

Health Technology Assessment on RT-PCR based diagnostic tools for tuberculosis case detection in India



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Policy Brief

Summary

Given India's high TB burden, this Health Technology Assessment (HTA) compared the costs and diagnostic performance of RT-PCR-based tools Quantiplus, GeneNAT, and PathoDetect against GeneXpert. Using a decision tree and a hypothetical cohort of 1,000 presumptive TB cases, the analysis showed GeneXpert was most expensive (₹1.44 million), while Quantiplus (₹0.20M), GeneNAT (₹0.72M), and PathoDetect (₹0.67M) were significantly cheaper. Per-test savings were ₹1232 (Quantiplus), ₹719 (GeneNAT), and ₹762 (PathoDetect). PathoDetect matched GeneXpert in detecting true TB cases (249), while Quantiplus and GeneNAT missed 12% and 2%, respectively, but had higher specificity. About 90% of costs came from lab consumables. The study concluded that RT-PCR based diagnostics, particularly PathoDetect, offer a less costly and accurate alternative to GeneXpert and could be integrated as add on diagnostic tools in India's National TB Elimination Programme.

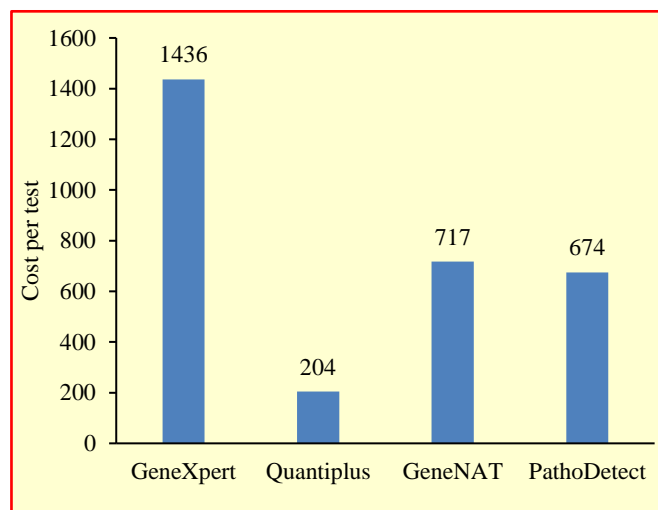
Problem Statement

India continues to face a high burden of tuberculosis (TB), and the widespread use of GeneXpert for TB diagnosis presents significant cost challenges due to its high per-test expense.¹ In contrast, emerging RT-PCR-based diagnostic tools Quantiplus, GeneNAT, and PathoDetect show promise in significantly reducing costs.^{2,3,4} However, their diagnostic performance, particularly in terms of sensitivity and true case detection, varies. There is a pressing 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.

Diagnostic accuracy of RT-PCR based diagnostic tests to detect pulmonary TB cases

	Sensitivity 95% CI	Specificity 95% CI	PPV (%)	NPV (%)
Quantiplus	85.9 (81.0-90.0)	96.3 (94.0-98.0)	88.8	95.3
GeneNAT	95.8 (85.8-99.5)	97.8 (95.2-99.2)	93.7	98.6
PathoDetect	98.1 (96.1-99.2)	94.2 (91.0-96.5)	85.2	99.3
GeneXpert	98.0 (96.0-99.6)	96.0 (93.9-97.9)	89.3	99.3

Cost per test of RT-PCR based diagnostic tests to detect pulmonary TB cases



Base case results of RT-PCR based diagnostic tests and GeneXpert for 1000 presumptive TB cases

	Cost per test	Total no. of cases [95% CI]	Cost diff	No. of cases (%)
True positives				
Quantiplus	204	218 [206-229]	-1232	-31 (-12)
GeneNAT	717	243 [218-253]	-719	-6 (-2)
PathoDetect	674	249 [244-252]	-762	0 (0)
GeneXpert	1436	249 [244-253]		
True negatives				
Quantiplus	204	718 [701-731]	-1232	2 (0.3)
GeneNAT	717	730 [710-740]	-719	13 (1.9)
PathoDetect	674	703 [679-720]	-762	-13 (-1.9)
GeneXpert	1436	716 [700-730]		

Recommendations

- ❖ PathoDetect is a cost-effective and accurate alternative to GeneXpert and is already in use under NTEP.
- ❖ Quantiplus and GeneNAT can be considered for specific settings prioritizing affordability and decentralization.
- ❖ Strategic integration of RT-PCR tools can strengthen the TB diagnostic network, reduce costs, and enhance case detection under NTEP.

References

1. Parwati I, et al. (2024) Evaluation of a real-time PCR assay performance to detect Mycobacterium tuberculosis, rifampicin, and isoniazid resistance in sputum specimens: a multicenter study in two major cities of Indonesia. *Frontiers in Microbiology*. 2024; 15:1372647.
2. Indian Council of Medical Research. January 2025. Diagnostic validation of an open RT-PCR test “Quantiplus® MTB FAST Detection Kit” (Huwel Lifesciences) compared to the microbiological reference standard for detection of adult pulmonary tuberculosis.
3. Indian Council of Medical Research. 10th July 2024, Multicentric evaluation of the PathoDetect™ test for the detection of tuberculosis and drug resistance to rifampicin and isoniazid in individuals suspected of having pulmonary TB and MDR-TB.
4. Rajiv Gandhi Medical College & Chhatrapati Shivaji Maharaj Hospital, Thane. 2024. Field evaluation report of Smart Sure™ MTB (GeneNAT) screening kit.

The policy brief is based upon the Health Technology Assessment on RT-PCR based diagnostic tools for additional Tuberculosis case detection in India and can be found on the link <https://dhr.gov.in/sites/default/files/>