

Sustainable interventions for improvement in external quality assurance (EQA) of Truenat MTB/RIF, Telangana State, India

Abstract

Background and challenges to implementation: National TB Elimination program (NTEP) in India has rapidly scaled up Truenat MTB/RIF testing as upfront molecular testing for TB diagnosis. External Quality Assurance (EQA) is a key step especially when new Nucleic Acid Amplification Test (NAAT) being offered. NTEP has developed EQA program by using CDC's dried tube technology for NAAT and evaluated for a score of 100. Score more than 80 is considered satisfactory while score less than 80 as unsatisfactory. Telangana State recorded poor EQA for Truenat Program in 2021 and 2022. Key challenges are frequent changes of staff at field level, equipment maintenance, limitation of knowledge and training for lab staff, inadequate site Monitoring visits.

Intervention or response: Communication mechanism was established whenever there was change in the staff operating Truenat machines. Post EQA visits were conducted for poor performing sites and the root cause analysis (RCA) was done. Based on the RCA corrective action and recommendations were given to the sites and implementation was monitored. Refresher training was conducted for all laboratory supervisors and technicians in 2022. Monthly virtual sessions were conducted for regular monitoring. Established data cell for analysis of monthly quality indicators and presented in virtual sessions to the sites. The State developed internal Quality checklist for continuous monitoring. Close coordination with the respective equipment vendors was maintained to resolve site wise issues.

Results/Impact: Stepwise improvement recorded for EQA performance from 2021 to 2023 in the following figure below

Conclusions: Telangana state of India has showed a significant improvement in all parameters of EQA in Truenat testing by implementing effective monitoring mechanism.

Keywords: External quality assurance, sustainable interventions, Truenat MTB rif assay

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Introduction

The National TB Elimination Program (NTEP) in India has made significant strides in combating tuberculosis (TB) through the adoption of advanced diagnostic technologies. One such breakthrough is the Truenat MTB/RIF testing platform, a rapid molecular test for TB that has been scaled up as part of the NTEP's effort to provide accurate and timely TB diagnosis. The introduction of Truenat testing marked a major shift toward molecular-based diagnostic methods, improving early detection and treatment of TB across India. The Availability of Truenat has made TB diagnostics accessible and did not require additional infrastructural arrangement like Air conditioner, back up for electricity.¹ The test also poses an advantage of quick results in case of MTB not detected (40min) unlike other molecular tests. Truenat MTB/RIF, a molecular diagnostic tool, is used for detecting Mycobacterium tuberculosis (MTB) and rifampicin resistance in patients suspected of having TB. It is a critical tool for diagnosing TB in a country like India, which bears one of the highest TB burdens globally. As part of its drive to scale up TB diagnosis, NTEP adopted Truenat testing, but ensuring its quality was an immediate challenge.

However, the effectiveness of these technologies' hinges on the quality of testing and its consistent application across the country. In this context, External Quality Assurance (EQA) plays a pivotal role, ensuring that the diagnostic results are accurate, reliable, and reproducible. This article explores the challenges faced by Telangana

in implementing and improving the quality of Truenat MTB/RIF testing, the interventions put in place, and the results achieved over three years i.e 2021,2022 & 2023.

External Quality Assurance (EQA) is essential in any testing system, especially when new technologies like Nucleic Acid Amplification Tests (NAATs) are introduced. NAATs offer significant advantages in terms of speed and accuracy compared to conventional methods.

In a study conducted in Uganda, truenat showed acceptable sensitivity and specificity when compared with other tests.²

Jay shree et al,³ in a study on operational feasibility and its impact in National TB Program of India showed that Truenat increased case detection and laboratory technicians were comfortable in truenat testing.³

However, they require meticulous handling, appropriate operational knowledge, and rigorous quality control. NTEP, in partnership with the Centers for Disease Control and Prevention (CDC), developed an EQA program to maintain the quality of Truenat testing. This program uses CDC's Dried Tube Technology (DTT) to evaluate testing sites and assigns a score based on the performance of the labs.

A score of 100 is considered excellent, while a score of less than 80 is deemed unsatisfactory. Telangana State, despite being one of the key regions for implementing Truenat testing, faced challenges

in maintaining quality standards, with the state recording poor EQA scores in 2021 and 2022.

Methodology

The indicators in External Quality Assurance of NAAT were listed for both the years 2021 and 2022. The factors were analysed Qualitatively in a fish bone diagram (Figure 1).

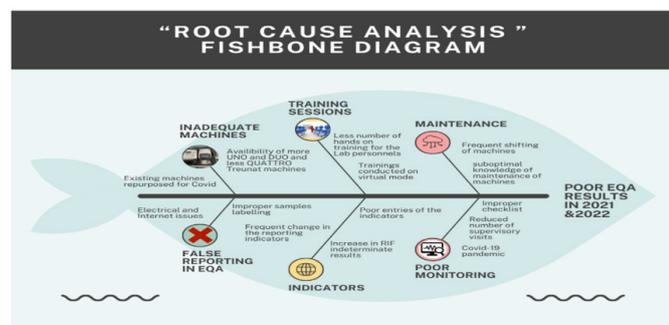


Figure 1 Root cause Analysis for Poor EQA results in 2021 & 2022.

