was not available in the supplied dataset; therefore, sensitivity, specificity, positive predictive value and negative predictive value could not be calculated.
2. Individual-level smear and CBNAAT results, demographic characteristics and specimen-wise distribution were not provided, limiting detailed subgroup and paired diagnostic analysis.
3. The laboratory method used to establish the reported 100 isoniazid-resistant cases was not described and requires clarification before the manuscript can be considered complete.

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