Health Technology Assessment on Cost-per-test comparison of molecular (real-time PCR-based) diagnostic platforms for tuberculosis in India

Policy Brief

Summary

Timely and accurate diagnosis is essential for tuberculosis (TB) control, enabling early treatment and reducing transmission. Molecular diagnostic tests are recommended by the World Health Organization (WHO), but their cost remains an important consideration for large-scale public sector implementation in resource-constrained settings such as India. This study conducted an economic evaluation within a HTA framework to estimate and compare the cost per test of four molecular TB diagnostic platforms GeneXpert MTB, Truenat MTB, Quantiplus MTB, and Pathodetect MTB. A health system perspective micro-costing approach was used and facility level data collected from ICMR-NIRT. Costs included consumables, human resources, equipment and overheads, assuming a reference volume of 50 tests per day. Quantiplus had the lowest cost per test, followed by Pathodetect, Truenat and GeneXpert. Consumables were the major cost driver across platforms and higher testing volumes reduced per-test costs. These findings provide evidence to support procurement and implementation decisions for molecular TB diagnostics in the public health system.

Introduction

India continues to face a high burden of TB, and the widespread use of GeneXpert for TB diagnosis presents significant cost challenges due to its high per-test cost.[1] In comparison, newer molecular platforms including RT-PCR based assays such as Quantiplus and Pathodetect, as well as chip-based systems like Truenat offer the potential for lower-cost testing.[2,3,4] However, their diagnostic performance, particularly in terms of sensitivity and specificity varies. There is a need to assess whether these affordable alternatives can maintain diagnostic accuracy while being scalable for national implementation under the National TB Elimination Programme (NTEP). This evaluation is essential to guide resource allocation and improve TB detection and treatment outcomes in India.

Sensitivity and specificity of molecular diagnostic tools
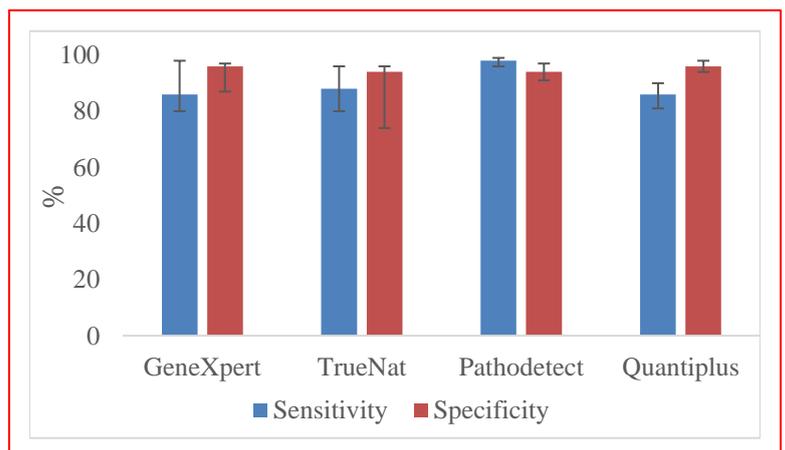
The diagnostic performance of GeneXpert, Truenat, Pathodetect, and Quantiplus, assessed against MGIT culture as the reference standard, is summarised in the Figure. All evaluated molecular diagnostic tests demonstrated sensitivity and specificity estimates within ranges considered acceptable for programmatic use for the detection of pulmonary TB. The range of sensitivity and specificity of the existing tests (GeneXpert and Truenat derived from multiple studies. For Pathodetect and Quantiplus derived from single study and hence the certainty of evidence may be lower than that for GenXpert and Truenat.

