Comprehensive Guidance for External Quality Assessment of TB Laboratories under National TB Elimination Programme

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

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Dr. Rajendra P. Joshi
Deputy Director General
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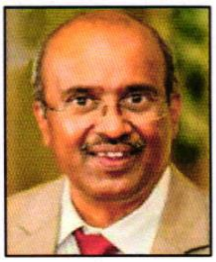

Message from DDG (TB), Central TB Division

Timely and accurate diagnosis of TB is a prerequisite for any successful TB Elimination Programme and Laboratory plays a key role in TB diagnosis, both at individual and Programmatic level. NTEP has the largest network of TB Diagnostic Laboratories globally spanning all levels in the health system. In addition to more than 5000 NAAT facilities at District /sub-District levels, presently there are more than 70 Laboratories certified for First and Second-Line Line Probe assay, 81 Laboratories are equipped to support liquid culture system, of which 64 are certified for First-Line Liquid Culture Drug Susceptibility Testing (FL LC DST), and 54 are certified for Second-Line Liquid Culture Drug Susceptibility Testing (SL LC DST). To strengthen the Quality Management Systems, 19 laboratories under NTEP are NABL accredited, and 13 additional Laboratories have initiated preparatory activities towards achieving NABL accreditation.

External Quality Assessment (EQA) is vital for monitoring Laboratory performance and maintaining quality of Laboratory services and is a valuable tool for identifying and assessing technology in use, identifying gaps in Laboratory performance and targeting training needs. An in-built routine system has been designed in NTEP for conducting EQA including all elements of internal quality control, on-site evaluation and external quality control. NRLs and IRLs conducts training, handholding, monitoring and evaluation for their respective State /District/ Block level facilities/ Laboratories.

Laboratory network has been scaled up over the years in phased manner with the introduction of newer diagnostic technologies. This required updating of the checklists and feedback formats used for supervision which mainly concentrated on smear microscopy. I appreciate the support provided by USAID's Infectious Disease Detection and Surveillance (IDDS) project to Central TB Division (CTD) in updating the supervision checklists and feedback formats in accordance with the existing Diagnostic technologies and policies of NTEP with a person-centric approach.

I am sure that the revised supervisory checklist and reporting formats, including the approaches for stringent supportive supervisory visit described in the guidance document will help the supervisory staff to comprehensively review the TB Diagnostic Care Cascade in NTEP and provide effective feedback for quality improvement with the person-centric approach.

Dr. Nishant Kumar
Joint Director (TB)
Central TB Division

Message from JD (TB), Central TB Division

Reaching the TB elimination goal requires a network of Laboratories that provide accurate and reliable TB testing for diagnosis, drug susceptibility testing, and treatment monitoring. The National TB Elimination Programme (NTEP) has established one of the most extensive TB diagnostic networks globally, spanning all health system tiers and encompassing six National Reference Laboratories (NRLs), 34 State-level Intermediate Reference Laboratories (IRLs), 58 TB C&DST Laboratories, 5090 District/sub-District level NAAT laboratories and over 23,000 microscopy facilities at the peripheral level.

Even amid the pandemic, our Laboratory network performed 36.3 lakhs NAAT tests, close to 3.3 lakh FL LPA, over 58,000 SL LPA, and 3.1 Lakh Liquid culture tests. I appreciate the efforts of TB Programme staff who showed resilience through these testing times and contributed to the testing of COVID-19 in addition to TB. Our goal is to ensure the availability of molecular diagnostics as close as possible to the community thereby ensuring access to high-quality diagnostics for each patient.

In order to ensure that the tests are performed accurately, and the results are comparable and reproducible, NTEP has had a robust Quality Assurance (QA) Programme in place. However, with the rapid expansion of the Laboratory network and the inclusion of newer WHO-recommended rapid diagnostics, it has become necessary to review and strengthen the existing External Quality Assessment (EQA) Programme across all TB laboratory tiers.

Supervision, monitoring and mentoring of linked State level Reference Laboratories and District Level Diagnostic facilities is one of the principal mandates of NRLs and IRLs. This strategic activity was severely affected due to COVID-19 pandemic. It is of paramount importance for all IRLs to analyze the District data, identify specific gaps in the TB Diagnostic Care Cascade and prioritize the field visits based on the analysis and try to address these gaps in coordination with the DTOs, WHO consultants and their respective NRLs. We need to strengthen systems for monitoring of quality assurance and time-bound delivery of laboratory services keeping patient perspective in focus.

The coming years are crucial and require a holistic approach and intensified efforts in expanding access and improving the quality of services. I am confident that the TB Program Managers and TB Laboratory Supervisors from all States and UTs will find this guidance document useful and implement it for continuous quality improvement along the TB/DR-TB Diagnostic Care Cascade in NTEP.

Dr. Ranjani Ramachandran
National Professional Officer
World Health Organization

Message from Dr. Ranjani Ramachandran

In recent years, the National TB Elimination Programme (NTEP) has made an unprecedented and ambitious attempt to enhance the coverage, quality, equity, efficiency, and effectiveness of the program despite facing challenges due to COVID-19. From the TB diagnosis point of view, NTEP is making efforts toward offering rapid molecular assays as the initial test to diagnose TB instead of sputum smear microscopy as per recommendation by the World Health Organization (WHO). NTEP has decentralized the NAAT testing at the sub-district level with rapid expansion of the NAAT (CBNAAT/ Truenat) facility and it continues to expand at a peripheral level.

NTEP has a well-established Quality Assurance (QA) mechanism in place consisting of all elements like internal quality control, on-site evaluation, and external quality assurance. It follows the WHO system of hierarchal control from the highest level of National Reference Laboratories to State Intermediate Reference Laboratories (IRLs) and TB C&DST Laboratories, to NAAT at the District/sub-District level, and then microscopy facilities at the peripheral level. On-site evaluation by supervisory staff is one of the key components of the EQA program. An effective supervisory visit depends on three main 'Rs' the Right supervisor (well-trained supervisor with updated information and troubleshooting skills), the Right tools (availability of checklists, forms, training materials, and job aids), and the Right resources (sufficient time and fund allocation).

With the revised TB diagnostic algorithm and integration of NAAT, Line Probe assay, and Liquid culture drug-susceptibility tests there is an increasing need to assure that the tests are performed appropriately at each tier of the laboratory network. This EQA guidance document is intended to educate the laboratory supervisors at each hierarchy level of the laboratory and provide an updated and comprehensive tool for conducting effective supervision and monitoring.

I hope that the guidance provided in this document will not only help to ensure the quality of tests offered but will also help to improve the overall laboratory quality management system, as well as support the Programme and patients through comprehensive supervision of TB diagnosticcare cascade.

Acknowledgements

The comprehensive guidance document for conducting EQA by laboratory supervisory staff in NTEP is the result of hard work, collaborative efforts and inputs from many institutions/laboratories and individuals, without whose help, guidance and support, this would not have been possible.

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- Dr. S Anand, National Consultant, TB Laboratories, WHO NTEP
- Dr. Lakshmi Rajagopalan, National Consultant, TB Laboratories, WHO NTEP
- Dr. Ajay Kamble, Technical Officer, TB Diagnostics, CTD
- Dr. Rohini Sharma, National Consultant, iDEFEAT-TB, The Union

and members comprised of

- Dr. Jyoti Kayesth, TB Manager, IDDS India
- Dr. Pravin Kumar Singh, Consultant, IDDS India
- Dr. Kishore Reddy, Senior TB Diagnostic Specialist, IDDS India and
- Dr. Sanjeev Saini, Team Lead, IDDS India

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- Dr. Abdul Mabood Khan, Scientist G & Director-in-Charge, National JALMA Institute for Leprosy and Other Mycobacterial Diseases (NJIL&OMD), Agra
- Dr. C. Padmapriyadarsini, Director, National Institute for Research in Tuberculosis (NIRT), Chennai
- Dr. N. Somashekar, Director, National TB Institute (NTI), Bangalore
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- Prof. (Dr.) Ravindra Kumar Dewan, Director, National Institute of TB and Respiratory Diseases (NITRD) Delhi, and
- Dr. Sanghamitra Pati, Director, Regional Medical Research Centre (RMRC), Bhubaneswar

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Abbreviations

AC	Air-Conditioner
ACF	Active Case Finding
ACH	Air-exchange per Hour
ACSM	Advocacy Communication and Social Mobilization
AFB	Acid-Fast Bacilli
AMC	Annual Maintenance Contract
ANM	Auxiliary Nurse Midwives
ART	Anti-retroviral Therapy
ASHA	Accredited Social Health Activist
ATR	Action taken report
AWW	Anganwadi Worker
Bdq	Bedaquiline
BMHRC	Bhopal Memorial Hospital & Research Centre
BMS	Basic Minimum Services
BMW	Biomedical Waste
BSC	Biosafety Cabinet
C&DST	Culture and Drug Susceptibility Testing
CAPA	Corrective and Preventive Actions
CBNAAT	Cartridge Based Nucleic Acid Amplification Test
Cfz	Clofazimine
CGHS	Central Government Health Scheme
CHC	Community Health Center
CMC	Comprehensive Maintenance Contract
CME	Continuing Medical Education
CMO	Chief Medical Officer
COVID	Coronavirus Disease
CPT	Co-trimoxazole Preventive Therapy
CTD	Central TB Division
DBT	Direct Benefit Transfer
Dlm	Delamanid
DM	District Magistrate
DMC	Designated Microscopy Center
DNA	Deoxyribonucleic Acid
DOTS	Directly Observed Treatment Short-course
DPC	District Program Coordinator
DPPMC	District Private Public Mix Coordinator
DPTC	District Pharmacy Training Coordinator
DR-TB	Drug-resistant Tuberculosis
DST	Drug Susceptibility Testing
DS-TB	Drug Susceptible TB
DTC	District Tuberculosis Centre
DTO	District Tuberculosis Officer
DTPB	Detect-Treat-Prevent-Build
DTS	Dried Tube Specimen
EPTB	extra-pulmonary tuberculosis
ESI	Employee State Insurance

EQA	External Quality Assessment
FEFO	First Expiry First Out
FL LPA	First line-line Probe Assay
FQ	Fluoroquinolone
FRU	First Referral Unit
HEPA	High Efficiency Particulate Air
HHC	Household Contact
HIV	Human Immunodeficiency Virus
HR	Human Resource
Hr-TB	Isoniazid-resistant Tuberculosis
HWC	Health and Wellness Centre
ICDS	Integrated Child Development Services
ICMR	Indian Council of Medical Research
ICT	Intensified (TB) Case Finding
ICTC	Integrated Counseling & Testing Center
IDDS	Infectious Disease Detection and Surveillance
IDHAP	Integrated District Health Action Plan
IEC	Information Education Communication
INH	Isoniazid
IPT	Isoniazid Prophylaxis Treatment
IQC	Internal Quality Control
IRL	Intermediate Reference Laboratory
IUAT	International Union Against Tuberculosis
KPI	Key Performance Indicators
LC	Liquid Culture
LIMS	Laboratory Information Management System
LPA	Line Probe Assay
LT	Lab technician
LTBI	Latent TB Infection
Lzd	Linezolid
MD	Mission Director
MDR	Multi-drug Resistant
Mfx	Moxifloxacin
MGIT	Mycobacteria Growth Indicator Tube
MNP	Minimum Needs Programme
MO-IC	Medical Officer In-Charge
MO-TC	Medical Officer-Tuberculosis Control
MoHFW	Ministry of Health and Family Welfare
MPW	Multipurpose Workers
MR-TB	Mono-resistant TB
MSDS	Material Safety Data Sheet
MTB	*Mycobacterium Tuberculosis*
NAAT	Nucleic Acid Amplification Test
NABL	National Accreditation Board for Testing and Calibration Laboratories
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NGO	Non-Governmental Organization
NHM	National Health Mission

NIRT	National Institute for Research in Tuberculosis
NITRD	National Institute of Tuberculosis and Respiratory Diseases
NJIL&OMD	National JALMA Institute for Leprosy and Other Mycobacterial Disease
NNT	Number Needed to Test
NPCC	National Programme Coordination Committee
NPCDCS	National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases, and Stroke
NPY	Ni-kshay Poshan Yojna
NRHM	National Rural Health Mission
NRL	National Reference Laboratory
NSP	National strategic plan
NTEP	National Tuberculosis Elimination Programme
NTI	National Tuberculosis Institute
NTM	Nontuberculous mycobacteria
NTP	National Tuberculosis Programme
OPD	Out - patient department
OSE	On-site Evaluation
Pa	Pretomanid
PCR	Polymerase Chain Reaction
PDR	Poly-drug Resistant
PFMS	Public Finance Management System
PHC	Primary Health Centre
PHI	Peripheral Health Institution
PIP	Programme Implementation Plan
PITC	Provider Initiated HIV Testing and Counselling
PLHIV	People Living with HIV
PMDT	Programmatic Management of Drug-Resistant TB
PMTPT	Programmatic Management of TB Preventive Treatment
PPA	Print Payment Advice
PPE	Personal Protective Equipment
PPM	Public Private Mix
PPSA	Patient Provider Support Agency
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QSE	Quality System Essentials
RBRC	Random Blinded Rechecking
RBSK	Rashtriya Bal Swasthya Karyakram
RCH	Reproductive and Child Health
RKSK	Rashtriya Kishor Swasthya Karyakram
RMRC	Regional Medical Research Centre
RNTCP	Revised National Tuberculosis Control Programme
ROP	Record of Proceeding
RR-TB	Rifampicin-resistant TB
SACS	State AIDS Control Societies
SC	Sub-Centre
SDS	State Drug Store

SDG	Sustainable Development Goal
SHC	Sub-Health Centre
SIDA	Swedish International Development Agency
SL LPA	second line-Line Probe Assay
SLIDS	Second-line Injectable Drugs
SLT	Senior Lab Technician
SOP	Standard Operating Procedure
STC	State TB Cell
STDC	State TB Training and Demonstration Centre
STLS	Senior Tuberculosis Laboratory Supervisor
STO	State TB Officer
STS	Senior TB Treatment Supervisor
TAI	TB Association of India
TAT	Turnaround Time
TB	Tuberculosis
TBI	Tuberculosis Infection
TB-HV	Tuberculosis Health Visitor
TDC	Tuberculosis Diagnostic Center
TOG	Technical and Operational Guidelines
TPT	Tuberculosis Preventive Treatment
TU	Tuberculosis Units
UATBC	Universal Access to TB Care
UDST	Universal Drug Susceptibility Testing
UNHLM	United Nations High-level Meeting
UPS	Uninterrupted Power Supply
USAID	United States Agency for International Development
VHSNC	Village Health Sanitation and Nutrition Committee
WGS	Whole Genome Sequencing
WHO	World Health Organization
WRD	WHO recommended Rapid Diagnostic
XDR	Extensively Drug-resistant

Definitions

A second-line TB drug. This is an agent reserved for the treatment of drug-resistant TB. First-line TB drugs used to treat drug-susceptible TB – ethambutol, isoniazid and pyrazinamide – may also be used in MDR-TB regimens (streptomycin is now considered a second-line TB drug and used only as a substitute for amikacin when amikacin is not available or there is confirmed resistance to it).

Active case finding (ACF). It is defined programmatically as systematic screening for TB disease through outreach activities outside health facility settings.

TB incidence The incidence of TB is the number of new cases of TB that arise in a given time period. It is usually reported as the total number of incident cases per year or as the number of cases for a given unit of population per year (such as the number of incident cases per 1,00,000 population or per million population). TB incidence changes relatively slowly. Even high-quality control programmes are expected to reduce the incidence rate by only 5–10% per year (in the absence of HIV coinfection)

Bacteriologically confirmed TB. TB diagnosed in a biological specimen by smear microscopy, culture or a WHO-endorsed rapid molecular test and adopted by NTEP such as Xpert MTB/RIF/Truenat.

Child. For programmatic purpose in India, a child is a person up to and including 18 years of age. [This includes adolescents aged 10–18 years].

Contact. Is any individual who was exposed to a person with active TB disease.

Contact investigation. Is a systematic process for identifying previously undiagnosed people with TB disease and TB infection among the contacts of an index TB patient and/ or other comparable settings where transmission occurs. [Contact investigation consists of identification, clinical evaluation and/or testing and provision of appropriate anti-TB treatment (for people with confirmed TB) or TB preventive treatment (for those without TB disease)].

Close contact. This is a person who is not in the household but shares an enclosed space, such as at a social gathering, workplace or facility, for extended periods during the day with the index TB patient during the three months before commencement of the current TB treatment episode. This group will be included for all interventions as applicable for household contacts in these guidelines.

Drug susceptibility testing. DST refers to in-vitro testing using either of the phenotypic methods to determine susceptibility.

Drug resistance testing. DRT refers to in-vitro testing using genotypic methods (molecular techniques) to determine resistance.

Extensively drug resistant TB (XDR-TB). TB caused by *Mycobacterium tuberculosis* (*M. tuberculosis*) strains that fulfil the definition of MDR/RR-TB and are also resistant to any fluoroquinolone (levofloxacin or moxifloxacin) and at least one additional Group A drug (presently to either Bedaquiline or linezolid [or both]).

High TB transmission setting. This is a setting with a high frequency of individuals with undetected or undiagnosed TB disease, or where infectious TB patients are present and there is a high risk of TB transmission. [TB patients are most infectious when they are untreated or inadequately treated. Transmission will be increased by aerosol-generating procedures and by the presence of susceptible

individuals. These settings with health-care workers, prisoners, miners, slum dwellers, tribals, migrant labourers etc. could be mapped out as part of the vulnerability mapping exercise done for and prioritized by states for specific TPT interventions guided by differential TB epidemiology in the respective state].

Household contact (HHC). Is a person who shared the same enclosed living space as the index TB patient for one or more nights or for frequent or extended daytime periods during the three months before the start of current TB treatment. [For simplicity, close contacts may be considered inclusive in this term throughout the guidelines].

Index patient of TB. This is the initially identified person of any age with new or recurrent TB in a specific household or other comparable setting in which others may have been exposed. [An index TB patient is the person on whom a contact investigation is centered but is not necessarily the source].

Infant. Is a child under one year (12 months) of age.

Isoniazid-resistant TB (Hr-TB). A TB patient, whose biological specimen is resistance to isoniazid and susceptibility to rifampicin has been confirmed.

Mono-resistant TB (MR TB). A TB patient, whose biological specimen is resistant to one first- line anti-TB drug only.

Multidrug-resistant TB (MDR-TB). A TB patient, whose biological specimen is resistant to both H and R with or without resistance to other first-line anti-TB drugs. MDR-TB patients may have additional resistance to any/all FQ or any other anti-TB drug.

Presumptive TB. This refers to a person with any of the symptoms or signs suggestive of TB. [Diagnosis of TB is difficult in certain key groups of the presumptive TB patients like extra- pulmonary, PLHIV, children, smear -ve /NA with x-ray suggestive of TB, other vulnerable groups as defined in TOG-2016 and DR-TB contacts, hence, NAAT is offered upfront for diagnosis of TB among these presumptive TB patients.]

Presumptive DR-TB. It refers to the patient who is eligible for rifampicin resistant screening at the time of diagnosis OR/and during the course of treatment for DS-TB or H mono/poly DR-TB. [This includes all notified TB patients (Public and private), follow-up positive on microscopy including treatment failures on standard first-line treatment and H mono/poly DR-TB regimen and any clinical non-responder including paediatric].

Pre-extensively drug resistant TB (Pre-XDR-TB). TB caused by *Mycobacterium tuberculosis* strains that fulfil the definition of MDR/RR-TB and are also resistant to any fluoroquinolone.

Poly-drug resistant TB (PDR-TB). A TB patient, whose biological specimen is resistant to more than one first-line anti-TB drug, other than both H and R.

Programmatic management of TB preventive treatment. PMTPT includes all coordinated activities by public and private health caregivers and the community aimed at scaling-up TB preventive treatment to people who need it.

Rifampicin resistant TB (RR-TB). A TB patient, whose biological specimen is resistant to R, detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to R, in the form of mono-resistance, poly-resistance, MDR or XDR.

Tuberculosis (TB). Is the disease that occurs in someone infected with *M. tuberculosis*. [It is characterized by signs or symptoms of TB disease, or both, and is distinct from TB infection, which occurs without signs or symptoms of TB. In this document, it is commonly referred to as "active" TB or TB "disease" to distinguish it from TB infection.]

Tuberculosis infection (TBI). Is a state of persistent immune response to stimulation by *M. tuberculosis* antigens with no evidence of clinically manifest TB disease. [There is no gold standard test for direct identification of *M. tuberculosis* infection in humans. Most infected people have no signs or symptoms of TB but are at risk for developing TB disease. TB infection is also known as "latent TB infection" (LTBI), although this term is being discarded given that infection cannot always be considered latent.]

Tuberculosis preventive treatment (TPT). Treatment offered to individuals who are considered to be at risk of developing TB disease, in order to reduce that risk. [Also referred to as treatment of TB infection.]

Universal DST. Refers to universal access to rapid DST for at least rifampicin, and further DST for at least fluoroquinolones among all TB patients with rifampicin resistance (preferably before initiation of treatment to maximum within 15 days of diagnosis).

Note: Please refer to latest guidelines for any updated definitions

Executive Summary

Effective control of tuberculosis (TB) is dependent on a network of laboratories that provide accurate and reliable testing for diagnosis and treatment monitoring. The availability and quality of diagnostic tests rely on training and monitoring the testing performance of individual laboratories. It is well known that serious deficiencies can occur in laboratory operations when sufficient attention is not given to the quality of the work product.

The National TB Elimination Program (NTEP) laboratory network is composed of a three-tier system. The National Reference Laboratories (NRLs) are expected to provide comprehensive supervisory and monitoring support to the next tier of labs for diagnostic services. The NRLs have the mandate to supervise, support and mentor the assigned state level Intermediate reference laboratories (IRLs) and culture and drug susceptibility testing (C&DST) labs. The IRLs have the mandate to ensure the quality of TB diagnostics services in the assigned geographies/districts. TB testing services at sub-district/peripheral level) is ensured by laboratory supervisory staff in the district and the quality of services is monitored closely by IRLs. NTEP has a robust mechanism to monitor the quality of services provided to the patients through a well-established external quality assessment (EQA) program which includes on-site evaluation (OSE), panel testing and rechecking activities.

The program has expanded both the laboratory network as well as WHO recommended rapid molecular diagnostic (WRD) facilities to cover the entire country. Rapid diagnostic technologies i.e., line probe assay (LPA), liquid culture (LC), CBNAAT and Truenat were introduced in NTEP in addition to conventional solid culture to provide diagnostic support for effective implementation of Programmatic Management of Drug-Resistant TB (PMDT) services. NTEP laboratory components have expanded tremendously with implementation of numerous interventions namely Universal Drug Susceptibility Testing (UDST), revision in integrated diagnostic algorithm, Drug Susceptibility Testing (DST) guided treatment, roll-out of second line LPA, extended LC DST for newer second line drugs and whole genome sequencing (WGS) at selected sites.