Challenges faced in Truenat testing implementation

Several factors contributed to the challenges faced by Telangana in the successful implementation of Truenat testing:

- i. **Frequent changes in field staff:** The turnover of laboratory technicians and staff at the field level was one of the primary obstacles to maintaining consistent testing standards. When experienced staff left, it often led to disruptions in testing quality, as new staff required time to familiarize themselves with the equipment and procedures.
- ii. **Equipment maintenance:** Regular maintenance of Truenat machines is critical for their proper functioning. However, frequent issues with machine calibration, wear and tear, and maintenance challenges often led to inconsistencies in test results, affecting the overall quality of testing.
- iii. **Limited knowledge and training for lab staff:** While the Truenat machines were introduced to many districts, laboratory staff often lacked adequate training in both the technical and operational aspects of using the technology. In some cases, this led to improper sample handling, incorrect interpretation of results, and failure to adhere to quality control standards.
- iv. **Inadequate site monitoring visits:** Monitoring visits by quality assurance teams were often insufficient. As a result, several sites faced delays in identifying and addressing issues related to Truenat testing, leading to poor performance in the EQA assessments.

These challenges were compounded by the scale of implementation, with several new districts and healthcare facilities adopting Truenat testing for the first time. The result was a significant dip in Telangana's EQA scores for Truenat testing in 2021 and 2022.

Intervention and response: addressing the challenges

Recognizing the need to address these challenges, the Telangana State TB control program implemented a series of corrective actions and interventions to improve the quality of Truenat testing. These steps were aimed at strengthening the monitoring mechanisms, providing training to lab staff, and ensuring that issues related to equipment and personnel turnover were effectively managed.

- i. **Establishing a communication mechanism:** One of the key actions taken was the establishment of a robust communication mechanism. Whenever there was a change in the staff operating the Truenat machines, the state ensured that there was prompt communication with the newly assigned staff. This helped mitigate disruptions and ensured that the necessary support was provided.
- ii. **Post-EQA visits and root cause analysis (RCA):** For sites that performed poorly in the EQA assessments, the Telangana TB control program conducted post-EQA visits. These visits involved conducting a thorough Root Cause Analysis (RCA) to understand the underlying reasons for poor performance. Whether it was due to equipment malfunction, staff inexperience, or operational issues, the RCA helped pinpoint the exact causes.
- iii. **Corrective actions and recommendations:** Based on the RCA, corrective actions were taken for each identified issue. Recommendations for improvement were provided to the sites, and the implementation of these corrective actions was closely monitored. This process was crucial for driving improvements at the ground level.
- iv. **Refresher training for lab staff:** In 2022, the state organized refresher training programs for laboratory supervisors and technicians. These training sessions were designed to update the staff on the latest best practices for using Truenat testing, ensuring better sample handling, result interpretation, and adherence to quality control standards.
- v. **Monthly virtual monitoring sessions:** To ensure continuous monitoring and improvement, monthly virtual sessions were held with all testing sites. These sessions allowed for the discussion of common challenges, sharing of best practices, and providing support to staff facing difficulties in maintaining quality standards.
- vi. **Data analysis and quality indicators:** Telangana developed an internal data cell to analyze monthly quality indicators for Truenat testing. These indicators were regularly reviewed during virtual sessions, allowing for timely identification of trends, areas of concern, and opportunities for further improvement.
- vii. **Coordination with equipment vendors:** Close coordination was maintained with the equipment vendors to resolve site-specific issues related to the Truenat machines. Ensuring that the equipment was well-maintained and functioning optimally was essential to improving the overall performance of the testing program.
- viii. **Internal Quality checklist for continuous monitoring:** An internal quality checklist was developed for continuous monitoring at the state level. This checklist was used to assess the quality of testing on an ongoing basis, ensuring that standards were consistently met across all sites.

Results and impact: stepwise improvement in EQA performance

As a result of these interventions, Telangana witnessed a stepwise improvement in its EQA performance for Truenat testing. The state's performance gradually improved from 2021 to 2023, with the EQA scores showing consistent upward trends. The improvements were seen across various parameters, including staff performance, equipment maintenance, and quality control adherence (Tables 1&2).

