Health Technology Assessment on Cost comparison of Molecular Diagnostic Platforms (Real-Time PCR based) for Tuberculosis in India

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Policy Brief

Summary

GeneXpert and Truenat are NAAT based closed RT-PCR systems which can perform MTB detection along with testing for rifampicin-resistance, while Quantiplus and MERINAT are open RT-PCR assays that can be run on any thermo cyclers but can only detect MTB. An additional truenat test is to be done for rifampicin-resistance testing.

All four platforms demonstrated acceptable diagnostic performance, with sensitivity ranging from 86% to 90% and specificity from 93% to 96% against MGIT liquid culture for Mycobacterium Tuberculosis.

At an estimated workload of approximately 50 tests per day, the estimated cost per test for MTB detection and rifampicin-resistance testing was ₹873 for GeneXpert, ₹701 for Truenat, ₹495 for Quantiplus, and ₹503 for MERINAT.

The indicative procurement analysis suggested that, since additional rifampicin-resistance testing is to be performed using Truenat, and considering that adoption of a new diagnostic strategy requires additional logistical, training, and procurement considerations, the kit price for Quantiplus and MERINAT would need to be procured approximately at ₹142 per test, inclusive of GST. Under the assessed reagent-rental model, the indicative threshold kit price for Quantiplus was approximately ₹153 per test, inclusive of GST.

Problem Statement

Tuberculosis (TB) remains a major public health challenge in India, requiring accurate, rapid and affordable molecular diagnostic strategies.

India has expanded access to molecular diagnostic technologies for TB, through established platforms such as GeneXpert and Truenat. However, the relatively high cost of molecular testing presents an important challenge for the sustainable expansion of TB diagnostic services.[1]

Open-system RT-PCR assays for TB diagnosis may have the potential to reduce the cost of Mycobacterium Tuberculosis (MTB) detection by utilizing the existing real -time PCR-based laboratory infrastructure. However, their economic value depends not only on the initial cost of MTB detection but also on their diagnostic performance, laboratory workload, infrastructure requirements and their ability to perform rifampicin-resistance testing.[2,3]

This Health Technology Assessment (HTA) compared the diagnostic accuracy and health-system costs of GeneXpert, Truenat, Quantiplus and MERINAT for the detection of Mycobacterium tuberculosis and rifampicin-resistance.

This HTA provides evidence to inform procurement and deployment decisions for molecular TB diagnostic platforms under the National TB Elimination Programme (NTEP).

Policy Brief

Diagnostic accuracy and cost of diagnostics platforms

Performance characteristic	GeneXpert	Truenat	Quantiplus	MERINAT
Sensitivity	90% *	88%*	86%	87%
Specificity	95%*	94%*	96%	93%
Cost per test (including rifampicin testing)	873	701	495	503

**Median value*

All four platforms demonstrated WHO acceptable diagnostic accuracy against the MGIT liquid-culture reference standard.

At the current prevailing price for the kits and including other resources, the cost per test of MTB detection along with rifampicin resistance is ₹ 873 for GeneXpert, ₹ 701 for Truenat, ₹ 495 for Quantiplus and ₹ 503 for MERINAT.

Since the existing open RT-PCR diagnostic kits do not test for rifampicin resistance, an additional Truenat test would continue to be used for testing rifampicin resistance which entails additional cost. Hence a shift from existing diagnostic strategies to newer open RT-PCR kits entails significant operational, logistical, procurement and workforce adaptation challenges associated with introduction of the technology nationwide. This suggests that, a substantial price reduction is required to justify such a programmatic shift.

A minimum threshold of 45% cost savings was established as the target benchmark necessary to justify this nationwide diagnostic paradigm shift. The price of the open RT-PCR MTB detection kits may thus, be set at Rs 142 per test to justify adoption of open RT-PCR kits in the NTEP program.

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 (PTB): a multi-centric study. Indian J Med Res. 2025;161(4):346–353.
4. Indian Council of Medical Research (ICMR). (2025). Diagnostic validation of the open RT-PCR test "MERINAT kit version 3.0" (Meril Diagnostics Pvt Ltd) compared to the microbiological reference standard for detection of adult pulmonary tuberculosis (PTB). Indian Council of Medical Research.

Indicative Procurement Threshold

₹142 per test including GST for procurement of open RT-PCR MTB detection Kits

and

₹153 per test including GST for procurement of open RT PCR MTB detection Kits under the assessed reagent-rental model

These are indicative threshold prices derived from the HTA costing assumptions

Recommendations

Quantiplus and MERINAT demonstrated acceptable diagnostic accuracy with substantially lower estimated costs for MTB detection compared with Truenat.

An additional Truenat test required for rifampicin-resistance detection, and this impacts the total cost saving while using open RT-PCR assays. The additional cost along with operation and logistical challenges should be considered in procurement decisions.

For Open RT-PCR assays that can detect MTB along with rifampicin resistance, the kits may be procured at a price of ₹260 per test (including GST)

If an additional platform (Truenat) is required for resistance testing, then the Open RT-PCR kit procurement price should be reduced to ₹142 pet test including GST and ₹153 per test including GST under the reagent rental model for Quantiplus.

The policy brief is based upon the Health Technology Assessment on Cost comparison of Molecular Diagnostic Platforms (Real-Time PCR based) for Tuberculosis in India and can be found on the link:https://dhr.gov.in/sites/default/ files/