The checklists that are presently being used for supervision and monitoring of lab network were developed by the program in 2005 and focus mainly on the quality assurance (QA) for sputum smear microscopy. The introduction of new rapid genotypic (CBNAAT, Truenat, LPA) and phenotypic DST (MGIT 960 LC and DST) methods necessitated the revision of checklists and reporting formats for effective and efficient on-site supervisory visits as well as reporting formats for providing feedback for quality improvement. Furthermore, some important aspects of OSE were missing, including a lack of pre-visit quantitative data analysis, a lack of uniform/standardized checklist for capturing all the areas or components as per the existing algorithm, insufficient data triangulation/analysis and infrequent feedback mechanism to the laboratories under supervision.

Since OSE of laboratories with standard checklists is a first step to promote effective and consistent supervision, the existing supervisory checklists and reporting formats were revised with support of Infectious Disease Detection and Surveillance (IDDS; supported by USAID) project to cover all existing diagnostic technologies in NTEP algorithm including quality system essentials.

This guidance document contains six chapters which have been prepared to provide guidance to the Microbiologist/Supervisory staff in tiered laboratory network on EQA and includes:

- Updated guiding supervisory checklists covering all diagnostic technologies as well as guidance in key technical areas, including QA and quality management systems (QMS), specimen collection, procurement, biosafety, data management, human resources, for comprehensive supervision with a patient centric approach.
- Feedback formats to capture and highlight key issues identified during the OSE visits.
- Formats for periodic reporting of activities to higher level [IRL to States and NRLs, NRL to Central TB Division (CTD)] and follow-up strategy for corrective actions.

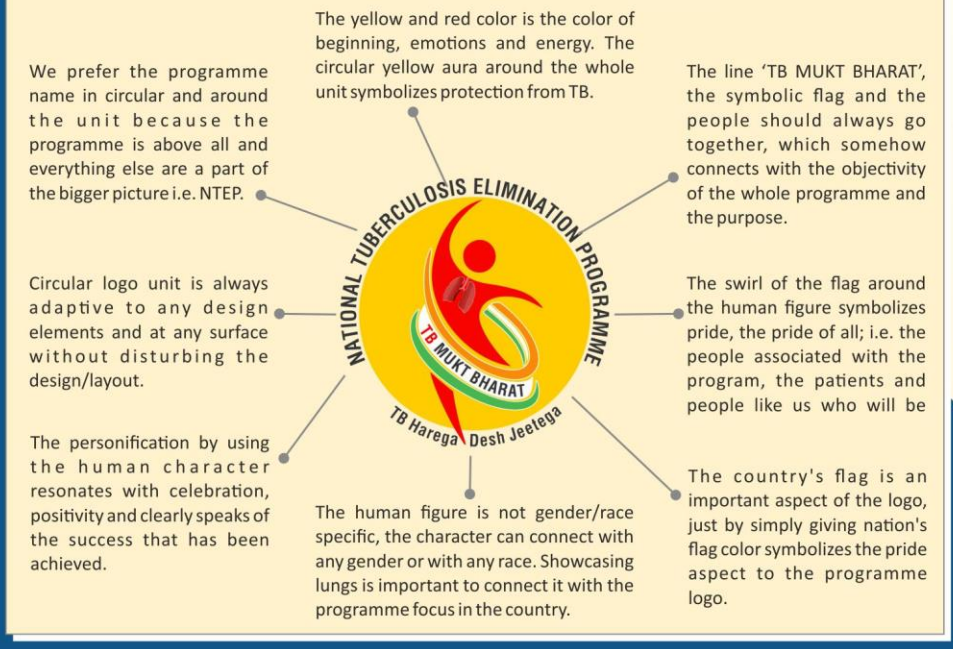
In addition to the above, the document has been designed to build the capacity of NRLs and IRLs supervisory staff, including new hires in understanding the implementation of the program, key monitoring indicators, their significance and analysis to help improve the quality of diagnostic services through stringent OSE visits and providing impactful feedback.

Several drafts of this document were provided to CTD lab team and NRL experts. The final version was reviewed and approved by all the NRLs. To improve the effectiveness of supervisory visits, this document should be used by the supervisory lab staff as a resource.

The guidance offered here draws on the international guidelines for EQA, and includes additional information, in particular on quality control, to ensure routine monitoring of all aspects of laboratory activity. It is hoped that this guidance will be adopted and implemented to strengthen the entire diagnostic network and for improving and sustaining the high-quality laboratory services for all patients in NTEP.

Chapter 1

Introduction to National Tuberculosis Elimination Programme (NTEP)



1.1. Introduction

India has been at the forefront of Tuberculosis (TB) control and research since the start of the 20th century. The first open-air sanatorium was established in 1906 by a Christian organization in Tilounia, in the Ajmer district of the north Indian state of Rajasthan. In 1929, India joined the International Union Against Tuberculosis (IUAT), and the King George V Thanksgiving Fund for TB control was established and administered through central, state, and provincial committees to support TB education and prevention, establish clinics, and train health workers. In 1939, the TB Association of India (TAI) was established to develop standard methods for managing TB and to develop model training institutions. In 1943, the Health Survey and Development Committee was established, with Sir Joseph Bhore as its Chairman, and recommended re-modelling the health services to integrate curative and preventive medicine at all levels. In 1946, the committee outlined a plan for the management of the estimated 2.5 million TB patients with a TB clinic in every district and mobile clinics in rural areas. In 1946, the Central Government established a TB Division within the Directorate General of Health Services of the Ministry of Health to oversee the plan.[1]

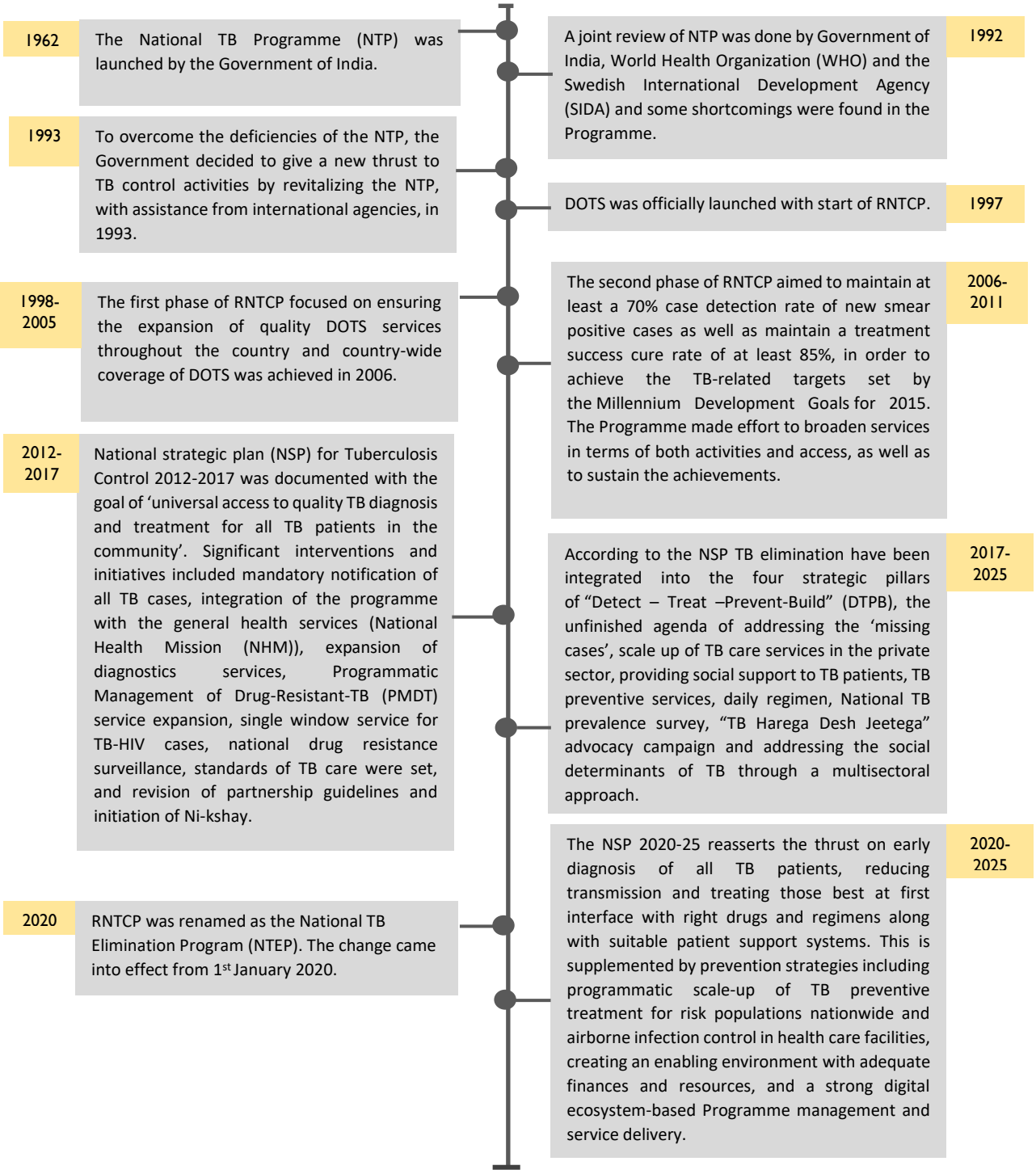
With mass vaccination of BCG (Bacillus Calmette-Guerin) in 1951, National TB Programme (NTP) started in 1962. To determine the prevalence of the disease, a national survey was undertaken by the Indian Council of Medical Research (ICMR) between 1955 and 1958, and the number of people with TB was estimated to be nearly 8 million, with 80% of cases residing in the rural areas. Following a review of 1992 which highlighted managerial weaknesses, over-emphasis on X-rays for diagnosis, underutilization of laboratory services, frequent drug shortages, and low rates of treatment completion, the Government of India decided to revitalize NTP with the assistance of international agencies and found that the NTP had not achieved its aims or targets. Based on the recommendations of the 1992 review, the Revised National Tuberculosis Control Programme (RNTCP), incorporating the components of the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy for the control of TB, was developed. The Programme had been implemented in the country for more than two decades and has expanded geographically to achieve nationwide coverage by March 2006. The spread of the human immunodeficiency virus (HIV) during the last two decades, the emergence of various forms of drug-resistant TB (DR-TB), and the unorganized and unregulated vast private sector posed additional challenges in effective TB control.

Over a period of time, there have been several landmark achievements including policy and system preparedness for universal access to TB care including mandatory notification of TB cases, development of Standards for TB Care in India, Comprehensive Real-time TB Information, Management System – NI-KSHAY, use of rapid molecular diagnostics, successful innovations in private sector engagement for TB care - Universal Access to TB Care (UATBC). Considerable progress in addressing DR-TB with focus on Drug Susceptibility Testing (DST) guided treatment including the introduction of newer drugs (like bedaquiline and delamanid), TB and comorbidities, pediatric TB, nutritional support through Ni-kshay Poshan Yojana by Direct benefit transfer (DBT), active case finding, intensified case finding, and urban TB control models have also been made and major progress has been achieved in advocacy and communication areas. (Figure 1.1) On January 1, 2020, RNTCP was renamed as the National

[1] World Health Organization. (2010). *A Brief History of Tuberculosis Control in India.* Retrieved from https://www.who.int/publications-detail-redirect/9789241500159

Tuberculosis Elimination Programme (NTEP) in line with the larger goal of eliminating the disease by 2025, five years ahead of the Sustainable Development Goals (SDG) target.

Figure 1.1 Journey of Tuberculosis control in India



1.1. Indian healthcare delivery system

Before going into NTEP implementation, it's important to understand the Indian healthcare delivery system. India has a mixed healthcare system, including public and private healthcare service providers. However, most of the private healthcare providers are concentrated in urban India, providing secondary and tertiary care healthcare services. The public health-care infrastructure in rural areas has been developed as a three-tier system based on population norms (Figure 1.2).

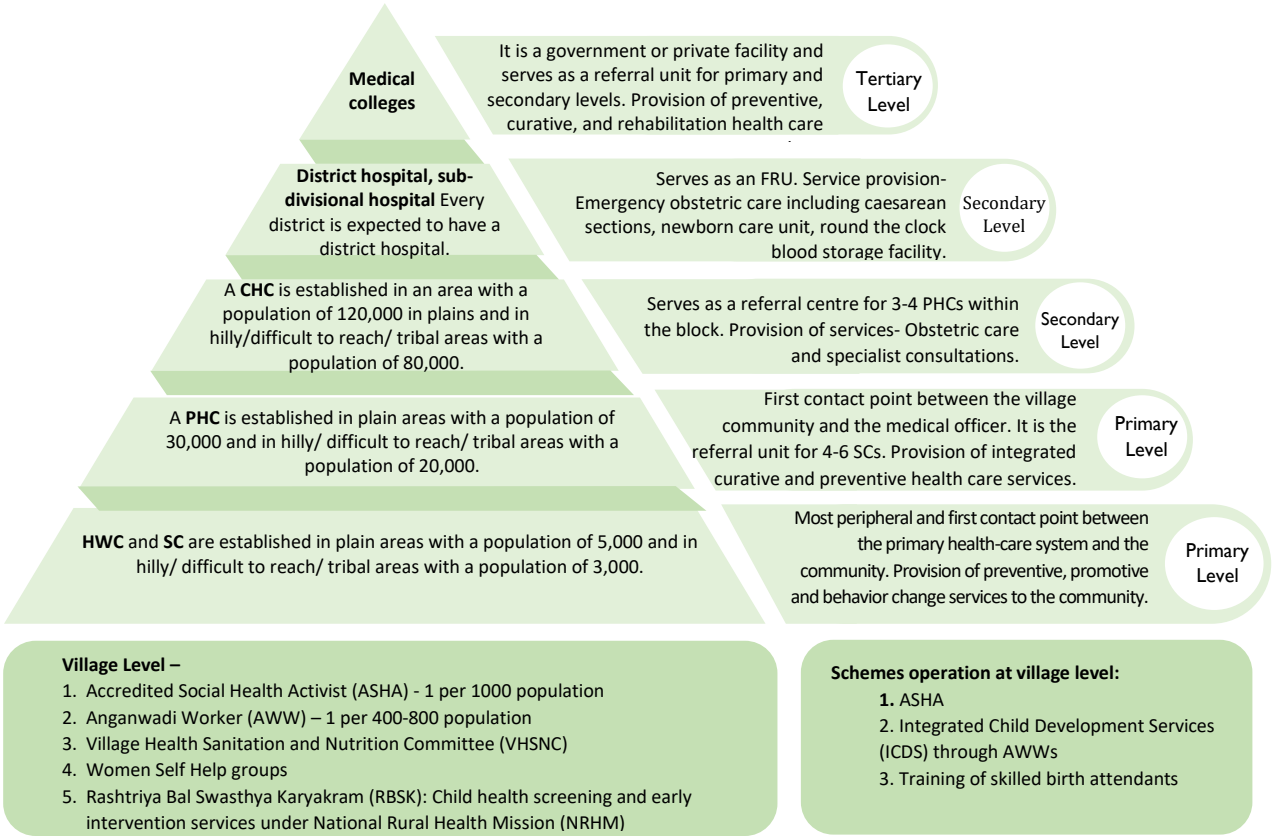
A Sub-Centre (SC) is the most peripheral and first point of contact of the community with the healthcare system. SCs are assigned tasks relating to interpersonal communication to bring about behavioral change and provide services in relation to maternal and child health, family welfare, nutrition, immunization, diarrhea control, and control of communicable diseases programs.

A Primary Health Centre (PHC) is the first contact point between the village community and the medical officer. PHCs were envisaged to provide integrated curative and preventive health care to the rural population with emphasis on the preventive and promotive aspects of health care.

Under Ayushman Bharat, around 1,50,000 existing Sub-Health Centres (SHCs) and PHCs are being transformed into Health and Wellness Centres (HWCs) to deliver Comprehensive Primary Health Care (CPHC), that is universal and free to users, with a focus on wellness and the delivery of an expanded range of services close to the community. The wide range of services provided at these HWCs will encompass maternal and child health services, communicable and non-communicable diseases, services for the elderly, and palliative care including free essential drugs and diagnostic services.

A Community Health Centers (CHCs) is established and maintained by the State Government under the Minimum Needs Programme/ Basic Minimum Services (MNP/BMS) programme and serve as referral centre for PHCs within the block and also provides facilities for obstetric care and specialist consultations. An existing facility (district hospital, sub-divisional hospital, CHC) can be declared a fully operational First Referral Unit (FRU) only if it is equipped to provide round-the-clock services for emergency obstetric and newborn care, in addition to all emergencies that any hospital is required to provide.

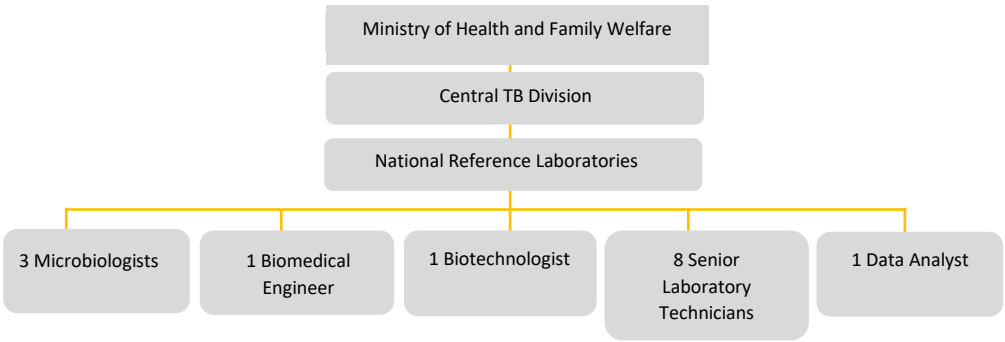
Figure 1.2 Indian public health system



1.2. NTEP implementation arrangements

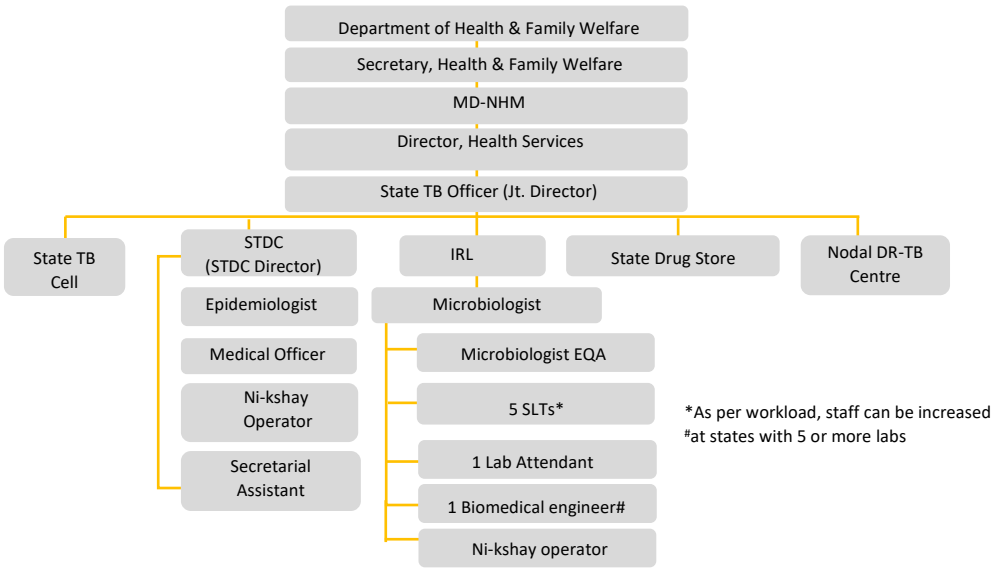
A. **NTEP** is a Centrally Sponsored Scheme being implemented under the aegis of the National Health Mission (NHM) with resource sharing between the State Governments and the Central Government. It is managed by the Central TB Division (CTD), the technical arm of the Ministry of Health and Family Welfare (MoHFW). The CTD is assisted by six national-level institutes and technical Expert group committee that have been constituted at the national level to provide technical guidance for programme implementation. The Programme has provided Human Resource (HR) support to all National Reference Laboratories (NRLs) as depicted in Figure 1.3.

Figure 1.3 NRL NTEP organogram



a. **At the State level,** State Health Secretary and Mission Director (MD) – NHM are responsible for programme implementation in the state where the planning, training, supervising, and monitoring of the programme in their respective states is as per the guidelines of the State Health Society and CTD. State TB Training and Demonstration Centre (STDC) supports the State TB Cell (STC) in most of the larger states. State drug store (SDS) has been established for the effective management of anti-TB drug logistics. The STDC is supported by the State TB Forums for community engagement, State level PMDT committee for implementation guidance and review of PMDT, State level TB comorbidity coordination committee, and Technical Working Group for HIV-TB for smooth TB-comorbidity coordination. Nodal DR-TB centres are established for the management of DR-TB with newer drugs, adverse drug reactions, and act as a referral unit. Figure1.4 depicts the NTEP organogram at the state.,

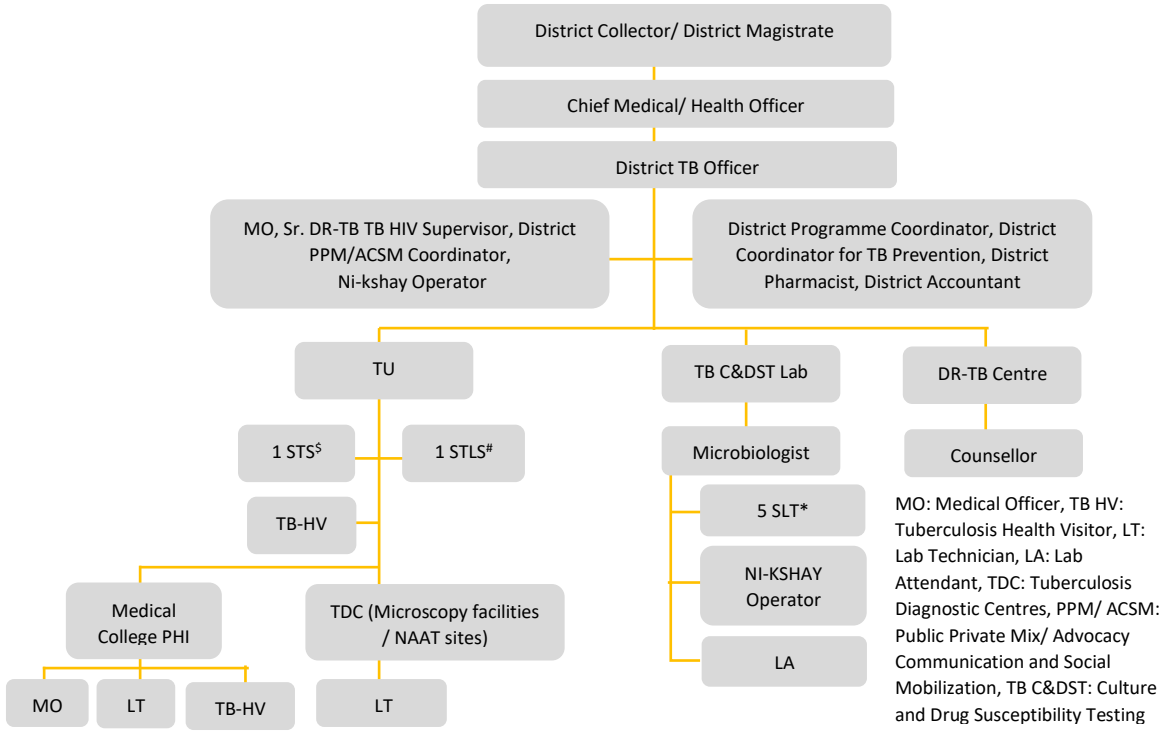
Figure 1.3 STDC and IRL level organogram



b. **The district** is the key level for the management of the primary health care services. The District Tuberculosis Centre (DTC) is the nodal point for all TB control activities in the district and has the overall responsibility of the management of NTEP at the district level as per the programme guidelines and the guidance of the District Health Society. District level TB comorbidity coordination committee is in-place for smooth TB comorbidity coordination.