Cost of various molecular diagnostic tools
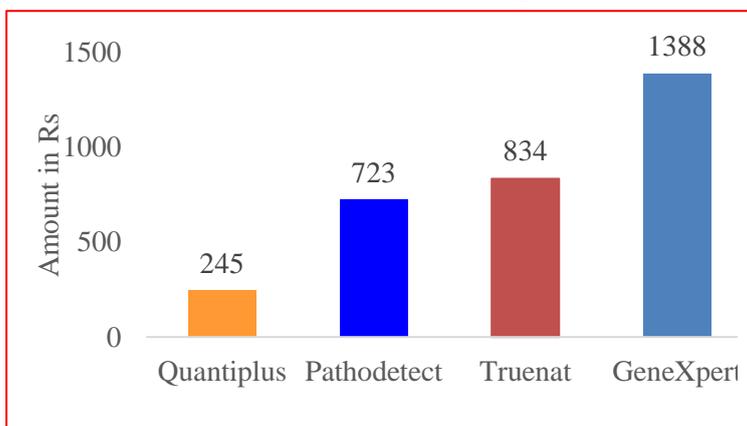
The cost per test for each diagnostic tools was estimated assuming a daily testing volume of 50 samples. Cost was calculated including different components such as test kits, human resource, equipment, non-laboratory consumables and overheads. Across platforms, consumable constituted the largest proportion of total per-test cost. Consumable and overall per-test costs were higher for GeneXpert and lower for Quantiplus. However, the Quantiplus detects MTB only in the present form, while Truenat and Pathodetect detect MTB and rifampicin drug resistance testing. In addition, Pathodetect and Quantiplus machines have a higher testing capacity of per day is added advantage.

The policy brief is based upon the Health Technology Assessment on Cost-per-test comparison of molecular (real-time PCR–based) diagnostic platforms for tuberculosis in India

Recommendations

❖ The molecular diagnostic tests for pulmonary TB namely, GeneXpert, Truenat, Pathodetect and Quantiplus show similar range of sensitivity and specificity for detection of Mycobacterium Tuberculosis (MTB) from sputum specimen compared with the gold standard test MGIT culture. The sensitivity and specificity of all four tests are within the WHO acceptability criteria.

❖ The cost of testing ~100 patients (including both symptomatic and asymptomatic individuals) by the molecular diagnostic tests was found to be Rs 34,091 for Quantiplus, Rs.72,300 for Pathodetect and Rs. 83,400, for Truenat. The advantage of Pathodetect is that the kit offers additional drug resistance testing for RIF and INH. For 100 samples 2 truenat machines will be required to be deployed in the facility.

❖ Truenat machines are closed systems, which are compatible only with Truenat MTB detection devices available in block level under the NTEP. Similarly, Pathodetect is a closed device, which can be used only with Mylab Compact XL/Q machine. However, Quantiplus is an open kit, which can be used with any RT-PCR machines available in district as well as tertiary care hospitals.

❖ The State and the Central government may negotiate the prices before procurement for further cost saving.

References

1. Lawn, S. D., *et al.* (2011). Xpert® MTB/RIF assay: Development, evaluation and implementation of a rapid molecular diagnostic for tuberculosis and rifampicin resistance. *Future Microbiology, 6*(9), 1067–1082.
2. Inbaraj, L. R., *et al.* (2025). Truenat MTB assays for pulmonary tuberculosis and rifampicin resistance in adults and adolescents. *Cochrane Database of Systematic Reviews, 3*, CD015543.
3. Jayaprakasam, M., *et al.* (2025). Diagnostic accuracy of real-time PCR assay Quantiplus® MTB FAST for detection of adult pulmonary tuberculosis: A multicentric study. *Indian Journal of Medical Research, 161*(4), 346–353.
4. Choudhary, H., et al. (2025). Multicentric validation of Pathodetect™ MTB RIF & INH assay for detection of Mycobacterium tuberculosis and drug resistance. Indian Journal of Medical Research, 161(5), 482–490.
5. Penn-Nicholson, A., et al. (2021). A prospective multicentre diagnostic accuracy study for the Truenat tuberculosis assays. European Respiratory Journal, 58(5), 2100526.