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Briefers for Programme Managers, Supervisory and Technical Staff to Help Optimize Truenat Testing in NTEP

April 2023

National TB Elimination Programme
Central TB Division,
Ministry of Health and Family Welfare
Government of India, New Delhi

State TB Officer (STO)/ State TB Cell (STC) role in efficient utilization of Truenat MTB-RIF assay

State TB Officer ensures the overall implementation, administration, and monitoring of National TB Elimination Programme (NTEP) diagnostic algorithm and guidelines in their respective states by:

- Guiding the STDC/IRL in consultation with NRLs to develop the annual training calendar and to periodically assess the performance of the Truenat sites and underlying challenges if M.tb invalid rates >3% and RIF indeterminate >5%.
- Forecasting enough Truenat MTB-RIF chips, if Truenat assay is used for UDST (on smear positive samples) and to meet the needs of retesting the samples in case of M.tb invalids and RIF indeterminate.
- Ensuring M.tb and RIF chips availability and release of the chips from state drug stores, as per the utilization trend and storage space with recommended temperature availability at the Truenat site.
- Human resource Management: Ensuring deployment of dedicated, and trained Laboratory Technician (LT) at Truenat sites and the availability of supervisory staff to ensure stringent monitoring.
- Equipment and site preparation: Ensuring checkpoints to monitor periodic preventive maintenance and continuation of annual maintenance contract (AMC) of equipment's at the Truenat sites.
- Quality Assurance: Reviewing the periodic monitoring and analysis of the laboratory performance indicators and bringing Truenat under an external quality assurance mechanism conducted by NTEP.
- Recording and Reporting: Regular Sensitization of Truenat lab staff to follow accurate and complete recording and reporting practices like diagnostic criteria, sample types, Presumptive TB, UDST (Universal Drug Susceptibility Testing), Key population and the results of Truenat MTB-RIF tests along with the documentation of different error types (in Trueprep, M.tb and RIF tests), CFU/ml values, Retesting results.

District TB Officer (DTO) role in efficient utilization of Truenat MTB-RIF assay

01

District TB Officer oversees the overall implementation and administration of the NTEP (National TB Elimination Programme) at the district level.

02

To perform a situational analysis of the Truenat sites:

- To ensure sufficient & trained workforce for performing NTEP services.
- Site-wise distribution of logistic support and to review the consumption of Truenat MTB RIF chips based on the workload of the Truenat sites.
- Establish and review a continuous monitoring and supervision mechanism.

03

To sensitize the STLS on effective implementation of diagnostic algorithms (NAAT testing).

- Efficient sample transportation mechanism to be monitored.
- To review effective recording and reporting mechanisms are implemented at the Truenat sites.

04

To monitor the timely collection and submission of monthly indicators to IRL (Intermediate Reference Laboratory) and STO (State TB Officer).

05

To review that preventive maintenance of the equipment/instruments is conducted periodically at the Truenat sites.

06

To monitor and review the supervisory activities of STLS related to NAAT sites.

07

To oversee the facility infrastructure and other requirements of the sites.

National Reference Laboratory (NRL) role in efficient utilization of Truenat MTB-RIF assay

NRL oversees the overall implementation, supervision, monitoring, and technical support to the Central TB Division and to assigned IRLs and Culture and DST laboratories.

Programmatic

- To conduct competency assessment and to plan refresher training(s) on a regular basis.
- To emphasize implementation of SOPs at the IRLs/C-DST laboratories including maintenance of equipment during visits as well as in review meetings.
- To identify gap areas for scope of improvement at the IRLs by analyzing the monthly indicators of Truenat performance and coordinate with the IRLs and associated Truenat sites to resolve them in a timely manner.
- To monitor, analyze and review the monthly indicators (before sending it to the CTD), to assess the states/IRL performance and to provide feedback to the CTD.

Technical

- To provide technical assistance to states and IRLs for conduct of Truenat training (including maintenance)

Quality Assurance

- To perform situation analysis on Truenat testing and on-site evaluation (OSE) visits periodically.

Recording and Reporting

- To provide periodic feedback reports to IRLs/culture and DST laboratories about monthly monitoring indicator analysis of key performance indicators (KPI's) along with recommendations.

Instrument related

- To support the IRLs and CDST labs, in case of breakdowns/machine failures by ensuring timely rectification of the site related issues.

State TB Training and Demonstration Centre (STDC) / Intermediate Reference Laboratory (IRL) role in efficient utilization of Truenat MTB-RIF assay

STDC/IRL provides technical support in the overall implementation of NTEP (National TB Elimination Programme) diagnostic services under the supervision of the State TB office.

Programmatic

- To identify the training needs and conduct comprehensive training for laboratory staff (LTs) and supervisory staff (STLS).
- To conduct competency assessment after Truenat training and to plan refresher training(s) on a regular basis.
- To monitor and review monthly indicators (before sending it to the NRL/CTD) to assess the laboratory performance.
- To identify areas of scope for improvement by analyzing the monthly indicators of Truenat performance and coordinate with the Truenat site to resolve them promptly.

Technical

- To emphasize implementation of all SOPs (Standard Operating Procedures) at the sites, including maintenance of equipment during visits as well as in review meetings.
- To provide periodic feedback to sites based on analysis of monthly laboratory performance indicators.

Quality Assurance

- To perform the situation analysis and on-site evaluation (OSE) visits periodically.
- To ensure action is taken on the recommendations provided during the last OSE visits.

Recording and Reporting

- To document the laboratory(s) performance and support the Truenat sites to improve the overall performance of Truenat laboratories based on their assessment.

Instrument related

- To detect any early signs of Truenat machine/module failure and provide feedback to the sites.
- To support the Truenat sites, in case of breakdowns/machine failures by ensuring timely rectification of the site related issues.