At the sub-district level TB activities are implemented through a Tuberculosis Unit (TU) which consists of a designated Medical Officer-Tuberculosis Control (MO-TC) supported by two full-time NTEP contractual supervisory staff exclusively for TB work - a Senior TB Treatment Supervisor (STS) and a Senior TB Laboratory Supervisor (STLS). The TU is generally aligned with the administrative blocks in the district with 1 STS /TU at NHM block or urban area and 1 STLS /5 lakh population. Figure 1.5 below depicts the district level NTEP Organogram.

Figure 1.4 District level NTEP organogram



$ 1 STS/TU at NHM Block or urban area (approximate population 1.5- 2.5 lakh; in case of tribal/hilly/difficult areas 1 per 0.75 to 1.25 lakh population to be aligned with blocks)

1 per 5 lakh population (1 per 2.5 lakh population for tribal/hilly/difficult areas)

* as per workload, staff can be increased

TU - 1 per 2,00,000 (1.5 to 2.5: lakh range) population for rural and urban population and 1/100,000 (0.75 to 1.25 lakh) population in hilly/tribal/difficult areas

For revised norms and costing of TB services please refer to https://tbcindia.gov.in/showfile.php?lid=3384

c. **Peripheral Health Level:** For NTEP, a Peripheral Health Institution (PHI) is a health facility that is manned by at least a medical officer. At this level, there are public or private (including Non-Governmental Organization (NGO)-supported) dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics or hospitals, and medical colleges. Some of these PHIs may also serve as microscopy facilities previously called Designated Microscopy Centres (DMCs), which is the most peripheral level laboratory in the NTEP structure. Through these microscopy facilities TB case-finding activities take place. Treatment may be initiated at the PHIs and in some instances (such as DR-TB) where initiation is at higher levels, the treatment of the patients may continue at the PHI level. For the establishment of a microscopy facility in the lab of a PHC, it must have adequate physical infrastructure, a binocular microscope/ Nucleic Acid Amplification Test (NAAT) machine, and a trained LT.

d. **Health and Wellness Centres (HWCs):** The services at HWC level includes early identification, basic management, counselling, ensuring treatment adherence, follow up care, ensuring continuity of care by appropriate referral, optimal home and community follow up, health promotion and prevention for expanded range of services. The Community Health Officer (CHO) is available at the HCWs and is supported by Auxiliary Nurse Midwives (ANMs), Multipurpose Workers (MPWs) and ASHAs. For the treatment of TB, it will serve as first point of care for continuation of treatment, adherence support and for ancillary drugs to support TB treatment. For more details access operational guidelines for TB services at HWCs through link https://tbcindia.gov.in/showfile.php?lid=3575

B. **Programme implementation plan and planning process:** As with other components of NHM, financial support to NTEP is provided through the Programme Implementation Plan (PIP) mechanism of the NHM. NTEP / NHM follows a bottom-up approach for planning and budgeting. The process begins at the district level by NTEP preparing the district PIP at the DTC which gets incorporated into the Integrated District Health Action Plan (IDHAP) which is further sent to the state level to form the State PIP. The PIP indicates the physical targets and budgetary estimates in accordance with the approved pattern of assistance under the NHM. This will cover all aspects of activities required to be carried out under NTEP in one financial year. The State PIPs are approved by the Union Secretary of Health and Family Welfare, based on an appraisal by the National Programme Coordination Committee (NPCC) which is chaired by the MD and includes representatives of the State, Technical and Programme Divisions of the MoHFW, other Departments and Ministries, as required. The approved Record of Proceeding (ROP) includes Central as well as State shares and includes cash as well as commodity component. The preparation of the PIP follows a standardized template specified by the NHM.

C. **Collaborative activities with other NHM components:** NTEP works in collaboration with other Programmes such as the National AIDS Control Organization (NACO) and the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases, and Stroke (NPCDCS). Bi-directional screening for HIV and TB, along with testing for Diabetes Mellitus is offered for all TB patients. Testing for co-morbidities is part of the bouquet of services provided to patients being treated under NTEP, to provide comprehensive care and support. NTEP adopts the Health Systems Approach of the NHM, as per which the entire health system machinery works together to achieve common goals of improved health, better responsiveness, and better financial protection for the patients. HR and infrastructure of the general health system and also of medical colleges are utilized to achieve maximum utility. E.g., many DR-TB treatment centres are situated in medical colleges, with medical college staff and infrastructure playing a crucial role in the treatment of DR-TB patients. Likewise, laboratory technicians from the general health system pool are re-appropriated for work under NTEP.

1.3. Conclusion

After decades of successful programme implementation, India has accomplished numerous impressive achievements in TB prevention, care and control to match the bold ambitions of the Government of India, as well as those the country has committed at the Global level including the United Nations High-level Meeting (UNHLM) on TB. The impact of many innovations and interventions since 2017 is seen in the increased coverage, increased utilization of TB services and decreasing incidence of the disease. The global public health and TB community is shifting its focus from control of the TB epidemic towards elimination.

Chapter 2

NTEP Laboratory Network

Courtesy:
Parigi Truenat center- Vikarabad District- Telangana State
NRL National Institute of TB and Respiratory Diseases, New Delhi
NRL National Tuberculosis Institute, Bangalore
Intermediate Reference Laboratory, Pune
TB C&DST Laboratory, BHU Varanasi

2.1. Introduction

Laboratories are a fundamental component of TB control program. Early and accurate diagnosis followed by prompt appropriate treatment is vital for ending TB. Effective and comprehensive supervision, mentoring and monitoring of the lab network is important to assure quality of diagnostic care cascade.

The TB diagnostics landscape in India has transformed in recent years with the scale up of free rapid TB diagnostics and treatment all across the country. Over the years, TB diagnostic laboratory network equipped with WHO recommended rapid diagnostic (WRD) tests has expanded under NTEP. The expansion is critical for the country's commitment to achieve the SDG goals. It has contributed to the effective implementation of the revised NTEP policies in the country to achieve the targets and milestones set for TB elimination in India at the UNHLM. In 2022, NTEP laboratory network has contributed to testing of over 18 million presumptive TB patients detecting more than 1.2 million microbiologically confirmed TB cases (total 2.4 million TB cases) and a total 79,754 patients with DR-TB[2].

In India with high burden of TB and a massive network of tiered laboratory system, continuous supervision and monitoring is important to assess the gaps and challenges that limit the efficiencies in performing their functions. This provides opportunities for finding possible solutions and optimizing services.

2.2. NTEP laboratory network

The services of the laboratory are utilized for diagnosing TB and DR-TB cases as well as for monitoring the treatment of these patients. The laboratory network under NTEP is a 3-tier system for the provision of diagnostic services and maintaining its quality.

At the central level, there are six designated NRLs namely the National Tuberculosis Institute (NTI), Bengaluru, National Institute for Research in Tuberculosis (NIRT), Chennai, National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi, ICMR National JALMA Institute for Leprosy and Other Mycobacterial Diseases (NJIL&OMD), Agra, ICMR-Regional Medical Research Centre (RMRC), Bhubaneswar and Bhopal Memorial Hospital and Research Centre (BMHRC), Bhopal. NIRT Chennai is also a Supra National Reference Lab (SNRL) for WHO for the Southeast Asia Region. NTI is a WHO collaborating centre for training, while NITRD is the WHO centre of excellence in TB laboratory services. The NRLs are equipped with WHO-approved diagnostic tests to provide TB Culture and Drug Susceptibility Testing (C&DST) services to a few linked districts in the state where NRL is located and other linked states (based on requirement). The NRLs are mainly responsible for External Quality Assessment (EQA) of the laboratory network, and drug resistance surveillance. NRLs also assist CTD, in developing laboratory guidelines, and Standard Operating Procedures (SOPs), conducting trainings for the state level Intermediate reference laboratories (IRL), and other technical support (Section 2.4).

At the state level, a nodal laboratory is designated as IRL, which is usually situated in the STDC / medical college/ public health laboratory. There are 34 IRLs equipped with WHO-recommended rapid TB diagnostics and provide line probe assays (LPA) and liquid culture and DST services at the state and

[2] Central TB Division, Ministry of Health and Family Welfare, Government of India. (2023). *INDIA TB REPORT 2023*. Retrieved from http://tbcindia.gov.in/showfile.php?lid=3680.

regional level. The main functions of IRLs are monitoring of laboratory services across the state and maintenance of its quality through EQA (Section 2.5).

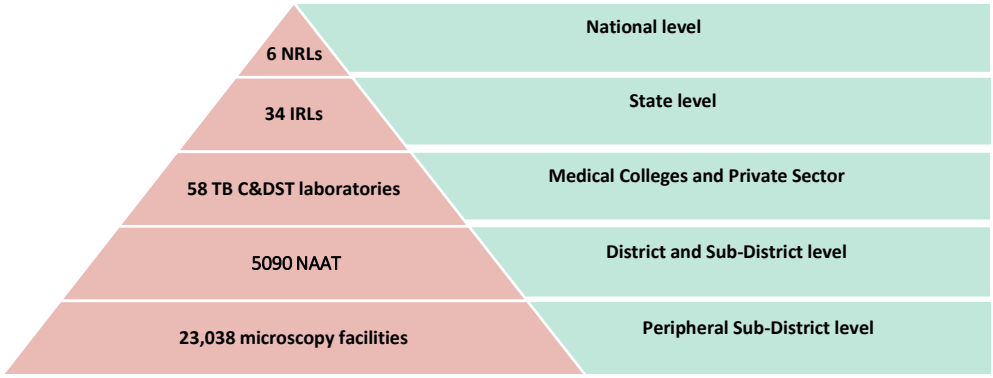
In addition to IRLs, there are 58 TB C&DST laboratories in medical colleges and private sector which also provide diagnostic services to the linked districts. Based on geographies, all states are distributed amongst the NRLs (Annexure 2.1).

Tuberculosis Diagnostic Centres: TDCs provide diagnostic services under the program. More than 23,000 microscopy centres are available across the country to improve access to TB diagnosis up to the peripheral level. To augment the capacity of diagnosing TB and DR-TB, 5090 NAAT facilities (Cartridge Based Nucleic Acid Amplification Test (CBNAAT) and Truenat) are decentralized at district and sub district levels to diagnose TB and Rifampicin resistance among all TB patients. They also serve to diagnose TB among presumptive TB cases from the key population.

The NTEP envisages to replace smear microscopy with upfront molecular testing using NAAT for diagnosis of TB at 8,000 high-workload microscopy facilities. The programme is working to further decentralize this capacity down to block levels.

Some of the labs that do not have the facility for sputum microscopy, function as a sputum collection centres, and such facilities are also established in areas such as tribal, hilly, desert and difficult to reach areas of the country for improving the access to diagnostic services.

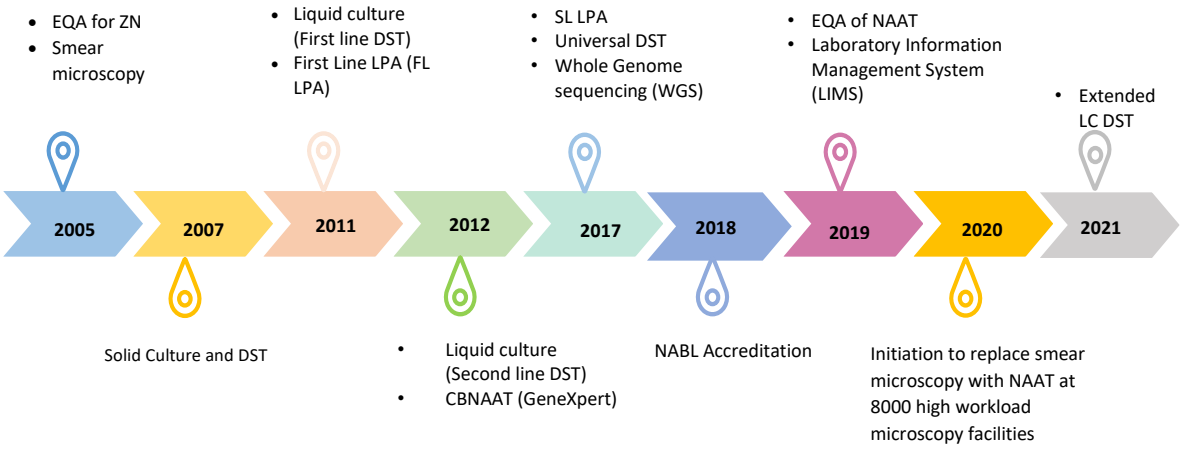
Figure 2.1 Diagnostic network in NTEP



Note: The numbers of these facilities are not constant and subject to change. Please refer to latest TB reports for updated numbers. TDCs include both NAAT sites and microscopy facilities.

Expansion of lab network and Diagnostic technologies: The programme expanded both the laboratory network as well as WRD facilities to cover the entire country. Since 2010, the laboratory network under NTEP has been expanded over the years. Rapid diagnostic technologies i.e., LPA, liquid culture (LC), CBNAAT and Truenat were introduced in TB C&DST laboratories (reference laboratories) under NTEP in addition to conventional solid culture to provide diagnostic support for effective implementation of PMDT services. NTEP laboratory components have expanded tremendously with the implementation of numerous interventions namely Universal Drug Susceptibility Testing (UDST), revision in the integrated diagnostic algorithm, DST-guided treatment, roll-out of second line LPA (SL LPA) and extended LC DST for newer second-line drugs.

Figure 2.2 Introduction of TB diagnostic technologies and newer initiative in NTEP



2.3. Quality Assurance (QA) of laboratory services

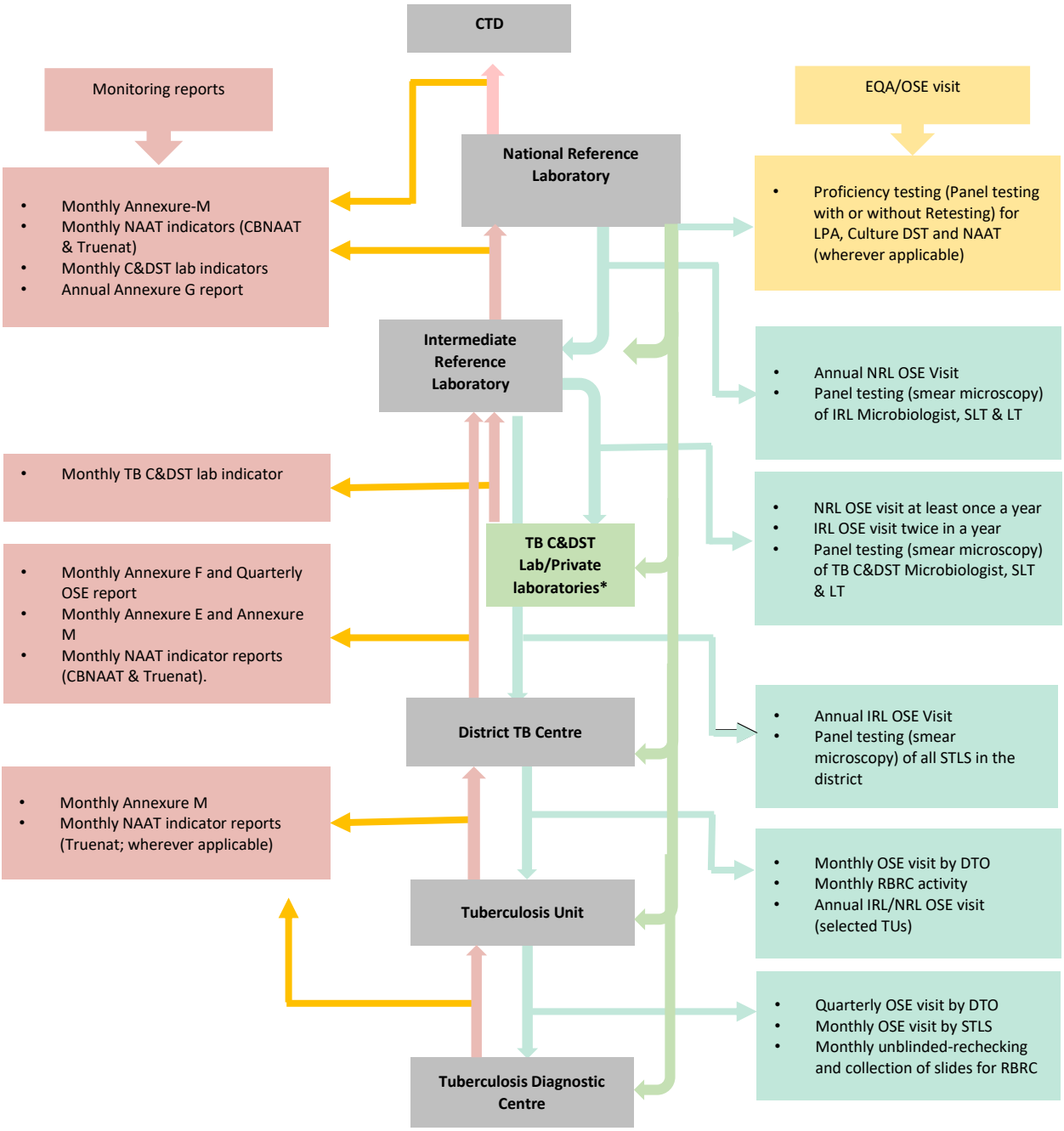
QA is a system consisting of Internal Quality Control (IQC), EQA, and continuous efforts for quality improvement of laboratory services. NTEP programme has a well-established QA mechanism which is in line with WHO system of hierarchical control from the higher level of NRLs to State IRLs and TB C&DST laboratories to the district/sub district level and then microscopy facilities at the most peripheral level. The system also provides credibility of laboratory results and motivation of staff for further improvement of their efficiency.

External Quality Assessment (EQA) for:

- Sputum smear microscopy EQA includes on-site evaluation (OSE), Panel Testing and Random Blinded Rechecking (RBRC).
- NAAT is conducted using Dried Tube Specimen (DTS) for public as well as private sector laboratories.
- Phenotypic DST (LC) and Genotypic DST (LPA) is through structured panel testing/Proficiency Testing (PT) exercise which is conducted annually (for more details refer chapter 3)

Figure 2.3 depicts the structure of laboratory supervision, monitoring which includes, (a) a fixed number of supervisory visit days for respective staff using standard checklists, (b) data records and reporting monitoring indicators, (c) review meetings to discuss performance and (d) EQA

Figure 2.3 Structure of laboratory supervision and monitoring



** All private laboratories should be treated as TB C&DST laboratories and visited by NRLs at least once and IRLs at least twice in a year*

2.4. Roles and responsibilities of NRLs

Supportive Supervision

1. Undertake OSE visits to IRLs and all TB C&DST labs (including identified districts and sample of microscopy facilities and NAAT sites) at least once a year for assessing the quality of microscopy, NAAT, LPA, Culture, and DST, and to improve the overall quality of laboratory testing. The visit also includes:
   a. Review the process of preparing and validating the panel slides performed by the IRL for panel testing of STLS.
   b. Panel testing of IRL lab staff and STLS (if required).
   c. Assessment of blinded rechecking of slides at DTC
   d. Liaising with the state for better diagnosis.
   e. To meet and appraise the findings of OSE visit to State TB Officer (STO), and MD-NHM/Health Secretary and submit the final report to STO and CTD
   f. Providing technical support and guidance to the state.

Mentoring

1. Training and capacity building of state and district level personnel.

State level personnel

   a. Training of STDC/IRL supervisory staff in the OSE of STLS, preparation/manufacturing of panel slides
   b. Re-training of STDC/ IRL supervisory staff, if required.
   c. On-site training for IRL and TB C&DST lab staff.
   d. Refresher training for IRL and TB C&DST lab staff.
   e. Facilitating training of STDC Director and STO.
   f. Creating a pool of expert trainers.
   g. Evaluate the work of STDC in terms of conducting lab trainings for state personnel and quality of training.
   h. Help the state and STDC to assess the estimated workload in the state, laboratory capacity of each C&DST lab within the state with exiting HR and infrastructure, number of districts linked to the laboratory, and expected workload from those districts.

District level personnel

   a. Training of MO-TC, District TB Officer (DTO), Sr. DR TB TB HIV Supervisor, LTs and STLSs (district level personnel).
2. Conduct visits to those labs which did not obtain satisfactory results in the annual PT.
3. Undertake DR-TB diagnosis at the NRL for states if any laboratory (ies) breakdown.
4. Handholding of laboratory staff in conducting and interpreting different diagnostic test results.
5. Support in building laboratory networks (public and private).

Monitoring

1. Collect and compile the monthly data from the linked IRLs. Monitor, analyze, and send feedback(s) on lab indicators/annexures from all IRLs and TB C&DST labs.
2. Monitoring implementation of integrated DR-TB diagnostic algorithm in the assigned states.
3. Assessment of gaps in sample collection and transport for testing as per diagnostic algorithm: microscopy facilities to NAAT and NAAT to IRL.
4. Conduct PT for the assigned labs annually for all the certified technologies.