Table 1 Analysis of sites with satisfactory results

Truenat EQA summary over last 3 years in Telangana				
Indicators		2021	2022	2023
1	Sites participated	31	85	91
2	No of truenat machines participated	36	90	95
Numerical analysis of sites with satisfactory results				
3	Satisfactory results (sites and percentage)	25 69.40%	72 80%	92 96.80%
4	No. of sites with a score 100/100	13 36%	51 71%	84 91.30%
5	No. of sites with a score 80-90	11 31%	21 29.20%	8 8.70%
6	No. of site which gave results within turnaround time	26 72.20%	20 22%	84 88.40%
7	Analysis of sites with score of 80 or 90 and with discrepant results	12 48%	21 29.20%	8 8.70%
8	No of sites showing Rif indeterminate errors with satisfactory scores	8 32%	15 21%	2 2%

Table 2 Analysis of sites with unsatisfactory results

Numerical analysis of sites with unsatisfactory results				
1	Unsatisfactory results (sites and percentage)	11 30.60%	18 20%	3 3.20%
2	Number of sites showing error and invalids	6	7	0
3	Number of sites reporting false positives	2	1	0
4	Number of sites reporting false negatives	3	4	0
5	Number of sites showing transcriptional error	2	1	0
6	Number of sites with less than 60-80 scores	4	12	3
7	Number of sites with less than 40-60 scores	4	5	0
8	Number of sites with less than 40 scores	3	1	0
9	Number of sites showing Rif indeterminate errors with unsatisfactory scores	6 17%	12 13%	2 2%

This progress is a testament to the effectiveness of the monitoring mechanisms put in place and the state’s commitment to improving TB diagnosis and treatment. The improvements in EQA performance have not only contributed to more accurate TB diagnoses but also reinforced the state’s commitment to the broader goals of the National TB Elimination Program.

Discussion

Early diagnosis and access to TB diagnostics was the key for National TB program in India.

Availability of truenat at all districts had revolutionized the diagnosis of TB and also the Rifampicin status. David J et al had expressed that having Truenat as point of care test would be more useful taking in account of all parameters like cost and ease to use.¹

External Quality Assurance for truenat was developed by CDC’s dried tube technology for NAAT. This was conceptualized and initiated in three sites of Telangana in 2020 as a pilot mode.⁴

There was a root cause analysis done by a team of experts at 3 sites in early 2022 to the state. In order to scale up, state purchased additional machines. Poor training of staff on technicalities and operations on the newly installed machines have led to erroneous results initially. Hands on training led to improved services and decreased errors.

The trainings were conducted as follows

A total of 6 batches were conducted to senior TB laboratory supervisor (STLS) with a batch size of 15. Hands on training were given with experts from National laboratories, Foundation of innovative and new diagnostics (FIND) and the vendor themselves.

The training was comprehensive including technical and operational aspects of Truenat testing for MTB and RIF which included daily maintenance, weekly maintenance and monthly maintenance.

Record keeping and data work was also discussed during the training. This actually helped in trouble shooting when machine shit down or for any service pending.

The training was given to all master trainers who in turn would train the lab technicians in their respective districts.

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Figure 2 Display of Standard operating procedure after training.

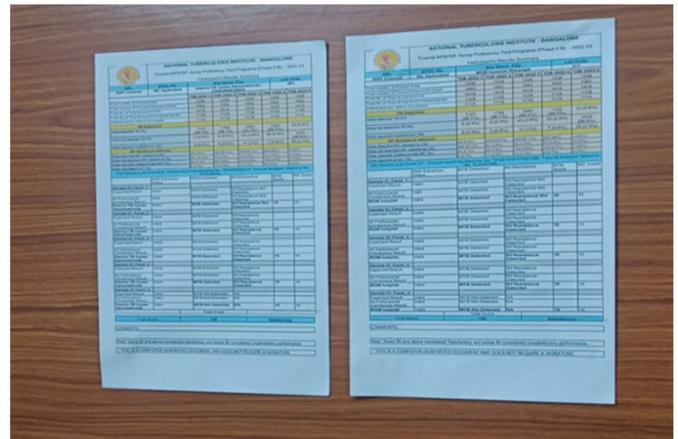


Figure 4 Display of EQA assurance in the laboratories.

Year	PHU	Health Facility ID	Monoculture confirmation test result	Result of Other tests (Xpert, FNAC, Clinical, Other, Specify)	Date of sample sent to LODIT (Not if not applicable)	Result of LODIT (If not applicable)	HIV Status	Collection Status	Status of treatment	Health facility for treatment (Specify)
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							
2023			2023 MTB not detected							

Figure 3 Mentioning CFU values for tests which showed Rifampicin indeterminate.

The policy adopted to have EQA as dried specimen for truenat had helped the program managers to address the issues at Truenat site.⁵

Conclusion

Telangana State’s efforts to improve the quality assurance of Truenat MTB/RIF testing have been highly successful. Through a combination of strong monitoring mechanisms, targeted training, and effective communication, the state has been able to address the challenges associated with Truenat testing. The significant improvement in EQA performance between 2021 and 2023 reflects the state’s commitment to strengthening its TB diagnostic capabilities. These efforts serve as a model for other regions looking to improve the quality of TB diagnosis and contribute to the national goal of eliminating tuberculosis in India. By continuing to refine its approach and implementing evidence-based interventions, Telangana is moving closer to its goal of a TB-free future.

Acknowledgement

None.

Conflicts of interest

We declare that there is no conflict of interest of any kind.

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