Senior TB Laboratory Technician (STLS) role in efficient supervision of Truenat MTB-RIF assay testing at Truenat sites

Senior TB Laboratory Technician (STLS) oversees the efficient implementation of diagnostic service delivery components in the NTEP at the assigned Truenat laboratories in the periphery at the district/sub-district level.

Programmatic

- To oversee the quality of Truenat MTB-RIF testing and smooth functioning of Truenat laboratory services.
- Regular supervision and monitoring of Truenat testing at the assigned Truenat sites.
- To ensure site-wise distribution of logistic support based on the workload and storage capacity of Truenat sites.
- To check and ensure the storage of equipments, kits, reagents, and samples at recommended conditions.
- To coordinate with STS to ensure that all diagnosed TB patients are timely initiated on treatment.
- To assess competency of Laboratory Technicians (LT) during onsite evaluation visits at the respective Truenat sites.
- To organize need based training and continuing education of the deputed laboratory technicians at Truenat sites.

Technical

- To ensure that procedural flowcharts, Job aids, SOPs and DO's and Don'ts are displayed and the LTs follow the testing procedures as per the NTEP guidelines/SOPs.
- To ensure that sites document the quality and quantity of sample received and follow the sample rejection criteria, (presence of PCR inhibitory substances like Gutka particles, Pan, Betel nuts, Tobacco particles and or blood).
- To ensure that a second sample of all MTB positive samples is sent to the linked IRL/Culture-DST Laboratories as per NTEP diagnostic algorithm.
- Supervise all designated microscopy centers at least once a month.
- To ensure proper disposal of contaminated material at the Truenat sites.

Recording and Reporting

- To routinely check the data recording, completion of test requisition forms, laboratory registers, and timely reporting of test results.
- To facilitate the timely data entry, maintaining the turnaround time and its validation in the Nikshay portal.
- To coordinate with STS and PMDT Coordinator in-updating of relevant NTEP records, line-list of DR-TB suspects and preparation of Quarterly Reports.
- Supervise that instrument related service reports/ preventive maintenance reports are filed and stored safely

Quality Assurance

- Will be responsible for maintaining the quality of sputum microscopy and smooth functioning of laboratory services.
- To monitor that Truenat monthly indicators are within the acceptable range of less than 5% and are duly filled correctly and timely communicated to linked IRL.
- To review the implementation of recommended action points based on the supervisory visits by IRL/other competent authorities during OSE visits.

Quality Assurance

- In case of breakdowns/machine failures, intimate DTO to direct samples to other Truenat facilities.
- To discuss any technical/operational issues related to Truenat sites with IRL/DTO to timely resolve the problem.
- Prior intimation/forecasting to DTO regarding scheduled maintenance, servicing of any equipments at the Truenat sites.

Laboratory Technician (LT) role in efficient testing of Truenat MTB-RIF assay at Truenat sites

Laboratory technician performs the day-to-day laboratory activities at the Truenat sites.

Programmatic

- To follow Standard Operating Procedures (SOPs) and guidelines for Truenat MTB-RIF testing as per the NTEP diagnostic algorithm.

Technical

- To document the date of sample collection, sample receiving, testing, and reporting.
- To document the sample quantity and quality and to follow the sample rejection criteria.
- To prepare fresh disinfectants daily for decontaminating the work area, equipment's, and pipettes.
- To perform the laboratory tests as per the SOP (proper liquification and incubation time prior to processing for Mycobacterium tuberculosis testing).
- To perform retesting of all samples with M.tb invalids, Errors, and RIF indeterminate as per NTEP guidelines.
- To follow Standard operating procedures (SOPs), good laboratory practices, with special emphasis on good pipetting techniques.
- To store the reagents, kits at recommended temperature ranges (till 30°C) and samples at 2-8 °C with daily recording of the storage conditions.
- Coordinate with other staff to ensure that patients with productive cough for two weeks or more and symptomatic contacts of TB patients undergo sputum examination and receive sputum containers and necessary instructions.
- To send second sample of all MTB positive samples to the linked IRL/Culture and DST Laboratories as per NTEP diagnostic algorithm.
- To maintain the stipulated turnaround time (TAT) for the sample testing and results reporting.
- To segregate and dispose of all contaminated waste materials as per the Biomedical waste management guidelines.

Recording and Reporting

- To document all the test results of MTB and Rifampicin testing including invalid, indeterminates, error types, CFU/ml values in the laboratory register.
- To prepare and check monthly Truenat indicators and its timely submission to IRL.
- Immediately update the available test results in the NIKSHAY portal.
- To maintain documents like stock registers, QC register, instrument service reports, warranty cards, etc.

Quality Assurance

- Assist STLS in implementation of NTEP Laboratory Quality Assurance.
- To run positive and negative control after every fifty tests, with new lot testing and document the same, as and when required.
- To participate in annual proficiency testing and timely communicate the panel results.

Instrument maintenance

- Daily cleaning of instruments (pre and post work).
- To ensure regular preventive maintenance and follow-up with the manufacturer for timely servicing.
- As per the recommendations,
 - Glass slider change- after every two hundred tests,
 - Replacement of the tray- after any leakage found,
 - Pipettes to be changed- after every six months.
- To inform the Manufacturer (Molbio) in case of any breakdown or instrument malfunctioning and intimate the STLS/MO regarding the same.
- Assist in implementation of new TB Diagnostic Tools in NTEP.

Developed collaboratively by National Institute for Research in
Tuberculosis (NIRT) Chennai & USAID's Infectious Disease Detection and
Surveillance (IDDS) Project under the guidance of
Central Tuberculosis Division (CTD)