Troubleshooting
1. Resolve issues of IRLs and TB C&DST laboratories regarding optimal implementation of lab processes and sample testing as per NTEP lab policies, to ensure the quality of test results, coping with laboratory accidents, practicing the biosafety measures, lab equipment maintenance, consumption of lab supplies, feedback on lab indicators, etc.
Others
1. Service delivery for few districts in diagnosis and follow-up for DR-TB. 2. Provide technical support to CTD in newer initiatives, conduct operational research, and evaluation of newer tools for diagnosis of TB in the program. 3. Assist CTD in developing laboratory guidelines and SOPs for the technical procedures, equipment maintenance, infection control, recording, and reporting. 4. Participate in NRL coordination committee meetings, regional PMDT review, and other meetings as directed by CTD. 5. Participate in an EQA programme for microscopy and TB C&DST by an external agency/SNRL.

2.5. Roles and responsibilities of IRLs

Supportive Supervision
I. Conduct OSE visits to all assigned districts, and a sample of NAAT sites, TUs and microscopy facilities at least once a year and submit report to the STO and respective NRL. 2. Prepare panel testing slides and conduct panel testing of all STLS at the district. 3. Assessment of blinded rechecking of slides at DTC. Prompt reporting of the results of EQA activities by Director STDC/ IRL to STO, CTD, and NRL. 4. Service delivery for assigned districts in diagnosis and follow-up for DR-TB. 5. To ensure proper implementation of EQA for sputum smear microscopy and NAAT in the state- annual visit to the districts allotted including NAAT sites.
Mentoring
1. Provide training to supervisory laboratory staff on sputum smear microscopy. 2. Training of EQA to LT/STLS, DTO, MO-TC. 3. Re-training of DTC LT/ STLS, if required. 4. Provide training to the district programme managers, STLSs, and laboratory technicians on sputum sample collection, and transportation procedures, monitor their performance and suggest corrective action when necessary. 5. Provide technical support to the other C&DST laboratories (including NAAT labs) in the state or other states when assigned. 6. Assist STO in QA and procurement of laboratory consumables at the state and district levels.
Monitoring
1. Monitor performance and quality indicators of all participating NAAT labs in the state. a) Oversee data entry into Ni-kshay by district (DTC) and sub-district level (TUs and microscopy facilities) TB laboratories. b) Assist the STC and STDC in conducting review of the quality of microscopy by analysis of microscopy data, EQA annexure reports and OSE reports. 2. Collect, analyze, and send monthly reports on laboratory performance to STO, NRL, and CTD.

Troubleshooting
1. Resolve issues of NAAT sites and microscopy facilities in the optimal implementation of lab processes and sample testing as per NTEP lab policies, to ensure the quality of test results, practicing the biosafety measures, equipment maintenance, consumption of lab supplies, feedback on monitoring indicators, etc.
Others
1. Maintain SOPs and Quality Management Systems (QMS) in the C&DST lab. 2. Engage maintenance agencies for C&DST lab equipment and monitor their performance.

2.6. Roles and responsibilities of DTC

Laboratory supervision and monitoring at district/sub-district level (DTOs and STLSs):

Supportive supervision and external quality assessment
STLS: 1. Conduct OSE visits to all assigned TDCs and sample collection centers at least monthly and submit the OSE report to the DTO. 2. Preparing smear microscopy reagents, quality control slides and their subsequent distribution to assigned microscopy facilities. 3. Conducting retesting of slides and collecting RBRC panel slides during his/her OSE visit to TDCs. Supporting DTO in conducting monthly RBRC exercise as per standard protocol as well as communicating OSE/EQA reports to IRL and STO. 4. Ensuring participation of all NAAT sites for annual panel testing (provided by NTI). 5. Enlisting and visiting all private laboratories in order to engage them for TB notification as well as implementing laboratory QA. 6. Reviewing and ensuring real-time enrollment for presumptive TB/DR-TB and other diagnostic and follow-up details. 7. In coordination with STS and DTO, visit to or conduct meeting with HWCs, Integrated Counseling & Testing Centers/ anti-retroviral therapy (ICTCs/ ART) center and C&DST lab/IRL (if located in the same district) on a monthly basis. **DTO:** 1. Conducting monthly RBRC activity under his/her direct supervision. 2. Conduct OSE visit to all TUs at least once in a month and all TDCs at least once in a quarter. *During OSE visit it is expected that DTO reviews all components of NTEP. With respect to TB diagnosis component DTO assesses the i) efforts towards presumptive TB diagnosis; ii) availability of HR, equipment and kits/reagents; iii) needs of training/ refresher training (to MO-TC/LTs), iv) adequacy of sample transportation mechanism, biomedical waste (BMW) management and testing infrastructure; and v) compliance to diagnostic algorithm and timely treatment initiation of all diagnosed TB patients.*
Mentoring
STLS: 1. Providing training and standard job aids to LTs on the diagnostic algorithm, biosafety, relevant test procedures (microscopy and NAAT), equipment maintenance and troubleshooting, sample packaging and transportation, recording and reporting (including Ni-kshay). 2. Competency assessment of LTs before allowing them to deliver patient diagnosis services independently. 3. Re-training/refresher training of LT, if required (at least once in two years).

4. Providing training to the CHOs, Patient Provider Support Agency (PPSA) staff, or private health facilities on the correct procedure for sample collection, packaging, transportation and filling the test request form.
5. Assisting DTO in establishing sample collection centers, sample transportation network and smooth testing services.

DTO:

1. Arranging NTEP training for MO/MO-TC and laboratory training for LTs.
2. Advising Medical Officer In-Charge (MO-IC)/MO-TC on how to strengthen NTEP activities (including TB diagnosis/laboratory services) and keep them up to date on any new programme updates.

Monitoring

STLS:

1. Collect, analyze and monitor the laboratory performance/quality indicators (including reflex DST as per diagnostic algorithm) of assigned TDCs.
2. Data compilation and communication to the DTO (for necessary action as well as further communication to IRL/ STO).
3. Providing inputs to the DTO for improving TB diagnosis services/indicators in the geography during monthly review meeting.
4. Monitoring for adequate supplies (kits and consumables) and equipment breakdown/repair/ preventive maintenance as well as HR availability at each assigned TDCs.

DTO:

1. Holding monthly review meetings and ensuring that the monthly OSE visit by STLS is completed and that each testing capacity of each TDC is utilized optimally.
2. Ensuring all monthly laboratory reports of all TDCs sites are complied, analyzed and further communicated to IRL/STO.

Troubleshooting

STLS:

1. Resolve technical issues of NAAT sites and microscopy facilities in service delivery as per NTEP guidelines.
2. Identify the operational issues related to TB laboratory services and try to resolve with the support of MO-IC/MO-TC and DTO.

DTO:

1. Supporting MO-IC/MO-TC for resolving the operational challenges, if any identified during OSE visits.
2. Resolving operational issues flagged by STLS and those critical for un-interrupted laboratory services as well as QA activities (including OSE visits by STLS).

Others

STLS:

1. Coordination with STS/ Tuberculosis Health Visitor (TB-HV) to ensure that notified NAAT is offered to all eligible patients (as per diagnostic algorithm), diagnosis samples from all microbiologically confirmed TB patients are sent to C&DST lab/IRL (for LPA/LC DST) and follow-up samples from all on-treatment patients are sent to C&DST lab.
2. Assisting MO-TC and District Coordinators (District Program Coordinator (DPC)/ District Private Public Mix Coordinator (DPPMC)/ District Pharmacy Training Coordinator **(**DPTC)) in preparation of different programme management reports (especially related to TB diagnosis and laboratory services) and subsequent reporting to DTO/STO.

DTO: Overall management of NTEP programme in the district. (for other responsibilities refer to https://tbcindia.gov.in/)

Annexure 2.1: States and UTs linkage with NRLs

			Certified for			
			FL LPA	SL LPA	LC FLDST	LC SLDST
National Institute for Research in Tuberculosis (NIRT), Chennai						
1	Tamil Nadu	IRL Chennai	✓	✓	✓	✓
		IRL Madurai	✓	✓	✓	✓
		TB C&DST lab, GCMCH, Coimbatore	✓	✓		
		K.A.P. Viswanatham Government Medical College, Trichy	✓	✓		
		Government Hospital of Thoracic Medicine (GHTM), Tambram	✓	✓	✓	✓
		Shankar Nethralaya, Chennai*			✓	
		Christian Medical College, Vellore*	✓	✓	✓	✓
2	Andaman & Nicobar	Regional Medical Research Centre (RMRC), Port Blair				
3	Andhra Pradesh	IRL, Visakhapatnam	✓	✓	✓	✓
		Damien Foundation Urban Leprosy & TB Research Centre (DFIT), Nellore	✓	✓		
		Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati				
		TB C&DST lab, Vijaywada				
		Rural Development Trust (RDT) Hospital Bathalapalli	✓	✓	✓	
		Sri Venkateswara Ramnarayan Ruia Government General Hospital, Tirupati				
4	Gujarat	IRL Ahmedabad	✓	✓	✓	✓
		M.P. Shah Government Medical College, Jamnagar	✓	✓	✓	✓
		Microcare, Surat	✓			
		Schmaka Technology, PVT, LTD, Vadodara, Gujarat	✓			
		Government Medical College, Surat			✓	✓
5	Kerala	IRL Thiruvananthapuram	✓	✓	✓	✓
		Government Medical College (GMC), Kozikode	✓	✓		
6	Puducherry	IRL Puducherry	✓	✓	✓	✓

7	Telangana	IRL Hyderabad	✓	✓	✓	✓
		Blue Peter Public Health and Research Centre (BPHRC), Hyderabad	✓	✓	✓	✓
		TB C&DST lab, Adilabad				
		TB C&DST lab, Warangal				
8	Dadar & Nagar Haveli					
9	Lakshadweep					
10	Daman & Diu					
National Tuberculosis Institute (NTI) Bangalore						
1	Karnataka	IRL, Bangalore	✓	✓	✓	✓
		Karnataka Institute of Medical Sciences (KIMS), Hubli	✓	✓	✓	✓
		Raichur Institute of Medical Sciences (RIMS), Raichur	✓	✓	✓	✓
		Kasturba Medical College (KMC) Manipal*	✓			
2	Maharashtra	IRL Nagpur	✓	✓	✓	✓
		IRL Pune	✓	✓	✓	✓
		Grant Medical College and Sir JJ group of Hospitals, Mumbai	✓	✓	✓	✓
		Group of TB Hospitals (GTB), Sewree, Mumbai	✓	✓	✓	✓
		Government Medical College (GMC), Aurangabad	✓	✓	✓	✓
		B. J. Medical College & Sassoon General Hospital, (BJMC), Pune			✓	✓
		Military Hospital Pune	✓			
		Mahatma Gandhi institute of Medical Sciences (MGIMS), Wardha				
		TB C&DST Lab, Seth G.S. Medical College & KEM Hospital, Parel, Mumbai			✓	✓
		TB C&DST Lab, Government Medical College (GMC), Akola				
		TB C&DST Lab, Government Medical College (GMC), Sangli				
		TB C&DST lab, Kasturba Hospital, Mumbai				

		P.D. Hinduja National Hosptial and Medical Research Centre, Mumbai *	✓	✓	✓	✓
		SRL Limited, Mumbai *	✓	✓	✓	✓
		Metropolis Tuberculosis Laboratory, Mumbai*	✓		✓	✓
		Thyrocare Technologies Limited, Navi Mumbai*	✓	✓	✓	✓
		Aspira Path Lab and Diagnostic Limited, Navi Mumbai*	✓		✓	
		Infexn Laboratories Pvt Ltd, Thane*	✓	✓	✓	✓
3	Rajasthan	IRL Ajmer	✓	✓	✓	✓
		Sawai Man Singh Medical College (SMS) Jaipur	✓	✓	✓	✓
		All India Institute for Medical Sciences (AIIMS), Jodhpur	✓	✓		
		Dr. Sampurnananda Medical College (SNMC), Jodhpur	✓	✓	✓	✓
		Sarder Patel Medical College (SPMC), Bikaner				
		TB C&DST Lab, Jhalawar Medical College				
National Institute of TB & Respiratory Diseases (NITRD) New Delhi						
1	Delhi	IRL New Delhi Tuberculosis Centre (NDTB)	✓	✓	✓	✓
		IRL All India Institute of Medical Sciences (Department of Medicine)	✓	✓	✓	✓
		C&DST Lab, Rajan Babu Institute of Pulmonary Medicine and Tuberculosis (RBIPMT), New Delhi			✓	
2	Himachal Pradesh	IRL Dharampur	✓	✓		
		C&DST Lab, Dr. Rajendra Prasad Government Medical College, Kangra				
		C&DST Lab, Indira Gandhi Medical College & Hospital (IGIMS), Shimla				
3	Punjab	IRL Patiala	✓	✓	✓	✓
		C&DST Lab, Guru Gobind Singh Medical College and Hospital, Faridkot				
4	Chandigarh	C&DST Lab, Post Graduate Institute of Medical Education & Research (PGIMER) Chandigarh	✓	✓	✓	✓
5	Haryana	IRL Karnal	✓	✓		

		C&DST Lab, Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak	✓	✓		
6	Bihar	IRL Patna	✓	✓	✓	✓
		C&DST Lab, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna			✓	
		C&DST Lab, Jawaharlal Nehru Medical College and Hospital (JLNMCH), Bhagalpur	✓	✓	✓	✓
		C&DST Lab, Damien TB Research Centre (DFIT), Darbhanga	✓	✓		
		C&DST Lab, Government Medical College Pawapuri, Nalanda				
		C&DST Lab, Narayan Medical College, Rohtas				
7	Jammu	IRL Jammu				
8	Srinagar	IRL Srinagar	✓	✓		
9	Ladakh					
ICMR-Central JALMA Institute of Leprosy other Mycobacterial diseases, Agra						
		IRL Lucknow	✓	✓	✓	✓
1	Uttar Pradesh	IRL Agra	✓	✓	✓	✓
		TB C&DST Lab, IMS, Banaras Hindu University (BHU), Varanasi	✓	✓	✓	✓
		TB C&DST Lab, J.N. Medical College, Aligarh Muslim University (AMU), Aligarh	✓	✓		
		Subharti Medical College, Meerut	✓			
		TB C&DST Lab, Ganesh Shankar Vidyarthi Memorial (GSVM) Medical College, Kanpur				
		TB C&DST lab, Uttar Pradesh University of Medical Sciences (UPUMS), Saifai Etawah	✓			
		TB C&DST Lab, Maharani Laxmi Bai (MLB), Medical College, Jhansi				
		TB C&DST Lab, Lala Lajpat Rai Memorial (LLRM), Medical College, Meerut	✓		✓	
		TBC&DST Lab, Motilal Nehru Medical College, Prayagraj				
		TB C&DST Lab, Baba Raghav Das (BRD) Medical College, Gorakhpur	✓			

		TB C&DST Lab, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow				
		TB C&DST Lab, Ram Manohar Lohia (RML), Lucknow				
		TB C&DST Lab, Shri Ram Murti Smarak Institute of Medical Sciences (SRMS), Bareilly				
2	Uttarakhand	IRL Dehradun	✓	✓		
		Sushila Tiwari Medical College, Haldwani, Nainital (Upcoming)				
		All India Institute of Medical Sciences (AIIMS), Rishikesh (Upcoming)				
		TB C&DST Lab, Jolly Grant Medical College				
ICMR-Bhopal Memorial Hospital & Research Centre (BMHRC), Bhopal						
1	Madhya Pradesh	IRL Indore	✓	✓	✓	✓
		National Institute of Research in Tribal Health (NIRTH), Jabalpur	✓	✓	✓	✓
		Gajra Raja Medical College (GRMC) Gwalior	✓	✓		
		IRL Bhopal	✓	✓	✓	
		AIIMS Bhopal	✓	✓		
		Choitram Hospital, Indore				
2	Chhattisgarh	IRL Raipur	✓	✓	✓	✓
		TB C&DST Lab, Government Medical College, Raigarh				
		All India Institute of Medical Sciences (AIIMS), Raipur	✓	✓		
3	Goa	IRL Goa	✓	✓	✓	✓
4	Jharkhand	IRL Ranchi	✓	✓	✓	✓
		Patliputra Medical college and Hospital, Dhanbad				
Regional Medical Research Centre (RMRC), Bhubaneswar						
1	Odisha	IRL Cuttack	✓	✓	✓	✓
		TB C&DST Lab, Burla Sambhalpur				
2	Arunachal Pradesh	IRL Naharlagun Regional Medical Research Centre (RMRC), Dibrugarh				
3	Assam	IRL Guwahati	✓	✓	✓	✓

		Regional Medical Research Centre (RMRC), Dibrugarh				
		TB C&DST Lab, Government Medical College Silchar				
4	Sikkim	IRL Gangtok	✓	✓	✓	
5	West Bengal	IRL Kolkata	✓	✓	✓	✓
		SRL, Kolkata*			✓	
		NBMC, Siliguri	✓	✓	✓	✓
		TB C&DST Lab, Murshidabad	✓	✓		
		TB C&DST Lab, Bardhhaman	✓	✓		
		TB C&DST Lab, Midanapore Medical College and Hospital				
		AMRI Hospital, Dhakuria, Kolkata*				
6	Manipur	IRL Imphal				
		Babina Diagnostics, Imphal*				
7	Meghalaya	Nazerath, Shillong	✓	✓		
		Reid Provincial Hospital				
8	Tripura	Agartala Government Medical College (AGMC), Agartala	✓	✓	✓	
9	Mizoram	TB C&DST Lab, Aizawl				
10	Nagaland	TB C&DST Lab, Kohima				

Note: Private labs are marked with an asterisk.
Refer to Annual TB Report for further expansion of laboratories.

Chapter 3

Supervision and Monitoring of IRLs and TB C&DST Laboratories

Courtesy:
NRL National Institute for Research in Tuberculosis, Chennai
NRL ICMR National JALMA Institute of Leprosy and Other Mycobacterial diseases, Agra
NRL Bhopal Memorial Hospital and Research Centre, Bhopal
NRL ICMR Regional Medical Research Centre, Bhubaneswar

Chapter 3: Supervision and Monitoring of IRLs and TB C&DST laboratories

3.1. On-site Evaluation of IRLs and TB C&DST Laboratories by NRLs

IRLs and TB C&DST laboratories are higher-level laboratories that provide advance and complex TB testing services for specimens referred from linked district and sub-district level TB laboratories. To ensure the quality of services at IRLs and TB C&DST laboratories, NTEP has a comprehensive QA programme that includes OSE, PT and rechecking, and performance indicator monitoring performed by designated NRLs. In addition to this, NRLs also supervise and monitor the QA programme that IRL facilitates for linked district/sub-district level TB laboratories (including TB C&DST laboratories).

A field visit is an ideal way to obtain a realistic assessment of the conditions and skills practiced in the laboratory. On-site visits from a higher-level laboratory provide an opportunity for immediate problem solving, corrective action, and on-site retraining. OSE of IRLs, DTC/ microscopy facilities, and NAAT sites is, therefore, an essential component of a meaningful QA programme and required to evaluate the overall operational conditions.

OSEs by direct contact with health workers through field visits

- Most popular monitoring method used
- Requires more time and resources
- Involves careful planning and good coordination of field activities

Activities during field visits include

- Direct observation of facility, staff performance, environment
- Review of records and reports
- Interviews of health workers, patients, etc.

In addition, the field visit provides opportunities to teach, supervise, and encourage laboratory staff; it allows interaction with the local field staff to jointly identify and analyze problems and find solutions. It provides opportunities to discuss with local decision-makers; this is useful for advocacy, information dissemination, and securing commitments from local officials.

3.2. Periodicity and team – NRL OSE visit:

NRL conducts OSE visits to all IRLs and TB C&DST laboratories within their geographic area at least once a year. NRL can plan an OSE visit for 3-5 days that includes visits to IRL, TB C&DST lab, and strategically selected district(s) (TUs and TDCs served by the IRL/ TB C&DST labs to be visited (Table 3.1). Follow up/repeat visits can be conducted based on need.

Table 3.1. Frequency, duration and sites to be visited by NRL

Sites to be visited by NRL (NRL-OSE)	Frequency	Duration of visit
• IRL • TB C&DST Laboratories/Private Laboratories • Selected district/(s) ○ *DTC, TU, NAAT site and* microscopy facilities	At least once a year (more visits can be planned based on need)	3-5 days (depending on the distance and geography)

During NRL-OSE visit, all core members and accompanied persons as specified by NTEP should be part of the visiting team (Table 3.2).

Table 3.2. Team members for the NRL OSE Visit

IRL and TB C&DST laboratory including District
Core members • NRL Microbiologist • SLT NRL • Biotechnologist/Biomedical engineer (need basis) ***Accompanied persons*** • WHO Consultant • Representative from STC/STDC • IRL Microbiologist and IRL SLT and DTO accompany during visit to District/TB C&DST laboratory

3.3. Visit planning:

The plan of the visit to IRL/TB C&DST laboratory, dates of visit, and schedule should be prepared well in advance (at least 15-20 days) in coordination with IRL In-charge/ Microbiologist, STO, and WHO consultant. This would help districts/DTOs to make necessary technical and logistic arrangements for the supervisory visit. Mark a copy to CTD in all communications.

Once planned, the dates and schedule are to be shared with CTD so that appropriate communication could be sent by CTD to the state regarding the visit and scheduling meetings with MD-NHM/Health Secretary/other higher officials on the last day of the visit.

When planning on-site visits, sufficient time should be allocated, making sure to include travel time. The extent of the evaluation during each visit will depend on the frequency of the visits, the capacity of the staff, and the performance of the laboratory, with more extensive evaluation needed in poorly performing sites.

NRL communication to STO and IRL regarding OSE

The STO is to be requested to ensure the following steps as part of the preparation for the OSE visit:

1. Send necessary instructions to the DTOs of the districts to be evaluated.
2. All staff at IRL, TB C&DST laboratory, and NAAT sites, are to be available at the time of visit for interaction with the team.
3. The team will carry out the evaluation of the laboratories/district as per the dates specified in the schedule shared.
4. Arrangements including travel of team from the state headquarters to the districts and back and field visits, as may be required.
5. Arrangements for suitable accommodation at the district and state headquarters.
6. STO may be requested to organize a meeting to appraise the Principal Secretary (Health), MD-NHM, and Director, Health Services.
7. The districts to ensure the availability of the following records at DTC/TUs/PHI
    - TB notification registers
    - Monthly laboratory abstract (microscopy facilities) and monthly NAAT indicators
    - Annexure M, RBRC & OSE records for the last three months
    - DR-TB diagnosis and treatment records
    - Records of TB notification from private providers and public health action

- All STLS of the district directed to be present at the DTC
- DTO may be requested to organize meeting to appraise the District Magistrate (DM) and Chief Medical Officer (CMO) about the findings of the OSE.
- The IRL and TB C&DST may also be instructed to keep the following ready:
  - Lab indicators, NAAT indicators, Annexure M and G (IRL only)
  - OSE reports and action taken received from districts (IRL only)
  - Testing records (C&DST laboratory register)
  - Records of training conducted (STDC/ IRL)
  - Quality control documents for all test procedures
  - Stock inventories
  - Log sheets of all major equipment

3.4. District selection and pre visit data collection and analysis:

Before visiting a district, it is important to acquaint yourself with baseline data of area/facility to be visited, analyze data beforehand, assess situation so that preparatory activities for possible interventions may be undertaken.

Selection of district for supervision:

The district/health facility may be selected by any one of the following criteria.

- Low performance/ extreme deviation/ high proportion of unfavorable outcomes in the Programme indicators.
- Decline in their performance when compared with the previous years i.e., areas with declining trend.
- Areas with high burden of disease/ clustering of cases.
- Areas with issues related to HR, Infrastructure, sample transportation, patient related services, inadequate utilization of NAAT/ high rates of errors/ invalids and indeterminate, and district recommended by IRL with persisting issues based on their experience .

Source of information:

- Annexure M
- NAAT monthly indicator report
- PHI monthly report
- Summary of monthly programme report
- LPA and LC DST indicators
- Monitoring indicators (refer chapter 6 regarding description of the indicators for selection of districts)

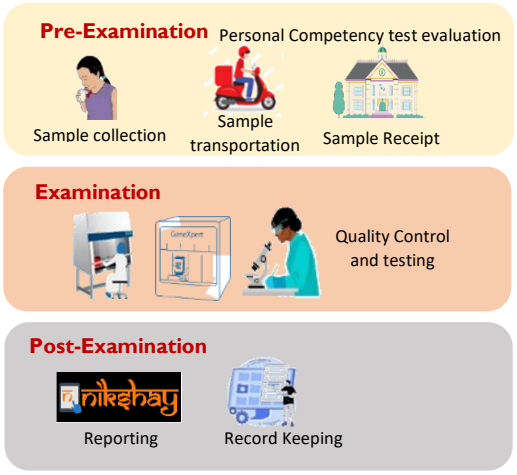
Some of the basic information (Population, facilities, non-functional microscopy facilities and NAAT sites, staff, training, etc.) regarding the state and districts planned for the visit can be collected by NRLs before the visit to save time and understand areas that require more focus during visits and discussions with DTOs and STO.

Data regarding lab indicators (contamination rates, turnaround time (TAT), positivity rates, resistance patterns, etc.), NAAT indicators (functionality, workload, error rates, calibration, etc.), annexure M, and indicators from Ni-kshay should be analyzed before the visit and can be validated during the visit. (Refer to chapter 4 – 6 for guidance regarding visit to districts and monitoring of programme indicators).

3.5. Assessment of IRL/TB C&DST laboratory

The OSE visit from NRLs to IRLs/TB C&DST laboratory should be planned carefully and should cover a comprehensive assessment of the pre-examination, examination, and post-examination phases of available testing technologies (like monitoring quality of collected specimen and pre-Lab TAT, quality control for all available diagnostic tests, release of reports within NTEP defined TAT, etc.) (Figure 3.1). Such an approach would ensure consistency in laboratory evaluations.

Figure 3.1 Pre-examination, examination, and post-examination phases of testing

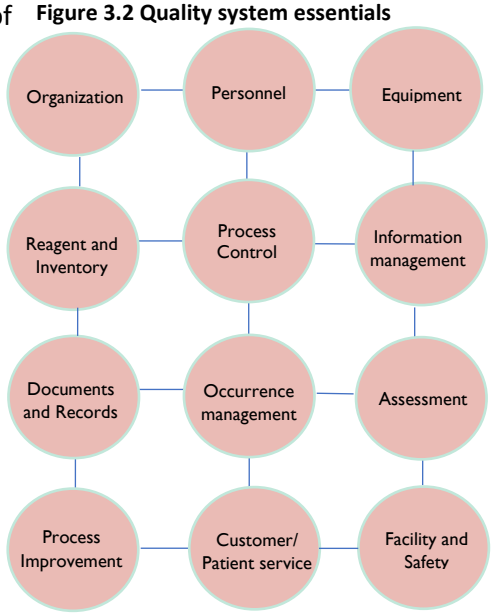


OSE visits should also be utilized as an opportunity to discuss concerns and solve problems, mentor staff on troubleshooting, facilitating quality improvement through on-site training (wherever needed) and to support IRL/ TB C&DST laboratories in implementing QMS.

QMS is defined as "coordinated activities to direct and control an organization with regard to quality". QMS organizes all aspects of the laboratory operation, from the organizational structure to the processes and procedures into 12 quality system essentials (QSEs). These QSEs are a set of coordinated activities that form the building blocks of a QMS. To have a functioning QMS in a testing laboratory, all 12 QSEs must be addressed. The IRLs are moving towards accreditation for ISO 15189 which is primarily based on the same 12 QSEs (Figure 3.2)

The visit should include a comprehensive assessment of laboratory safety including infection control measures, conditions of equipment, adequacy of supplies as well as the technical components of all diagnostic technologies available in the IRLs (Smear microscopy, NAAT, LPA, LC DST). A review and analysis of trends in quality indicators should always be conducted.

Figure 3.2 Quality system essentials



A QMS incorporates pre-examination, examination, and post-examination phases of testing (*WHO LQMS Handbook*)

3.5.1. Checklists for supervision

A standardized checklist must be utilized for consistency in supervisory visits and completeness of the information. The checklists should cover all thematic areas and quality parameters which directly or indirectly help the supervisor/assessor to evaluate the overall functioning of the lab and find areas that require more focus and have scope for improvement. Sufficient time must be allotted for the visit to include observations.

The checklists for supervision of IRLs /TB C&DST laboratories have been developed that cover all QSEs. In addition, there is a checklist specifically for assessing the supervisory, monitoring, and mentoring activities of IRLs for the linked districts (Annexure 3.1). The checklists, however, may need to be revised if newer diagnostic tests are introduced or there is significant change in the diagnostic algorithm.

3.5.2. Guide to supervisory visit and sites preparedness

Following sections discuss briefly the key areas on which NRL should focus during their supervisory visits to IRL and TB C&DST laboratories, as well as how the sites to be visited can prepare themselves to fulfil the requirements.
The checklists corresponding to these sections are annexed (Annexure 3.1).

Human Resource, Training, and Competency

Human resources: Skilled HRs are required to provide reliable and accurate laboratory tests in a timely manner. The labs should be strengthened with the placement of required number of approved staff at all levels (IRLs/ TB C&DST lab/district level). Efforts should be made by states to fill all vacant positions for effective implementation of NTEP supervision, mentoring, monitoring, troubleshooting, and diagnostic work.

[Note: Additional positions of SLT have been sanctioned for IRLs as well as TB C&DST laboratories in accordance with the norms and basis for costing in the NSP considering the addition of workload after the introduction of newer diagnostics and revised diagnostic algorithm.]

Job description: A job description is a document describing the tasks and responsibilities of a specific position. In NTEP, job description for all key positions is available and can be accessed at https://tbcindia.gov.in/showfile.php?lid=3617 (DO-letter TOR and need norms for NTEP staff). Besides the job description, any trained and competent staff may be delegated additional responsibilities (e.g., Safety Officer and Quality Manager) or tasks (e.g., in-house maintenance of laboratory equipment, store management). Hence, an individual staff member may occupy multiple positions in the organization and in this situation, they must be authorized by laboratory administration along with necessary addition into their job description.

Personnel files: Laboratory should maintain personnel file for all laboratory staff, and it should contain at least:

- Up-to-date curriculum vitae (less than 1 year old)
- A copy of the staff member's complete education certificates, degrees and diplomas
- Laboratory training records (including induction training, safety and laboratory techniques).
- Competency assessment reports
- Certificates of trainings followed as part of continuous education for the current job tasks
- Possible reports of accidents that have happened to the staff member during working hours
- Record of medical checkup of each staff

Personnel replacement matrix: Laboratory should develop a **personnel replacement matrix**. This is a matrix with the names of all the staff members. Next to each name the names of one or two other staff members are given that can take over the work of the first staff member when he/she is absent. It is important to see the work burden for staff members. If the number of tasks is too high for some staff members, it can be corrected by-a) reorganization of tasks over other staff members b) hiring new staff.

Training and retraining of IRLs/ TB C&DST laboratories: Staff must have adequate training and experience for the position to which they are assigned. To implement the diagnostic components of the NTEP effectively, there is a need for an effective well-trained workforce. Capacity building is the primary step to ensure the availability of trained manpower to achieve the target set by the NSP. Presently at the country level, the most common approach is "training the trainers", in which selected participants (usually Microbiologist & Senior LTs) from the NRLs/ IRLs are provided intensive content training at one of the NRLs. These participants once deemed competent, then provide training to staff in their laboratories and peripheral laboratories within the country.

Before new staff can be authorized to perform a specific procedure, they must be introduced to it and the laboratory must sure that the staff member is competent to perform it correctly.

Broadly, there are 4 types of training envisaged under the NTEP which are listed below:

1. Induction training. The goals of the **induction programme** are to familiarize the new staff member with the laboratory rules, train the staff member on what to do in specific situations such as an emergency, and familiarize the new staff member with the procedures that are relevant for his/her position. Initial comprehensive training before resuming responsibilities of NTEP
2. Re-training. Periodically retraining already trained staff in NTEP need to be considered (every 2 years).
3. Update training. Newer initiatives or changes in the policy of NTEP are to be conveyed to the health personnel as short update training.
4. Refresher training. It is important that the training needs of each staff member are assessed and that if gaps are detected the staff member receives adequate training. Staff must always be appropriately trained for the tasks performed, and refresher training must be given to keep staff knowledge up to date.

Mandatory trainings for IRL and TB C&DST staff:

All staff at IRLs and TB C&DST should undergo the following trainings. Trainings can be conducted either at NRL/on-site by a laboratory Microbiologist trained at NRL.

- Induction training at the time of joining which may include:
  a) Orientation to the department,
  b) Various sections, and their functional areas
  c) Biosafety and waste management
  d) Staff facilities, health, and safety requirements
- This should be followed by training in all Diagnostic technologies (Smear microscopy, CBNAAT, Truenat, FL and SL LPA, Mycobacteria Growth Indicator Tube (MGIT) culture and DST (First and Second line), lab SOPs, and assigned work processes (for technical staff).
- Biosafety training
- BMW management (Annexure 10, PMDT guidelines; (ref only) 8368587497Guidelines for PMDT in India 2021.pdf
- Laboratory Information Management system (LIMS)

Joining of any new staff/ needs of training of existing staff should be communicated to NRL/ CTD by IRL In-charge. NRL should arrange for the onsite/training at NRL in consultation with IRL In-charge and STO.

If the trainings are conducted on-site by a trained IRL Microbiologist, the proof of the training (agenda/schedule, copy of certificate, etc.) should be maintained in the personal files of the lab staff.

Retraining of IRL and TB C&DST staff:

Retraining of IRL and TB C&DST staff should be undertaken by NRLs. A training calendar for the training should be prepared and shared with the linked laboratories and CTD. Retraining should consider revision of

- All diagnostic technologies, focusing mainly on difficulties encountered by IRL staff, possible solutions, and troubleshooting activities.
- Discuss any newer initiatives/guidelines of the program.
- Discuss common issues related to filling of annexures and indicators with a focus on key areas for improvement.

Competency assessments:

Competency assessments should be performed to investigate if each staff member can correctly and competently perform the tasks and responsibilities assigned to him/her. The competency of each staff member must be assessed annually or when a staff member starts performing a new technique: as soon as the formal induction and training period is over with documented proof.

Performance appraisal: The performance of all employees of the laboratory must be assessed regularly to ensure and record that everybody performs according to expectations. This way, potential problems are also detected in an early stage, preventing bigger problems later. A performance appraisal is broader than a competency assessment and involves not only assessment

of technical competency, but also observation of adherence of staff members to safety rules, punctuality, adherence to policies, communication skills (including communication with patients), and professional behavior. It is usually performed annually/before the renewal of the contract by the appointing authorities (NHM).

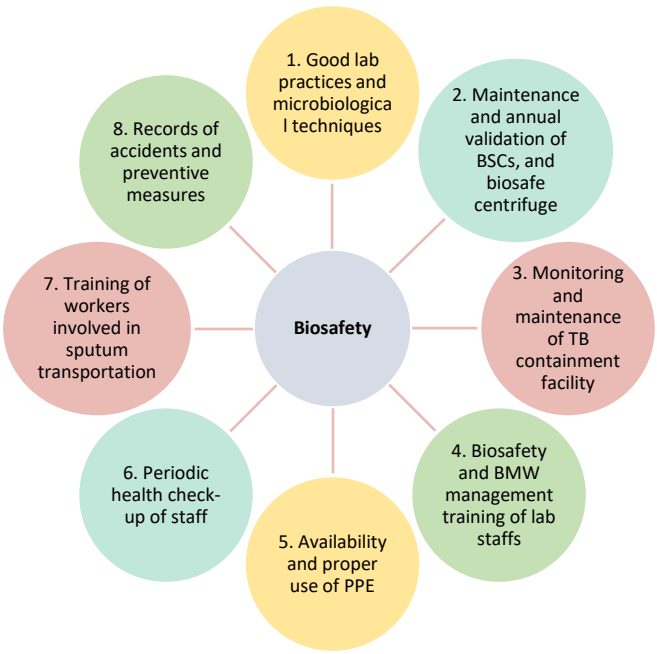
Review by supervisory staff

Sanctioned competent staff with adequate training with the capability of undertaking corrective action when appropriate.

Facility & Biosafety

Biosafety manual for TB laboratories: A comprehensive TB laboratory biosafety manual and its monitoring mechanism has been developed containing all facility requirement, good microbiological practices, safety procedures as well as emergency preparedness plan for TB laboratory. All staff members must read the biosafety manual to know how each procedure should be done correctly. The Safety officer should be able to train colleagues/staff, perform safety audits, risk assessment and provide advice on laboratory biosafety and therefore needs to be fully trained him/herself. Laboratory accidents should be reported/documented, and a proper root cause analysis should be performed in order to implement appropriate corrective/preventive measures.

Figure 3.3 Important components of biosafety in TB laboratory



Some of important components of biosafety are depicted in fig. 3.3.

Prevent access of unauthorized persons to the lab: Access to the laboratory by unauthorized persons must be prevented by displaying appropriate signage. Sputum should never be collected inside the lab (always outside the laboratory in open, non-trafficking and ventilated area).

Floor plan: It is important that the laboratory floor plan is logical. When staff has to walk a lot through the laboratory the work efficiency decreases and the risk of bumping into each other and potentially causing a spill is increased. The floor plan should be designed to increase work efficiency and create a unidirectional workflow where possible. Laboratory floor should be slip-resistant, non-staining, non-permeable, durable, easy to clean (with disinfectant) and easy to maintain. It is always better to have all the diagnostic technologies in the same premises, if not, lab linkages as defined by the NTEP should be followed to complete the cascading tests as per the algorithm.

Dedicated areas for different procedures: There should be dedicated areas for different procedures and areas should be separated if conflicting activities are performed. Adequate staff facilities should be provided, including i) separate rest area/room where staff can have breaks, ii) separate office space where staff can do paperwork iii) storage space for staff's personal belongings (handbags, clothing), iv)

drinking water; v) toilets and vi) adequate ventilation and lighting in all rooms. Areas, where patient samples are collected, must be safe and comfortable for the patient.

Regular cleaning of the laboratory: The laboratory must be regularly cleaned with suitable disinfectant (e.g. Phenyl/Lysol) by dedicated and trained cleaning staff with a documented cleaning schedule. However, workbench should always be cleaned by laboratory technologists as they are familiar with the risks of the laboratory and safety procedures.

Uninterrupted supply of electricity: Lab should ensure an uninterrupted power supply (UPS) as well as power generator back-up to all critical equipment (like biosafety cabinet (BSC), safety centrifuge, air handling unit, Thermocycler, MGIT 960, CBNAAT, GT Blot machine, TB containment facility etc.). UPS should support sufficient back-up to avoid risk of aerosol exposure or test failure or loss of product/samples.

In the case of power-failure electricity needs to remain available in the laboratory rooms and for critical equipment such as the computer server. E.g.: if one is working in a flow cabinet with LCs, the cabinet should not shut down in case of a power failure, or when a polymerase chain reaction (PCR) is running, a shut-down due to power failure would negatively influence the examination or even make it useless.

Storage space: Arrange and monitor adequate storage space and environmental conditions for samples, documents/ records, equipment, consumables, etc. Storage area should be organized rationally to make everything easily accessible. Furthermore, by implementing a first expiry first out system (FEFO), the cost associated with reagent expiration can be reduced.

Safety equipment, personal protective equipment (PPEs) and good microbiological practices: Minimum requirement of PPEs and safety equipment based on risk level of associated risk is recommended to laboratory staff and they must adhere to the same. However, safety equipment (including PPEs) greatly adds to but can never replace the good microbiological practices. Induction and refresher training of lab staff must always include the good microbiological practices and special technique to minimize the aerosol generation. Laboratory staff must be given adequate training on the use of safety equipment, appropriate donning and doffing of PPEs, safe handling of specimens and TB isolates and all possible precautions should be taken while working with the biological products and minimizing aerosol production. As part of QA, NRLs and IRLs should assess the laboratory safety during OSE visit. A detailed monitoring checklist is available in the TB laboratory biosafety manual.

Occupational health: Given the risk of occupational exposure, laboratories should implement an occupational health programme, and workers should be provided with occupational medical services such as a baseline medical checkup (prior to commencing work in the TB laboratory), periodic medical evaluation, and treatment, as needed. The staff should be trained to recognize symptoms of TB and should be offered vaccination against Hepatitis. Laboratory should consider excluding highly susceptible staff (e.g., pregnant women or immunocompromised persons) from hazardous work. Availability of first aid kit should be ensured by the laboratory and staff members should be trained in providing first aid, especially in laboratories that are not situated in a hospital.

Hazardous chemicals/ material: The lab should have an inventory list of all hazardous materials and their location within the facility. Material Safety Data Sheet (MSDS) must be collected, stored and should be easily available to all staff for reference. Chemicals/reagents should be kept at recommended environmental condition and location. Continual monitoring of the safety performance of the staff, including a logbook of accidents and preventive measures, should be maintained.

Dealing with spills: Laboratory spills have a high risk for infection when not cleaned up safely. Staff should be trained in using spill kits for handling spills. Spill kits for both biological and chemical spills should be available in strategic locations, taking into account the facility's design and laboratory activities. For more details regarding handling of spills refer Biosafety Manual.

TB containment laboratory: Manipulating LC and DST activity require TB containment facility. Ensure restricted access into the laboratory room so that only authorized persons can access the laboratory

room. Negative pressure in the lab should be monitored and recorded. The facility should be under Annual Maintenance Contract (AMC). Besides this system, an indicator also needs to be installed next to each entrance door that shows the air pressure difference in the laboratory and outside the laboratory. The negative pressure system must be connected to a backup electricity source to ensure that it keeps functioning during a power failure. Appropriate installation, certification, annual validation, maintenance, and proper use of BSCs, and periodic change of High Efficiency Particulate Air (HEPA) filters, are some of the important measures which should be considered by the labs to maintain the safety of the staff.

Optimized communication channels: Where necessary and convenient, communication channels (eg: Intercom facility) must be established to increase the efficiency of work. E.g.: when one is working in a TB containment laboratory and has to speak to a colleague in the office area, it is easier to call this colleague instead of having to take off his/her gown and gloves, wash hands, and walk to the office area. It may also be possible that some laboratory rooms are situated in another building/another floor. Mobile phone use should not be allowed inside the laboratories because of the risk for infection (staff touching the phone without washing hands, potentially contaminating it which increases the risk for infection). Besides, mobile phones may distract staff from jobs requiring all their attention and focus.

Directional airflow in the laboratory rooms: It is important to make sure that the air is not flowing in the direction of the workbench (blowing the bacteria towards the staff). A staff working should monitor/check the airflow patterns before starting the work.

Waste segregation and disposal: The laboratory produces many different types of waste which may be dangerous for the environment and/or for the community. Therefore, the laboratory must adhere to strict procedures regarding waste disposal and processing. Write a SOP on Waste Segregation and Disposal based on current national/State BMW guidelines and color coding. A waste segregation chart should be designed that depicts how to segregate the waste at the point of generation. This can be printed and put on the walls of the laboratory rooms so that staff can quickly see how they should segregate specific types of waste. Laboratories must also acquaint themselves with amendments made from time-to-time in the BMW management guidelines.

Review by supervisory team:

- *Proper infrastructure, standard layout/requirement for with separate areas for defined work and workflow within the laboratory should be assessed*
- *Restricted entry for unauthorized personnel*
- *Uninterrupted supply of electricity*
- *Storage space sufficient, arranged and monitored*
- *Staff trained in biosafety and following good lab practices*
- *Safety equipment in use being calibrated and maintained*
- *TB containment lab under AMC*
- *Appropriate installation, certification, annual validation, maintenance, and proper use of BSCs*
- *Staff trained in BMW and segregation and disposal as per guidelines*

Equipment

NTEP Laboratories over the years have been supported with equipment and maintenance centrally by CTD with funding support from various sources (Global fund support). These activities are being recently transitioned to make the laboratories self-reliable and sustainable.

Maintenance of all CBNAAT machines under NTEP, MGIT 960 equipment used for LC and GT Blot, and Twincubator for LPA has been presently covered from the central level.

States and UTs are provided a budget through their PIP, for maintenance of all other critical equipment. NRLs should coordinate with all linked IRLs and C&DST labs and IRLs should coordinate with STC and districts and render the required support for covering all important equipment under AMC.

Equipment registers: Making an overview of which equipment is present in the laboratory is the first step in implementing a QMS for equipment. The equipment register contains specific details about each piece of equipment (such as maintenance and calibration dates, maintenance frequency, who is responsible for the equipment, etc.).

Labeling equipment: Each piece of equipment must be uniquely labeled to link the piece of equipment to its file in the equipment register and mention the last maintenance/calibration was performed and when the next service is due. This label needs to be renewed each time the piece of equipment has been serviced.

Procedures for operating: To ensure that equipment is operated and always maintained correctly, the lab should have SOPs (in alignment with manufacturer's recommendations) for using and maintaining all critical equipment. SOPs help in ensuring the standardization of practices and to reduce instrument downtime, testing variations, and errors.

Not all the equipment present in the laboratory needs to be supplied with an SOP. E.g., simple equipment such as vortex and clocks don't need SOPs for correct operation. The Biomedical engineer placed at NRLs should support/guide IRLs and TB C&DST laboratories in developing the manuals, providing training regarding usage and maintenance, and information regarding vendors for AMC.

Prepare Bench aids for each piece of equipment including daily maintenance instructions: Bench aids are stepwise procedures for routine use of the piece of equipment; they contain the procedure for operating the piece of equipment and, if necessary, the basic preventive maintenance steps and calibration procedure that needs to be carried out regularly. Laminated Bench Aids can be placed near the appropriate equipment. Put them in plastic document pouches to protect them from water and other deteriorating factors and place them at a visible, logical location near the piece of equipment they have been written for.

Authorize staff for use and maintenance: For all equipment, staff members must be authorized to use the equipment and the lab must make staff members responsible for the equipment. This creates an overview of who uses the equipment and ensures that usage logs are maintained and that users receive appropriate training and instructions before using the equipment. It also helps to ensure that preventive maintenance and calibration are performed, and it facilitates the early detection of defects.

Monitor and record environmental parameters and equipment parameters: The environment and equipment can have a considerable effect on many examinations and reagents. The lab should monitor and record environmental and equipment parameters.

- Make a list of parameters that could influence reagents, equipment, or the examination. Examples of critical parameters:
  - Temperature of incubators
  - Temperature of refrigerators and freezers
  - Environmental temperature
  - Environmental pressure differential between the laboratory and the external environment (in case of a negative pressure system is in place)
  - Calibration of equipment
- Define for each parameter the critical interval. This means that when the parameter has a value above or below this interval, corrective action is necessary to correct the parameter and bring it back to normal values.
- Define for each parameter the frequency with which it should be monitored (e.g., daily/weekly/monthly).
- Develop for each parameter a monitoring log sheet that will be put on the wall.
- Explain to all staff members the procedure and reason for monitoring critical parameters.
- Start monitoring critical parameters.
- After some time, check if the monitoring of the parameters is done consequently and correctly.
- Regularly check if log sheets need to be replaced. Store the completed log sheets in a folder.

The lab should have the following documents and records of each piece of equipment and store these in the Equipment Archive:

- Equipment identification page
- Equipment register
- Maintenance log sheets
- Maintenance forms/calibration forms
- Completed usage log sheets/logbooks
- Manufacturer's instructions
- Validation reports

Maintenance and calibration: Laboratory should determine the following for each piece of equipment:

- The frequency and method of maintenance/calibration
- Whether maintenance can be done by the laboratory itself or must be done by an external specialized company
- When maintenance is done internally: if additional training is needed for the staff member assigned to perform this maintenance

- Which companies are suitable for maintenance/calibration of equipment for which the laboratory cannot perform maintenance themselves
- The annual budget needed for maintenance

Lab should plan and conduct preventive maintenance and calibration for each piece of equipment in a yearly/biannual schedule as applicable. Project the budget required for AMC of all critical equipment in the annual PIP.

A maintenance log for scheduled and as-needed maintenance should be developed to ensure that all maintenance procedures are performed and documented. In addition, a calendar should be developed to ensure that all scheduled maintenance is performed when required.

Annual/comprehensive maintenance contracts: Service contracts for all critical equipment should be acquired from the manufacturer or the manufacturer's representative/authorized vendors. These contracts are necessary not only to maintain the proper functioning of the instrument but also to extend its life span. The contract should stipulate that the provider must be responsive for timely and appropriate service. Records of all maintenance, including preventative maintenance performed by a service representative, should be documented in specific log forms or books.

Troubleshooting: Testing failures or instrument malfunctions may occur during the routine use of instruments. Troubleshooting of these failures or malfunctions is necessary before testing is continued. A corrective action log sheet should be developed to record any problems and error messages that may occur (e.g., MGIT 960 instrument). The corrective action is taken to resolve the problem, including advice or service calls from the manufacturer, should be documented. This log should be reviewed periodically to check for trends, and any technical errors that are identified should be immediately addressed.

Defective equipment: The laboratory should have the SOP that provides all the procedures that must be followed when a piece of equipment is defective; from disinfection and removal from the laboratory to returning to the laboratory following proper validation.

Condemnation of equipment: Continuous use of the equipment & various other factors including environmental factors cause progressive wear and tear and render the equipment unserviceable. Such equipment needs to be replaced to avoid interruption in services. However, prior to replacement, the equipment needs to be condemned appropriately. The process of condemnation is usually delayed, or the condemnation does not happen due to the lack of specific guidelines for condemnation and subsequent replacement of condemned TB laboratory equipment. Few states and institutes follow their policy but largely the condemnation procedures are not undertaken regularly, and a lot of space remains occupied by the non-functional equipment in the lab awaiting to be condemned. Formation of a condemnation committee is important. For more details refer condemnation guidelines from link below.

Note: *List of equipment required for the functioning of TB lab, history sheet to be maintained for all equipment, and condemnation guidelines (if do not exist at state) can be accessed from the link https://tbcindia.gov.in/showfile.php?lid=3426 Specifications of equipment and TB containment laboratory can be accessed from the link*

https://tbcindia.gov.in/WriteReadData/TechnicalSpecificationForTBLaboratory.zip.

Review by supervisory staff

- *Inventory of equipment maintained and updated as required*
- *All critical equipment under AMC*
- *SOPs and bench aids for equipment exist and followed by lab personnel*
- *Maintenance procedures performed and documented*
- *User log sheets and daily maintenance*
- *Condemned equipment labelled and removed from the laboratory*
- *Condemnation committee and mechanism for condemnation of equipment in place*

Process control and process improvement

Monitoring transportation of samples: Correct transportation of samples to the laboratory is crucial for the delivery of correct and quality assured results. Samples that have deteriorated due to bad conditions during transport to the laboratory will never lead to a quality result. Moreover, the samples also need to be packed safely to protect the courier and other persons involved in sample transport and reach to IRLs and TB C&DST laboratories within 48 -72 hours in a cool chain. The safety of staff involved in the transportation of samples is also important. Health and safety guidelines for staff/ workers involved in sputum transportation can be accessed through the link https://tbcindia.gov.in/showfile.php?lid=3440

If samples are received in a bad state due to incorrect transport, or if they are packed in an unsafe manner, the cause of the problem needs to be identified and appropriate corrective and preventive actions need to be undertaken. If bad quality samples are received, always follow these up by attempting to discover what has led to the deterioration of the sample or the incorrect packaging. If the cause is found, try to develop preventive measures to prevent the deterioration of more samples in the future due to this cause. E.g.: if a leaking sample is received at the laboratory because the wrong container was used, the DTO of the district must be contacted to inform him/her about this and to instruct on the correct sample container to be used. Recording this will give insight into the frequency of problems occurring in sample transport. E.g.: when a lot of samples are contaminated or there are chances that the bacteria are dead due to long transportation time, recording this occurrence helps in determining the scale of this problem and enabling the laboratory to formulate specific corrective and preventive actions in an attempt to resolve this problem. It subsequently helps the lab to see if these actions have helped to solve the problem.

Standard operating procedures: The first step in standardizing the primary process is the documentation of the procedures of all the tests currently performed in the laboratory in SOPs. The laboratory should develop SOPs for all the tests. The generic SOPs always need to be checked and adapted to the situation in the laboratory otherwise the procedure described in the generic SOP may be different from the procedure performed in your laboratory. SOPs for the different tests can best be written in consultation with staff members who perform the test. These staff members know the small details that make the tests perform optimally and can be described in the SOPs. However, instead of making separate SOPs for every small procedure, it may be better to make one SOP compiling all these support procedures e.g., internal communication: organization of meetings and drafting of minutes.

Develop sample acceptance/rejection criteria: The results of the laboratory will be flawed if bad quality samples are accepted, even though the rest of the testing process is completely quality controlled and quality assured. Having a well-functioning sample reception unit that checks the quality of each sample and rejects those that are of inadequate quality is thus the first step in ensuring that the testing process runs correctly and produces a quality result. If the sample doesn't completely comply with the criteria, it must be rejected and a request for a new sample must be sent to the district/linked lab. In case of precious samples that cannot be collected again, all efforts should be made to process the same with remarks mentioned in the register.

The sample reception and processing unit are one of the most important elements of the analytical process. If this unit is not properly organized the integrity of the complete analytical process is compromised. It should be kept in mind that research has shown that most laboratory errors take place in the pre-analytical stage, of which the sample reception is a central part.

Quality controls:

- Recording of sample quality and quantity
- Sample rejection criterion
- Use of negative control during sample processing.
- Use of unstained positive and negative smears for every new batch stains/reagent set.
- Quality control of all reagents and drugs prepared in-house.
- Use of H37Rv and any resistant standard strain with every batch of DST.
- Use of positive (Deoxyribonucleic Acid (DNA) from sensitive and resistant strains) and negative controls (both for Master mix and DNA) with each batch of LPA tests.
- QC of the new batch of MGIT media/LPA kits/drugs for DST
- Maintenance of registers and other records related to QC.

Internal Quality Controls (IQC): The purpose of IQC is to control the quality of every single step of each procedure performed in the laboratory. However, to assure the quality of each procedure the IQC need to be monitored. When deviations and quality control failures are detected, the laboratory needs to act quickly to prevent reporting of faulty examination results. The laboratory should list the IQCs for all procedures in the laboratory, not only the examination procedures, and determine the frequency with which these controls should be done (e.g., "Daily", "Weekly", "With each new batch", etc.). Also, preparation of reagents, preparation of media, checking correct transcription of results on result reports, etc. need quality control steps. The results of IQCs must be archived. These records need to be used for a periodical review of QC results. The protocol for performing the QCs must be included in the SOPs for each procedure. i.e., QC must become an integral element of all the procedures performed in the laboratory. The staff should be explained the concept of IQC and who should do which quality control and at which time.

Continuous monitoring of IQC results: The objective of this system is to detect QC failures and deviations from trends in an early stage to prevent reporting of flawed results. If necessary, make use of graphs and statistical analyses. When deviations and QC failures are detected, the laboratory needs to act quickly to prevent faulty examination results are reported. Examination results should not be reported in case of QC failure. The IQC data must also be monitored to identify possible trends and deviations over time. Deviation of QC results over the long term could indicate deterioration of reagents, deterioration of staff competency, etc. When deviations/QC failures are detected, action must be undertaken according to the procedure in the SOP for IQC to solve the deviations/QC failures.

Quality indicators which can be validated during the visit:

Indicator	Target
Service interruption due to stock outs	No stock outs leading to service interruption
Service interruption due to equipment downtime	No equipment downtime leading to service interruption
TAT	90% of results meet test-specific TAT
EQA results	>90% EQA panels are passed
QC results	>90% QC results meet expected criteria
Specimen rejection	<1% specimens rejected
Contaminated cultures in solid	3-5%
Contaminated cultures in liquid	5-10%
Contaminated DST	<3%
X200/X400 errors in LC DST	<3%
Invalids/Uninterpretable results in LPA	<10%
Errors/Invalids/no results in CBNAAT	< 4%
Invalids/ Errors in Truenat	<5%

If necessary, perform an analysis to find the cause underlying the failure or the deviation from the trend, and formulate preventive and corrective actions.

Determine the turnaround time (TAT) and monitor adherence: The diagnostic decision is, among others, based on the results of laboratory testing. The longer it takes before the laboratory results are known, the longer it takes before a proper diagnostic and treatment decision can be made. In the meantime, the patient remains ill, and the disease may even progress, burdening the patient even more or even leading to death. It is therefore critical that laboratory results are delivered in the shortest amount of time possible.

The TAT (pre and post) are defined by NTEP. To control and improve the TAT of laboratory examinations, it is crucial to continuously monitor adherence to TAT. Monitor every month/quarter the adherence to TAT for each test. The PMDT registers capture the sample reception date and the reporting date. Calculate the percentage of samples exceeding the TAT for each examination. The goal should be to decrease the percentage of samples exceeding the TAT to 0%: Try to identify factors that could cause delay of the TAT within the process of each examination. See if these factors can be corrected to decrease the percentage of samples exceeding the TAT. Determine if the corrective/ preventive measures have worked by analyzing the data of the TAT assessment in the following quarter.

Quality Indicators: Continuous monitoring of the correct performance of the total testing process (consisting of the pre-analytical stage, the analytical stage, and the post-analytical stage) of the laboratory helps to identify potential errors quickly and is one of the most important activities to create continuous improvement. Monitoring the correct performance of every single step of the total testing process is not feasible. Instead, the lab can monitor the quality indicators monthly. If a sudden change in the trends is seen for a specific indicator, identify the cause, resolve the nonconformity to get the value of the quality indicator down to its normal level, and formulate preventive actions to prevent the same problem from reoccurring. IQC must be implemented to have daily control over the correct execution of procedures. Continuously monitoring quality indicators and resolving errors in the total testing process detected by these quality indicators facilitates continuous improvement of the laboratory.

After quality indicators are monitored for a certain amount of time (approximately 6 to 12 months), set a limit of acceptability for each indicator and try to optimize laboratory processes such that you achieve these limits. E.g., if the indicator "percentage of samples rejected" the value is normally around 5%, set the limit of acceptability on 3% sample rejection. Identify the causes leading most often to rejection of samples and try to resolve these causes. See if the percentage of rejected samples subsequently decreases. Repeat this process until the 3% limit is achieved. Setting limits of acceptability for each indicator and trying to optimize the laboratory processes such that their performance doesn't exceed these limits is called benchmarking. Try to minimize the limits of acceptability as much as possible to trigger maximum laboratory performance improvement. However, laboratory staff should not be pressurized to achieve the benchmarks as it will then become a perverse activity that does more harm than good.

Review by supervisory staff

- *SOPs for all diagnostic technologies/ laboratory processes*
- *Validate lab indicators*
- *Check usage and monitoring of IQCs for all diagnostic technologies*
- *Monitoring of lab indicators by IRL and discussion with staff for quality improvement*
- *Monitoring and adherence to the TAT*

Quality Assurance

Proficiency testing: All the laboratories under NTEP follow the QA protocol for all technologies as per the WHO guidelines. The EQA for DST is through structured panel and retesting exercises (Figure 3.4). While on-site supervision and routine monitoring of quality indicators are the most critical components of QA, PT helps to identify major non-conformities, allowing supervisors to target the most poorly performing laboratories for on-site supervision. The rule is that EQA results will only provide an effective insight into the quality of results if the EQA samples are treated in the same way as routine samples. If EQA samples are treated differently from routine samples then the results may be excellent, but nothing will be learnt about the quality of the routine service. Instead of making the best staff member perform the examination of EQA samples and rechecking the results several times before submitting them, it is much more instructive when each time a different staff member (that is authorized to perform the test) performs the examination of EQA samples. This reflects much more the actual situation of how laboratory testing on normal patient samples is performed. For annual PT of LPA (FL and SL) and MGIT (FL and SL), 20 cultures are sent by NRLs to IRLs. While annual PT does not measure routine laboratory performance, it may identify laboratories with major deficiencies. NTEP has a well-established PT mechanism for all diagnostic technologies, but if the results of activities are not reported back to the laboratories in a timely fashion, or support for corrective actions is not available, it leads to missed opportunities for quality improvement.

The panels should be sent by NRLs by the end of the first quarter of every year (in April). Fresh pure subcultures (not more than 15 days old) should be sent to IRLs / TB C&DST labs. The IRL should acknowledge receiving of cultures and subcultures as soon as possible. Storing panel cultures for a long can lead to contamination/no growth. If one or two cultures are contaminated, the cultures should be reprocessed to revive the same at the earliest. If unsuccessful, NRLs should be contacted for sending the cultures to be resent again.

Results should be communicated to NRL within the defined time (7-10 days for LPA and 6- 8 weeks for MGIT DST). Figure 3. 4 depicts the PT mechanism for LPA and MGIT DST. Rapid feedback is needed to enable prompt initiation of corrective actions. After NRL receives all the results, the final report should be shared with IRL/TB C&DST laboratories & CTD.

EQA of NAAT using 5 dried tube specimens has been expanded across the country. Coordination of the EQA activity, manufacture, and validation of the panels is undertaken by NTI, Bangalore presently. The same is being extended to Truenat sites. Each panel carries a score of 20 marks (i.e., 10 for *Mycobacterium tuberculosis (*MTB) detection and 10 for Rif result). The laboratory performs testing and reports results through a EQA portal. Performance is considered satisfactory if the laboratory obtains a score of 80 or more. A root cause analysis visit is to be carried out for sites which obtain unsatisfactory score, and a repeat panel is shared after corrective actions are taken based on the the visit.

Figure 3.4 Proficiency testing mechanism in NTEP

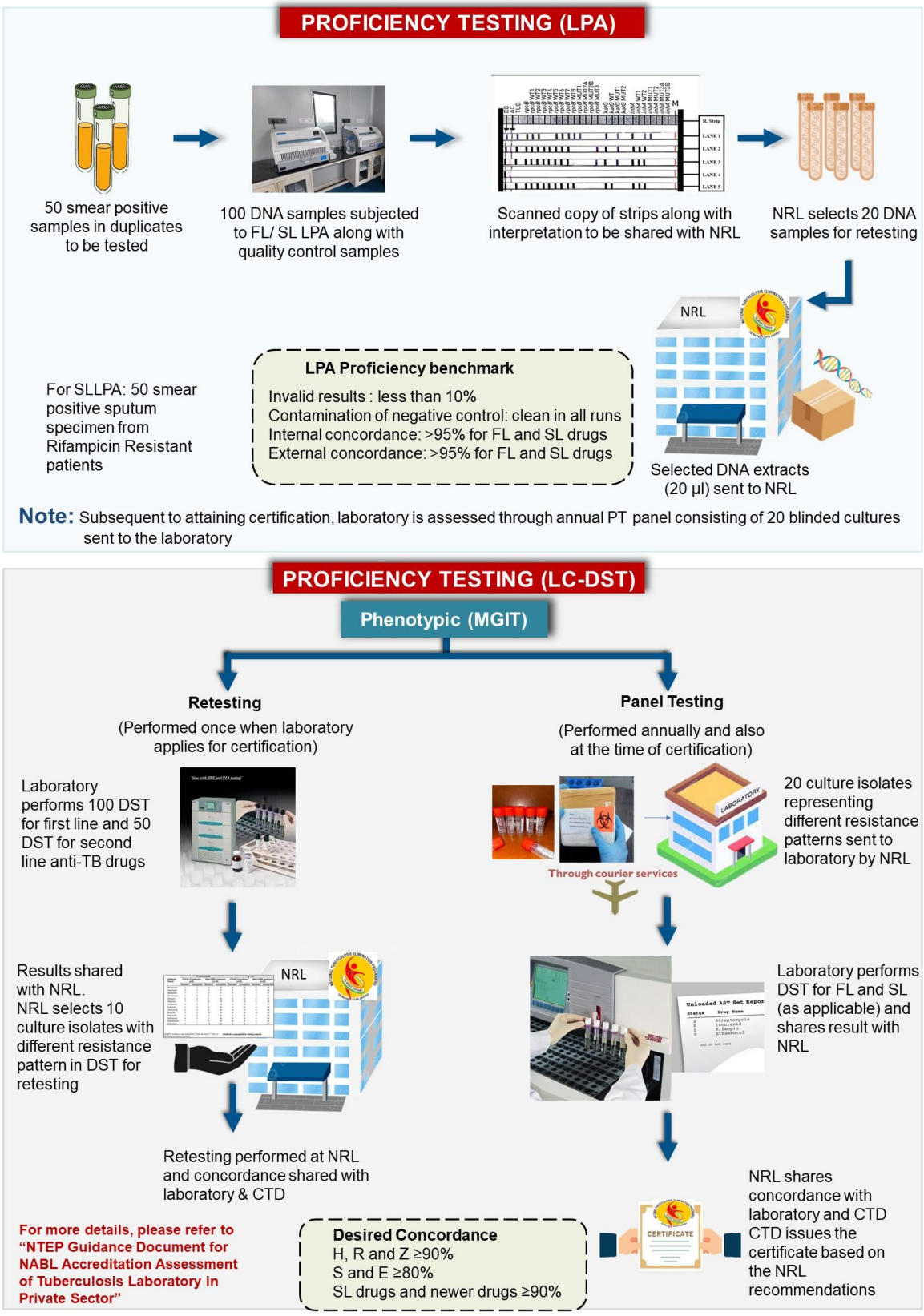
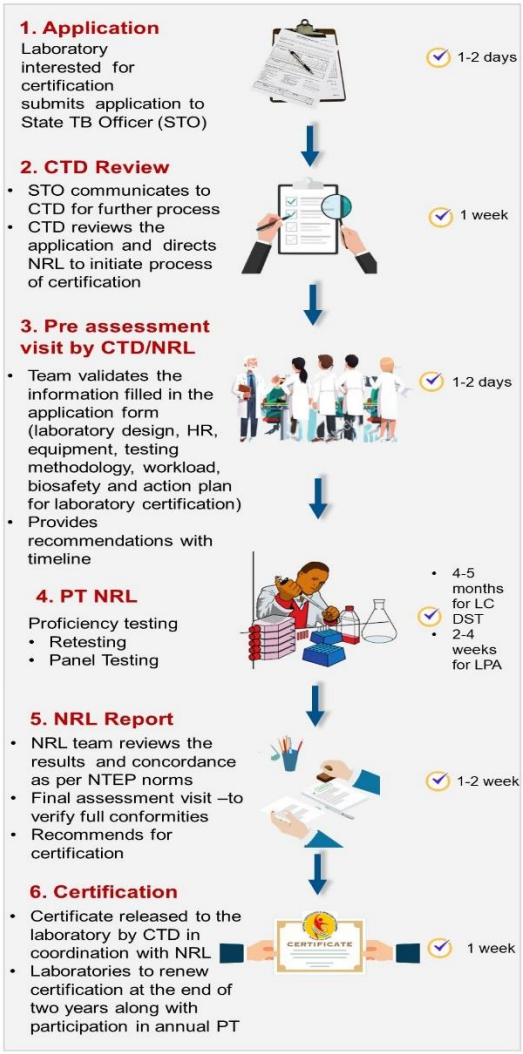


Figure 3.5 Private laboratory certification process in NTEP



Achievement of the desired concordance in PT panel:

The laboratory in charge must discuss the results at least with the staff members involved in the examination, but preferably with all the laboratory staff so that everybody knows how the laboratory performs. If deviating/incorrect results were produced an analysis must be performed to identify the problem and the cause(s) of this problem. When all the causes have been found, the laboratory must implement corrective actions to solve the problem.

If the IRL/ TB C&DST lab fails to clear PT, the lab should be informed immediately regarding the results. The IRL should stop reporting patient results for the component/ drug. NRL should try to figure out the reason and assess the need for on-site visits/retraining. In addition, a repeat panel should be sent at the earliest. In the interim, until the laboratory clears the PT for the particular drug, assigned geographies should be linked with another TB C&DST laboratory for providing DST services for the same drug.

In case of any inadvertent event/ non-receipt of panel through SNRL, Belgium Antwerp, the NRLs can coordinate with NRL NIRT for LPA/MGIT and NRL NTI for NAAT for a repeat panel after approval/intimation to CTD.

Renewal of certification for different diagnostic modalities:

Certification for genotypic (FL LPA and SL LPA) and phenotypic DST (FL and SL) is provided by CTD to all laboratories (IRLs, TB C&DST labs, medical college, private labs) after successful completion of PT (both retesting and panel testing). The certificate is awarded for a period of two years. CTD is encouraging the private sector laboratories for NTEP certification. Through this certification, patients are assured quality diagnostic care therefore avoiding the repeat testing in public sector, and prompt initiation of treatment. The process of certification is depicted in Figure 3.5. The PT schedule for phenotypic DST as well as LPA is annual, and the certification process is biennial for all technologies. Valid certificates must be available with all IRLs and TB C&DST labs. IRLs/ TB C&DST labs should submit Part B of form “Application form for Mycobacteriology Laboratory Accreditation and Renewal of Accreditation (AMLA)” along with the last PT results to NRL at least one month before the date of expiry of the certificate.

Review by supervisory staff

- *All staff participate in PT*
- *PT results reported timely*
- *Valid certificates exist for all Diagnostic tests*
- *Root cause analysis and Corrective and Preventive Actions (CAPA) performed in case of non-achievement of concordance in panel*

Information Management

A Laboratory Information Management System (LIMS) is the backbone for the management of laboratory data on samples, instruments, results, and quality indicators.
CTD is introducing LIMS across all TB C&DST sites in a phased manner and LIMS-Ni-kshay integration has been developed. LIMS automates the processes at TB C&DST Laboratories from specimen receipt, decontamination, sample preparation and performing additional test and specimen specific workflows.

It has a built-in mechanism for reviewing results and important information and authorizing each result report for release. The review is done to verify that all the data and results in the report have correctly been transcribed from the work forms and the register. It must also be verified that results are legible (in case of scanned reports) and that quality controls were correctly performed on the day the results were produced. Once this is made sure, the authorizer may sign the report and thereby authorize the report for release. Discuss with the districts to assure that reports are always received by them and as timely as possible. All patient data must be stored in such a way that it remains easily retrievable for those who need it. Moreover, patient data is confidential and must be stored in such a way that it remains confidential. Also, it is important to ensure that data are stored in an environment free of insects, dust, humidity, etc. If laboratory information is stored digitally a good backup system must be in place to protect the data similar to a paper-based information system.

Review by supervisory staff

- *The reports are reviewed by microbiologist before dispatch of results*
- *The computer having patient data are protected and back up maintained periodically*
- *Ni-kshay entries are up to date*

Supervision and Monitoring (Only for IRLs)

The IRLs have the mandate to supervise their linked districts and TB C&DST laboratories and they have to perform OSE of all districts at least once yearly and to the linked TB C&DST laboratories twice in a year.

Collection and collation of indicators from districts, IRLs, and TB C&DST laboratories:

IRLs collect data on monthly basis, using a standardized NTEP format. The compiled indicators are sent by IRLs to NRLs (by 6th of every month). NRLs analyze and collate the indicators of all linked

states (Annexure M, CBNAAT, Truenat, LC DST and LPA) and submit the same to CTD (by 9th of every month).

Analysis and feedback regarding annexures and indicators:

Quality performance indicators should be reviewed by the Microbiologist/Lab in charge and must always be linked to corrective actions if any unexpected results or trends are observed. Timely feedback should be provided IRLs to their linked labs for improving the quality of lab processes and to address any gaps if any in the implementation of the diagnostic algorithm. Documentation of corrective actions and subsequent improvement and normalization of laboratory indicators following the corrective actions are critical.

Coordination among IRL and district: The indicators can be reviewed and deliberated in monthly/quarterly meetings. The feedback from IRLs and possible solutions/corrective actions to be taken can be discussed during monthly/quarterly meetings with district lab staff. Review and feedback on annexures and performance indicators are important for decision-making and programme improvement. A robust feedback and monitoring mechanism is important at all levels with regular coordination and adhering to the agreed targets and timelines.

Review by NRL

- *Quality of OSE reports*
- *Issues in completion of required OSE visits*
- *Trainings/refresher trainings conducted by IRL (Agenda and Material used for training)*
- *Coordination among IRL and district staff*

3.6. Recording the result of supervision and sharing the feedback

The team should brief the STO and discuss all major issues identified at IRL and Districts visited. All major administrative issues to be discussed with MD-NHM/Health secretary should be deliberated prior with STO and WHO consultant. During field visits, the team should provide oral feedback to the local staff. The team should apprise the DTO/DTO team of the salient observations and recommendations, DM/the CMO of the district about issues (if any) which can be sorted out at their level (Refer chapter 5 for OSE visits to Districts).

3.6.1. OSE report (NRL to CTD)

It is crucial that high-quality supervision is carried out regularly and that a feedback mechanism is developed. Providing immediate feedback to laboratory staff facilitates rapid corrective actions. The standard reporting format to be submitted on the last day of the completion of the visit. The report should clearly define the responsible person and timeline for completion of the activity/sorting of issue (Annexure 3.2). OSE report should be shared with all relevant staff and stakeholders (IRL/DTOs/STO/WHO consultant and CTD).

3.7. Post visit follow up

The IRL should submit an action taken report on the team's recommendations to the NRL/CTD within a month of the NRL visit. Districts should send their Action taken report (ATR) to IRL. IRL should compiled the action taken report, mention the issues resolved and tentative time for completion of any pending issues/tasks.

In case action taken report is not received from IRL within a month, NRL should ask for the same. Reminders should be sent to IRL with copy to STO so that the ATR is received from IRLs, and districts visited.

The action taken by the IRL can be discussed in the monthly virtual meetings. Based on the discussions NRL can assess and follow-up visit can be planned after a quarter if required.

3.8. Repeat OSE visits

When poor performance has been identified through OSE, failing of annual PT by IRL, breakdown of lab, unsatisfactory action taken report, additional visits by NRL are mandatory to perform a comprehensive evaluation of all laboratory procedures, implement corrective action, and provide training. NRLs can access the situation virtually, understand the concerns and provide immediate possible solutions before the visits.

3.9. Quarterly reporting to CTD

A quarterly report summarizing the below mentioned areas should be communicated from NRL to CTD. (Annexure 3.3). This report helps CTD in monitoring the supervision activities carried out by respective NRLs as well as understanding any state-specific issues in which the NRLs require assistance. The report covers:

- Details of supervisory visits, state specific issues and possible solutions
- Summary of panel testing results
- Trainings conducted.
- Coordination meetings conducted.
- Other visits like assessment/meetings attended.
- PT status of linked labs
- Newer initiatives/projects/publications

3.10. Remote monitoring through virtual sessions

NRLs should conduct monthly meetings with IRLs along with other key state level officials and key stakeholders to discuss technical, programme and administrative issues about supervision and monitoring to analyze gaps, troubleshooting, with specific agenda covering all relevant programme components and develop action plan including assigning the responsibilities. Minutes of the meeting to be shared with CTD within a week.

Few potential areas for discussion which can be included in presentation template shared with IRL can include the following:

- Issues/challenges faced by IRL in supervision, mentoring and monitoring activities
- Any ambiguity in monthly indicators received by NRL.
- IRL data and resistance patterns (RIF, Isoniazid (INH), Fluoroquinolone (FQ), Injectables, newer drugs)
- Issues regarding equipment AMC/procurement of consumables
- Newer initiatives by IRL
- Analysis and presentation of district wise data and interpretation by IRLs
  NRL can share feedback on
- Completion, accuracy and interpretation of monthly indicators
- Quality of OSE reports and possible solutions to improve the impact of visits
- Any other state/IRL specific issues

3.11. On-site evaluation of TB C&DST laboratories by IRL

In addition to NRL-OSE, IRL also conduct OSE to all TB C&DST laboratories within their geographic area at least twice in a year. The IRL team can plan OSE visit to TB C&DST Laboratories with their routine OSE visits to the districts. The IRL team (Microbiologist/In-charge IRL/STDC, SLT) should be accompanied by the DTO of the respective district and WHO consultant during the IRL-OSE visit at TB C&DST laboratory. For assessment of TB C&DST laboratory, IRL may use the same checklist (Annexure 3.1) and strategies that NRL used during their OSE visit at the laboratories (except for checklist for supervision and monitoring). The standardized reporting format to be submitted on the last day of the completion of the visit. The report should clearly define the responsible person and timeline for completion of the activity/sorting of issue (Annexure 3.4).

3.12. Guidance regarding usage of checklists

The checklists in the annexure 3.1 are guiding checklists. These are developed to cover the quality system essentials keeping in view the existing diagnostic technologies and supervision and monitoring to be performed by IRLs for their districts. The checklists can be referred by NRLs during their visit to IRLs and TB C&DST laboratories and by IRLs during their visit to linked TB C&DST laboratories (except supervision and monitoring). Most of the questions in the checklist will be covered during the visit to different sections or the laboratory/interactions with the laboratory staff /while observation of the work practices/review of documents and records. At the end of the visit before leaving the laboratory, the Microbiologist can go through the checklists to see if any important parameter is missed/not covered. Simply filling of the checklist should not be the sole purpose during visit. Understanding the issues/challenges being faced by the laboratory and providing possible solutions for improving the quality of Diagnostic services would benefit the programme and patients.

The checklists also contain some quantitative figures/indicators that should be collected (from Ni-kshay/ shared reports by the laboratories) and analyzed before the visit. Validation of actual data and the entered report should be done at each level to ensure the quality of digitally available information.

Things to consider while supervisory visit

- Do adequate homework on lab indicators/programme indicators prior to the visit
- Use appropriate PPE during laboratory visit
- Understand the workflow and start from sample collection area to microscopy, followed by LPA and TB containment area (visit should be unidirectional from clean to dirty area, for e.g., visit Master mix room first followed by amplification and hybridization and TB containment area)
- Interactions should not be authoritative. Even if there are some non-conformities, try to understand the reasons and suggest possible solutions
- Fix timelines and responsible persons for completion of tasks in consultation with Microbiologist/Lab in-charge
- Practice hand hygiene at all points indicated by the laboratory supervisor
- Tour of the laboratory must always be guided
- Make entries in the visitor register

Annexure 3.1: Guiding checklists for visits to IRLs/TB C&DST laboratories (to be used by NRLs and IRLs)

Annexure 3.1 A. Quantitative indicators/information (to be collected/analyzed before the visit and validated during the OSE visit)

S.No.	Particulars	Number (%)	Remarks
Specimen transportation			
1	Number and proportion of specimens received within 1-3 days of collection from patient		
2	Number and proportion of specimens rejected due to leakage/other issues		
Culture			
3	Total number of cultures performed in last quarter		
4	Number and proportion of diagnostic AFB smear negative specimens that were culture positive for MTB		
5	Number and proportion of follow-up specimens that were culture positive for MTB		
6	Number and proportion of cultures reported as NTM		
7	Number and proportion of contaminated cultures for last quarter *(Acceptable level of contamination 5-10%)*		
MGIT DST			
8	Total number of DST performed in last quarter		
9	Number and proportion of isolates inoculated for DST that were discarded due to contamination (X400) *(acceptable <3%)*		
10	Number and proportion of isolates inoculated for DST that were uninterpretable due to lack of growth of control (X200) (drug-free) tubes/plates *(acceptable <3%)*		
Line Probe Assay			
11	Total number of FL LPA and SL LPA tests performed in last quarter *(smear +ve and for smear -ve culture positive samples)*		
12	Number of valid results obtained for FL and SL LPA		
13	Number of invalids/indeterminate results for FL and SL LPA		
14	Number of tests repeated for non-interpretable results of specific gene		
NAAT			
15	Number of NAAT test conducted in last quarter		

16	Number and proportion of specimen with un-successful result (errors, invalids, no result)		
17	Number and proportion of MTB positive specimen		
18	Number and proportion of MTB positive specimen with Rif resistance detected		
19	Number and proportion of MTB positive specimen with Rif resistance indeterminate		
Gaps in diagnostic algorithm (last year data)			
20	Number of NAAT tests conducted (by feeding sites)		
21	MTB detected		
22	Rif resistant		
23	Rif resistance not detected		
24	FL LPA offered		
25	H mono resistant detected (LPA)		
26	SL LPA performed (total)		
27	SL LPA for conducted H mono resistant		
28	Any FQ resistance detected in SL LPA		
29	LC DST conducted for Z		
30	LC DST conducted for Mfx, Lzd		

Note- *For serial no. 20-23 consider data for NAAT facility at IRL/TB C&DST laboratory as well as other NAAT sites which are linked to IRL/TB C&DST laboratory for sending samples for FL LPA and SL LPA. Using the above data assess the gaps in FL LPA, SL LPA and MGIT DST.*

Annexure 3.1 B. Guiding Checklists for use during OSE visit to IRLs and TB C&DST laboratories

1. Human Resources

Staff	Number of Staff		Number of trained staff	Remarks
	Regular	Contractual		
Supervisors				
Microbiologists				
Laboratory technicians				
DEO				
Laboratory attendants				
Other (describe):				

S. No.	Particulars	Responses	Remarks
1	Is available manpower in compliance with NTEP requirements? *IRL- 1 EQA Microbiologist, 1 TB C&DST Microbiologist, SLT for EQA, 5 SLTs, DEO, Lab attendant* *TB C&DST Lab- 1 Microbiologist, 5 SLTs, 1DEO, 1 Lab Assistant*	Yes No	

S. No.	Particulars	Responses	Remarks
2	Are the lab staff assigned additional responsibilities (such as Quality Manager, Safety Officer, Store Officer etc.) in addition to their routine job responsibilities?	Yes No	
3	Has the Safety Officer received laboratory biosafety training?	Yes No	
4	Are records of the relevant educational and professional qualifications, training and experience, and competence of all personnel maintained?	Yes No	
5	Does the laboratory have an induction program for new staff with relevant documentation?	Yes No	
6	Are all staff members appropriately trained for all existing diagnostic methodologies? (CBNAAT, Truenat, LPA, liquid culture and DST including Biosafety and BMW management)	Yes No	
7	Is staff trained in EQA? If yes, how many staff are trained and level of training?	Yes No	
8	Does the laboratory have adequate training policy, procedures, and/or training plan? (Check for agenda, attendance sheet, pretest/posttest, training material/PPTs used for training)	Yes No	
9	Is the competence of each person to perform assigned tasks assessed by internal quality control (IQC) and proficiency testing (PT), at least annually?	Yes No	
10	Are performance appraisals performed for all staff members every year?	Yes No	

2. Infrastructure

S.No.	Particulars	Responses	Remarks
1	Is the condition of the laboratory premises adequate? Mention any concerns in remarks. *Parameter: Signages for restricted entry; lockable doors flooring [absence of structural defects, slip resistant], ceiling [absence of leaks, non-porous coating], benches [sturdy, easy to clean, resistant to commonly used laboratory chemicals and disinfectants], doors and windows [sealable], ample lighting, cooling system(s) to maintain ambient temperature, cleanliness, furniture without any cloth covering, old building requiring renovation etc*	Yes No	
2	Are all TB diagnostic activities performed in the same location?	Yes No	
3	Whether dedicated area/room exists for the following activities?	Yes No	

S.No.	Particulars	Responses	Remarks
	Registration, Smear preparation, Staining and reading of smears, Washing and sterilization, Space for storing sterilized Items, Media preparation, Primary culture, Identification and DST, Culture reading, CBNAAT/ Truenat, Line Probe Assay, Equipment room (if any), Walk-in incubator Room, Walk-in Cold Room, Store(s), Staff room, Record keeping, LIMS equipment area.		
4	Is the laboratory floor plan available?	Yes No	
5	Is the flow chart of the workflow available/displayed?	Yes No	
6	Is the work flow of laboratory adequate? Mention any concerns in the remarks.	Yes No	
7	Whether regular supply of electricity and running water available?	Yes No	
8	Is there a back-up power source in case of power failure (emergency generator)? *Check records to see frequency of power failure, how is it switched on (manually/automatic), maintenance of log books for utilization etc.*	Yes No	
9	If not, have power failures caused any disruptions in service or test failures in the past?	Yes No	
10	If yes, does it provide backup to all critical lab equipment? *Freezers, Bio-safety cabinets (BSCs), MGIT, Centrifuges, Thermocycler, Microscopes, Computers, GT-Blot 48 , CBNAAT, Negative pressure in TB Containment Laboratory*	Yes No	
11	Are voltage stabilizers available?	Yes No	
12	Are UPS available? *BSCs-3KA, MGIT -3KVA, Centrifuges -2KVA, Thermocycler -2KVA, CBNAAT -2KVA, GT-Blot 48 -3KVA*	Yes No	
13	Does the laboratory show adequate housekeeping (free of clutter, moisture etc.); and is properly lighted and ventilated? Whether a log is maintained for routine housekeeping activities?	Yes No	
14	Is the TB containment lab having separate electrical supply and backup and is functioning well with no issues in last one year?	Yes No	
15	Are theft control/lab security measures in place and functional?	Yes No	
16	Are measures in place to shield patients in the waiting area and primary sample collection facility from rain and direct sunlight? Are there enough chairs for patients? (Wherever applicable)	Yes No	

3. Safety

S.No.	Particulars	Responses	Remarks
1	Is the TB laboratory biosafety manual easily accessible to the laboratory staff, and is it read and signed by all laboratory staff?	Yes No	
2	Is the work area properly secured from unauthorized access and safety precautions posted (biohazard labeling) in the laboratory, including prohibitions for eating, drinking etc.?	Yes No	
3	Does the laboratory staff receive laboratory safety training (including safe practices, use of safety equipment, facility design, emergency response, occupation health etc.), when hired and at least annually thereafter? *(Avoiding vigorous mixing, forcibly dispensing of liquid, measures to prevent contamination of the micropipette's barrel, correct donning-doffing of PPE and appropriate storage if re-used, washing of every time after handling biological material or removing the gloves; before eating/drinking and leaving the laboratory; or when hands are known or believed to be contaminated, use of micro-incinerator when reusable metal loop is used inside the BSC, restricted handling of electronic gadgets with gloved hands, prohibit eating and drinking inside the laboratory, foods and drinks are not stored in refrigerator/cupboard used for storage of laboratory materials, staff aware of* harm from radiation and trained to avoid exposure*.)*	Yes No	
4	Has the laboratory identified and evaluated potential biosafety and biosecurity risk (as per NTEP biosafety manual-risk assessment checklist)? *(Review risk assessment records)*	Yes No	
5	Are the potential measures (including safe practices, safety equipment, infrastructure and facility design) in place for all biosafety and biosecurity risks identified during assessment?	Yes No	
6	Is the training of the first aid providers up to date?	Yes No	
7	Are first aid kits present and placed at accessible locations?	Yes No	
8	Does the lab decontaminate all PPE and lab wastage before it leaves the lab area?	Yes No	
9	Is the staff using appropriate PPE for working in different sections of lab and adequate stocks available? (Gloves – latex, Gloves- other, Lab coats, Protective gowns, N95 respirators, safety	Yes No	

S.No.	Particulars	Responses	Remarks
	goggles for use during handling of phenol, acids, and other corrosive chemicals)		
10	Are occupational injuries or illnesses documented in the safety/ occurrence log?	Yes No	
11	Does the lab provide medical evaluation, X-ray to new employees and annual health check-up for lab personnel?	Yes No	
12	Are the BSCs certified at least annually? *Discuss how is the functioning of the BSCs monitored and how often*	Yes No	
13	Is the work area clean and properly disinfected and pest control activity in place (if required)? *Review if schedule is available for cleaning/disinfection of floor, workspaces, telephones, door handles, incubators, refrigerators, BSCs and all equipment*	Yes No	
14	Is staff involved in sputum transportation trained in health & safety guideline?	Yes No	
15	Are respirators fit-tested?	Yes No	
16	Are there spill kits present in adequate numbers and are these kits complete?	Yes No	
17	Is there a dedicated area for breaks/lunch?	Yes No	
18	Is staff trained for fire safety education, use of fire extinguishers, fire extinguishers available in laboratory including TB containment laboratory and routinely inspected? *Review type of extinguishers, location and maintenance, exit plan, corridors and fire exits are unobstructed etc.*	Yes No	
19	Is an operational fire alarm system in place in the laboratory?	Yes No	
20	Are there any overloaded electrical sockets, extension boards or faulty/damaged/spliced wires?	Yes No	
21	Are hand washing sinks with job aids adequate?	Yes No	
22	Is staff taking precautions while using alcohol near open flames?	Yes No	
23	Is work area free of clutter and all chemicals stored in shelves not very high /cabinets/cupboards? *Observe if flammable solvents are stored kept in ventilated areas away from sources of ignition*	Yes No	
24	Is the comprehensive 'Safety Audit' conducted in last one year and are the issues identified by 'Safety Officer' resolved? Review the last safety audit report and assess whether in-place safety measures are effective. Mention potential laboratory safety concern, if any. *(Refer 'NTEP- Safety audit checklist for Low, moderate, and high-risk TB laboratories')*		

4. TB Containment Laboratory

S.No.	Particulars	Responses	Remarks
1	Is negative pressure functional and optimal? *Review records maintained to check how is it monitored*	Yes No	
2	Is access to the containment laboratory restricted to authorized personnel only *via Biometric system/Entry-exit log /Monitored for 24 hr a day (using CCTV camera).*	Yes No	
3	Is the lab under controlled access?	Yes No	
4	Are standard safety equipment/measures available and functional? *Chairs with adjustable height for working inside the BSCs, Airlocked pass boxes, hand washing station, centrifuges with safety cups containing O rings, BSCs; preferably ClassII Type A2 with thimble/canopy connection for exhaust to outside, eye washing station, shower, spill kits, easy access to autoclave unit, availability of spilll kits at strategic locations, UPS with sufficient capacity to keep BSCs running for at least 15 minutes, appropriate PPE. etc.*	Yes No	
5	Does the lab have BSL2 facility in addition to TB containment laboratory?	Yes No	
6	Is there an emergency exit in TB containment lab?	Yes No	
7	Are interlock door available and working?	Yes No	
8	Does the Microbiologist/staff know about the exhaust of Hvac system and if it is cleaned properly?	Yes No	
9	Is smoke test done to confirm the unidirectionality of air (check records and frequency)?	Yes No	
10	Is intercom facility available in TB containment lab?	Yes No	
11	Is hygrometer available and humidity monitored in TB containment lab?	Yes No	
12	Is sufficient light available in TB containment lab and inside the BSC?	Yes No	

5. Equipment

S.No.	Particulars	Responses	Remarks
1	Are equipment installed and placed as specified in operator's manuals?	Yes No	
2	Is equipment inventory data available for all equipment? *Name of equipment, serial number, calibration done on, next calibration due on etc. Review list of equipment with quantity and details*	Yes No	

S.No.	Particulars	Responses	Remarks
3	Is proper earthing available for protecting all equipment?	Yes No	
4	Are all equipment functioning? If no, what all equipment are not functioning?	Yes No	
5	Are there functional back-up available in case of equipment failure for critical equipment?	Yes No	
6	Has any laboratory activity been disrupted due to missing and/or malfunctioning equipment in the last one year?	Yes No	
7	Are up to date instructions of the use readily available on the equipment for laboratory personnel?	Yes No	
8	Is user-relevant equipment service information available in the laboratory and preferably pasted over the equipment? *Unique ID, Serial number, Service contract information, Contact details for service provider, Last date of service, Next due date of service*	Yes No	
9	Is it documented who is responsible for each piece of equipment and authorized to use the equipment and is the staff responsible for a piece of equipment aware of their responsibilities?	Yes No	
10	Have funds been identified for annual maintenance and calibration of equipment?	Yes No	
11	Is an annual maintenance contract (AMC) in place for the laboratory equipment? *Review duration of AMC and files for few equipment*	Yes No	
12	Are details of each equipment (installation, breakdown history, calibration, preventive maintenance, service reports etc.) maintained in a file?	Yes No	
13	Is there any critical equipment being used beyond its calibration expiry? (Review calibration of BSCs, Pipettes, Centrifuges, Autoclaves, Ovens, Incubators, Deep freezers, Refrigerator, MGIT, NAAT, Thermal Cycler, Twincubator, GT-Blot, Balances, Thermometers etc.)	Yes No	
14	Is equipment condemnation committee constituted?	Yes No	
15	Are there any equipment pending for condemnation? If yes has the process been initiated?	Yes No	
16	Does the laboratory have an SOP for equipment repair, including a clear procedure for disinfection and clear labeling the equipment as “non functional”?	Yes No	

S.No.	Particulars	Responses	Remarks
17	Is equipment breakdown register available and maintained?	Yes No	
18	Comment on adequacy of existing instrumentation capacity to support the laboratory workload for NAAT, LPA and Liquid culture and DST *(Not adequate, adequate, excess)*		

6. Reagents and Inventory

S.No.	Particulars	Responses	Remarks
1	What is the source of supply of reagents /kits/ consumables*?* *Central, State, Local procurement.* *Review list of the items supplied from central level and procured by state/locally*		
2	Is the laboratory facing any challenges in procuring reagent/materials, briefly describe the main reasons	Yes No	
3	Does the laboratory have a documented procedure on selecting, ordering, acceptance testing and storing of new reagents and consumables?	Yes No	
4	Is Microbiologist part of the technical committee of state?	Yes No	
5	Has any laboratory activity been disrupted due to stock outs in the last year? If yes, briefly list these activities and the disruption duration.	Yes No	
6	Is an inventory control system with criteria and procedures for acceptance/ rejection, and storage of consumables in place?	Yes No	
7	Are incoming orders inspected, receipted, and labeled with date of expiration?	Yes No	
8	Is the consumption monitored based on the stock registers?	Yes No	
9	Is a physical stock count performed periodically? If yes, how frequently (e.g., monthly)?	Yes No	
10	Are storage areas set-up and monitored (e.g., for temperature, moisture etc.) appropriately; and is space sufficient?	Yes No	
11	Is mechanism for re-location of consumables to other labs is in place? If no, please mention the constraints:	Yes No	
12	Is the lab sending the inventory details regularly to CTD and nominated agency?	Yes No	
13	Are all reagents and supplies stored under the proper conditions, protected from unauthorized access and easily retrievable?	Yes No	
14	Are MSDS sheets present for all hazardous materials in the laboratory and is staff trained regarding its importance and usage?	Yes No	

S.No.	Particulars	Responses	Remarks
15	Does the laboratory routinely perform acceptance tests on newly delivered products before they are taken into service	Yes No	
16	Are records of supplies kept with the following details? *Name of the item and supplier, date of receipt, whether or not acceptance criteria were met and any follow-up actions, Expiry date can often be found through internet if not visible on supply package.*	Yes No	
17	Are all supplies stored and used according to the first-expiry first-out (FEFO) system?	Yes No	
18	Is the lab maintaining the list of expired reagents, reasons, and its disposal?	Yes No	

7. Specimen Receiving, Registration and Processing of Specimens

S.No.	Particulars	Responses	Remarks
1	Review collection of specimens (if laboratory is attached to OPD/ hospital) *Parameters: instructions given to patients, staff supervision, number of samples collected, organization (isolation/ventilation) of waiting area and collection site if patient is coming directly to the facility*		
2	Are the received specimens subjected to quality and quantity checks? *Parameters: unpacking done preferably in BSCs/ ventilated place, leakage verification, patient's name verification, labeling, sputum quality verification, Samples stored at required temperature (refrigerator) and away from clean material (like kits, consumables and reagents)*	Yes No	
3	Does the lab communicate with districts to ensure that adequate specimen is obtained from districts and to promote understanding of quality assurance parameters?	Yes No	
4	Does the lab communicate with districts regarding poor quality specimen, labelling and transport containers leakage in case of any issues?	Yes No	
5	Does the lab monitor delivery time between specimen collection and arrival in the laboratory?	Yes No	
6	Does the lab report unsatisfactory specimens to the districts within 24 hours of receipt?	Yes No	
7	Does the lab review and record number of specimen rejected and reasons for rejection?	Yes No	
8	Does the lab keep a record of repeat samples (contaminated, rejected, leaked etc.)?	Yes No	

S.No.	Particulars	Responses	Remarks
9	What is the sample retrieval mechanism from district facility? (in case of rejection /culture contamination etc.)		
	Sample processing		
10	Does the laboratory routinely process and culture specimens within 24 hours of receipt in the laboratory? *Check for batch of samples last processed and any unprocessed specimen kept in cold rooms/ refrigerators*	Yes No	
11	Is a reagents preparation register available and maintained?	Yes No	
12	Is QC of inhouse prepared reagents for decontamination of specimens being performed? *Review the same*	Yes No	
13	Which processing method is used for processing specimen? Reasons if NALC NaOH is not being used. *Check: concentration of NaOH and other reagents, storage of NALC, reasons if more that 4% NaOH is being used, troubleshooting, use of refrigerated biosafe centrifuge(s) at a relative centrifugal force (RCF) of at least 3,000 x g for 15-20 minutes etc.*		
14	Review the decontamination method D*econtamination solution preparation, storage and QC, cross-contamination prevention, inoculation, workflow organization*		
15	Is Negative control being used with each batch of specimens processed for culture? *Check for the results of negative controls*	Yes No	

8. Line Probe Assay

S.No.	Particulars	Responses	Remarks
1	Are LPA rooms under controlled access?	Yes No	
2	Is general cleanliness (unidirectional with separate mops) and housekeeping maintained?	Yes No	
3	Is separate reagent preparation, DNA extraction area, master mix preparation, amplification and hybridization are available with unidirectional workflow?	Yes No	
4	Are cupboards for keeping stock of consumables of immediate use available in near vicinity?	Yes No	
5	Is decontamination of laboratory surfaces and floor done regularly and documented? *Review and ask how it is done?*	Yes No	
6	Is enough power back-up available? *Check for functional UPS*	Yes No	

S.No.	Particulars	Responses	Remarks
7	Are separate sets of pipettes as well as refrigerators/ deep freezers available in master mix preparation area, amplification area and hybridization area? *Review log sheets*	Yes No	
8	What is the frequency of preparation of master mix in a week? *Check data sheet being maintained*		
9	What is the frequency of performing hybridization in a week?		
10	Are positive and negative controls (DNA and master mix) being used with each batch?	Yes No	
11	Review the maintenance of GT blot, and other equipment		
12	Are all result sheets with strips kept securely? *Review the result strips, bands, and reporting. Check for the intensity of positive control bands and intensity of rest of the strips.*	Yes No	

9. Culture and DST

S.No.	Particulars	Responses	Remarks
	MGIT 960 equipment		
1	Is daily maintenance being conducted, documented and are calibration tubes within expiry date?	Yes No	
2	Is the printer functional and all daily print outs maintained in files and secured?	Yes No	
3	Is UPS providing backup? Is there frequent power failure, temp alarm? Are the records being maintained? *Review the records*	Yes No	
	Culture and DST		
4	Discuss the concentration of PANTA being used Has the concentration of PANTA been increased to control high rates of primary culture contamination; if so, to what concentrations?	Yes No	
5	Is supplement, MGIT tubes and other reagent kept at desired temperatures? *Check storage conditions*	Yes No	
6	Are any MGIT tubes/supplements kits expired? *Check for the expired stocks in inventory/cold room*	Yes No	
7	Is ZN smear and purity check performed for all positive cultures?	Yes No	
8	Does the laboratory, correlate the smear positive and negative results with culture positive and negative results to evaluate smear/culture quality?	Yes No	
	Identification of culture		
9	Are AFB smear microscopy and lateral flow immunochromatographic tests performed for positive cultures?	Yes No	

S.No.	Particulars	Responses	Remarks
	Same day/next day; Any delays due to batch testing?		
10	Check for the visible growth in MGIT tubes flagged positive on the day of visit		
	LC DST		
11	Is the laboratory using blood agar/BHI plates to check purity of cultures before DST? If no, why	Yes No	
12	Review the drugs used, supplier, concentration, method of calculation of drug concentration, potency calculations, solvent used, expiration of working stocks, storage etc.		
13	Are drug stock solutions stored at -80^{o}C for no more than one year in containers with expiration dating?	Yes No	
14	Is QC ($H_{37}Rv$ and mono resistant strains) being included in each batch of DST and before using new batch of drugs prepared. If no, what is the frequency? *Check results of few controls*	Yes No	
15	Are reference strains of *M. tuberculosis* ($H_{37}Rv$/$H_{37}Ra$) and non-tuberculous mycobacteria (NTM) available? *Parameters: source of strains, stock preparation, storage, expiration (for QC of MGIT media and new drugs preparations)*	Yes No	
16	Is an analytical balance (four decimal) used to weigh out drug powders for second-line DST drug solutions? *Check for calibration of balance used to weigh the drugs*	Yes No	
17	Is trending data available for DST set results in terms of drug resistance, sets lost to contamination or over-inoculation (X400 error subcode), slow growth of the Growth Control (X200 error sub-code, or "timing out"), other errors that invalidate DST sets, and false resistance and false susceptible determinations?	Yes No	
18	Are cultures sent to linked lab for DST of newer drugs?	Yes No	
	Culture media (LJ slants)		
19	Is LJ being used for culture as backup? *Parameters: quality of eggs [freshness, antibiotic-free, cleanness], quality of other reagents, glassware, inspissation, presence of bubbles, color, expiration, QC [sterility check, growth of characterized strains]*	Yes No	
20	Primary culture reading *Parameters: incubation, periodicity, data recording*		

S.No.	Particulars	Responses	Remarks
21	Number and proportion of contaminated cultures leading to uninterpretable results *(acceptable 3-5%)*		
22	What is the policy for the retention of cultures? *Discuss*		
23	Identification of culture *(In-house or commercial kits)*		

10. Bio-Medical Waste Management

S.No.	Particulars	Responses	Remarks
1	Is waste disposal separated into infectious and non-infectious waste and waste storage space provided suitable?	Yes No	
2	Is the lab having copy of MOU with BMW agency and written guidelines/ procedures on how the agency is dealing with the waste from the lab?	Yes No	
3	Monitor during lab visit- *Is bio-hazardous waste discarded properly into containers with covers?* *Are splash proof containers being used for liquid discard?* *Are sharps containers present and in appropriate use?* *Are appropriate color-coded bags and bin used for waste disposal and proper segregation performed by the lab?* *Is infectious waste autoclaved before disposal and removed from laboratory within 48 hours*	Yes No	
4	Facility for liquid waste treatment. Is effluent treatment plant available?	Yes No	
5	Is the staff trained in latest BMW management guidelines and updated of any changes in guidelines? *Observe the practices during lab visit*	Yes No	
6	Are guidance posters (segregation of biomedical waste) available near the bin?	Yes No	
7	Is adequate phenol stock available? *Discuss type of disinfectant being used for culture, LPA, floor, door handles etc. Check frequency of preparation and expiry etc.*	Yes No	
8	Are adequate trolleys available for transporting discards to washing and sterilization area?	Yes No	
9	Is freshly prepared 1% sodium hypochlorite available for use in LPA lab?	Yes No	
10	Are quality-control indicators (biological, chemical) used at standard frequency for autoclaves? *Review record*	Yes No	

11. Recording & Reporting

S.No.	Particulars	Responses	Remarks
Recording			
1	Mode of recording results	Manual Electronic	
2	Retention period in case manual *As per NABL/state policies*		
3	Is recording done using NTEP formats?	Yes No	
4	*If no, then please specify*		
Reporting			
5	Mode of reporting results *If electronic check vis email/LIMS, Ni-kshay/HIMS/ others*	Manual Electronic	
6	Comment on report management practices *Prioritization of reporting, handling of annexures etc.*		
7	Whether LIMS is functional and in practice (section wise LIMS entry)? Comment on optimal functioning of LIMS *Internet service provider, speed, issues and constraints, help desk support in resolution of bugs Back up mechanism of reporting if LIMS is non-functional, system properly protected by antivirus, protected by password and used by authorized personnel etc.*	Yes No	
8	Is the turnaround time monitored on a continuous basis for each examination? *Check registers and Ni-kshay/LIMS entries for Lab TAT for*		
a.	Truenat *(1-2 days)*		
b.	CBNAAT *(1-2 days)*		
c.	FL LPA (2-3 days)		
d.	SL LPA (2-3 days)		
e.	LC *(8–10 days for smear positive samples, 2–6 weeks for smear negative samples; check from LIMS/Register)*		
f.	LC DST 2nd line *(Time till LPA testing 5–7 days + *22– 48 (in most cases 30 days)*		
g.	LJ (Solid culture) *(4-8 weeks)*		
9	Is a procedure in place that ensures verification of correct transcription of results on reports and are all tests reviewed before results sent for reporting?	Yes No	
10	Does the lab have a procedure for withdrawal of wrong report?	Yes No	

12. Quality Assurance

S. No.	Particulars	Responses	Remarks
Internal Quality Control			
1	Review adequacy of quality manuals and other documents for each methodology	Yes No	
2	Are written protocols (SOPs) for performing each laboratory activity available and referred by staff?	Yes No	
3	Are all SOPs reviewed and if necessary revised by laboratory management at least annually?	Yes No	
4	Are internal quality control (IQC) policies and procedures (including indicator selection and data collection) clearly defined and enforced?	Yes No	
5	Are reference materials/strains/cultures available?	Yes No	
6	Is quality control (QC) testing performed (performance and sterility) when a new batch of reagent/kit/media/drug is put into use?	Yes No	
7	Are in-house prepared reagents, media etc. properly labeled?	Yes No	
External Quality Assessment System (EQAS)			
8	Is the lab certified for all Dx technologies available including DST for any newer drugs? If no, discuss issues and constrains	Yes No	
9	Is there any excess delay in reporting the result of PT panel (NAAT, FL LPA SL LPA and MGIT DST) to NRL? Mention the reason of delay, if any	Yes No	
10	Did the lab clear annual PT and achieved desired concordance as per NTEP benchmark. If not, was root cause analysis performed and CAPA taken. *Discuss with the Microbiologist*	Yes No	
NTEP Certification			
11	Is the laboratory having valid certificates for FL LPA/SL LPA/ LC FLDST/LC SLDST?	Yes No	
12	If expired, status of renewal (with date) and reason of delay. *Discuss action taken by IRL for renewal of certification*		

13. Supervision, Monitoring and Mentoring (applicable for visit to IRLs only)

S. No.	Particulars	Responses	Remarks
Supervision			
1	Is calendar of visit schedule prepared and shared?	Yes No	
2	Are panel slides made and relevant documentation available? *Check for documentation and validation procedure*	Yes No	

3	Number of district OSE visits conducted by IRL team in the last 4 quarters. (Actual/Expected)		
4	Reasons for not completing expected OSE visits (if applicable)		
5	Review EQA activities for Microscopy *Review the reports of IRL OSE visits available and comment on the quality of reports and action taken on the report, panel testing of STLS, performance problems identified, corrective actions recommended and implemented, action taken received, if no, was any communication sent from IRL to district for ATR?*		
6	Are quarterly reports of OSEs conducted by IRLs sent to NRL? If no, mention reasons	Yes No	
7	Is Annexure M and E being received regularly from districts? *Review the dates of sending the reports to next tier*	Yes No	
8	Is IRL monitoring entry of annexure M into Nik-shay?	Yes No	
9	Are NAAT indicators being received from all sites? (Tentative delay if any). *Discuss any issues regarding same*	Yes No	
10	How many NAAT were visited during OSE? Are visits to NAAT sites prioritized based on analysis of NAAT indicators?		
11	Is IRL monitoring errors/invalids/indeterminates through the indicators at NAAT sites? *Check for any feedback sent to the sites*	Yes No	
12	Is any feedback sent regarding annexures and NAAT indicators? *Review and comment*	Yes No	
13	Discuss any challenges related to on-site visits?		
14	Is IRL conducting visits to all linked TB C&DST labs/private laboratories as per NTEP defined schedule? *Review reports, actions recommended and ATRs receive*	Yes No	
Mentoring/Training			
15	How many trainings were conducted during the assessment period? *Review details of trainings (in-person and virtual) conducted at IRL (Retraining/Refresher)*		
16	Any challenges related to conducting trainings		

17	What is the frequency of formal communication with linked districts and C&DST labs for various issues? *Regular coordination meetings with district staff/only telephonically/whatsapp group when required etc.*		
18	Is IRL participating in DTO review meeting? *Review minutes of last DTO review meeting and issues escalated by IRL available*	Yes No	
Monitoring			
19	Is IRL analyzing and discussing regular data and trends of UDST from districts?	Yes No	
20	Is IRL monitoring the usage of NAAT machines to their full capacity? *Check the average number of tests being done by sites*	Yes No	
21	Is IRL discussing the details of NAAT machines and functionality of modules during meetings with district staff?	Yes No	
22	Is IRL monitoring availability and expiry of CBNAAT / Truenat cartridges and chips?	Yes No	
23	Is IRL analyzing data of all districts to assess the gaps in Diagnostic algorithm/issues in sample transportation etc.	Yes No	

14. Laboratory Management

S.No.	Particulars	Responses	Remarks
1	Do regular staff meetings occur? *Check MoM, frequency, major actions suggestions, action taken*	Yes No	
2	Is roster system followed in the lab? (Basis of selection of staff for particular test) If yes, then what is frequency of staff rotation. If no, then reasons.	Yes No	
3	Lab management during special situations *Back up during/ replacement during festivals/ unforeseen conditions/ staff on leave*	Yes No	
4	Does the laboratory have a procedure for employees to communicate concerns about test quality and laboratory safety?	Yes No	
5	Are Microbiologists participating actively in State level meeting/ trainings?	Yes No	
6	Is there a system to monitor, forecast and supply consumption in the laboratories and procurement of same?	Yes No	
7	Does lab analyze and use data routinely for decision-making and program improvement (including network management and equipment maintenance, supply chain, quality assurance)?	Yes No	

S.No.	Particulars	Responses	Remarks
8	Is statistical data analyzed, used for decision making purposes and shared and discussed with respective NRLs?	Yes No	
9	Is the present laboratory infrastructure/manpower/equipment adequate to support workload? If not, briefly describe major bottlenecks and ways to remediate them	Yes No	
10	Is the IRL Microbiologist/staff sharing the knowledge after the national level trainings? *If no, discuss the same with In-charge and Microbiologists*	Yes No	
11	Does the lab has any linkages/back-up plans in case of lab breakdown or inability to perform certain tests as per Diagnosis algorithm?	Yes No	
12	Are timely corrective actions on issues identified by supervising laboratory taken and report submitted? *(by NABL/NRL)*	Yes No	
13	Is there a system in place (Entry/exit log or gate pass) are in-place to ensure that valuable biological materials are transferred out/in by authorized persons only	Yes No	
14	Is there a system in place to receive complaints from patients/DTOs and address the same?	Yes No	
15	Are complaints handled in a standardized way and complainers informed about the solution that was developed based on their complaint? ?	Yes No	

16. STDC Details (only for use by NRLs)

S.No.	State TB Training and Demonstration Centre (STDC)	Responses	Remarks
1	Is functional STDC available?	Yes No	
2	Comment on number of rooms in STDC with seating capacity, hostel facility availability, audio visual aids like OHP, LED projector, white board & flip chart screens		
3	Number of binocular microscopes available to meet the training needs		
4	Is updated training material available?	Yes No	
5	Review documentation of trainings conducted in last 6 months at STDC		
6	Number of supervisory visit conducted by STDC in last one year		

Annexure 3.2: On-Site Evaluation for NRL Personnel to IRL

I. Summary of sites visited

S.No.	Sites visited/Officials met	Details
1.	Name of State	
2.	Number of IRL(s)/TB C&DST laboratory(ies)/Districts	IRL(s)_____ TB C&DST Laboratory (ies)_____ Districts_____
3.	Date of OSE visit	
4.	IRL visited	
5.	Details of IRL staff	Microbiologist- EQA Microbiologist- SLT/LT- DEO- LA- Others-
6.	TB C&DST laboratory visited	
7.	Details of TB C&DST laboratory staff	Microbiologist- SLT/LT- DEO- LA- Others-
8.	**Name of District 1 visited-**	
	Names of microscopy facilities visited	
	Names of CBNAAT sites visited	
	Names of Truenat sites visited	
	DTO and other officials met	
9.	**Name of District 2-**	
	Names of microscopy facilities visited	
	Names of CBNAAT sites visited	
	Names of Truenat sites visited	
	DTO and other officials met	
10.	Officials met (State)	
11.	Visiting NRL staff details	

II. Action required as per the previous visit to IRL:

Date of the previous visit:

Was action taken report (ATR) received from IRL/TB C&DST laboratory/District(s): Yes/No
Date of receiving ATR--------

(Highlight actions pending for long in red)

Actions recommended by NRL during previous OSE visit	Action taken by IRL/TB C&DST laboratory/District(s)	Completed/Pending /Additional remarks by NRL

III A. Observations and issues identified at IRL/TB C&DST laboratory during visit on lab components (refer the guiding checklist):

Add columns if additional IRL/TB C&DST laboratory visited

Categories	Key observations and issues identified
Human resources and training (Manpower, trainings, records of educational and professional qualifications, competencies)	
Infrastructure (Floor plan, dedicated areas for different activities, all activities performed in same location/floor, power back up, communication systems)	
Biosafety (Trainings and handling of spills, access to the lab, surface and equipment cleaning, disinfection, certification of BSC, appropriate PPE and annual medical evaluations of lab staff)	

Categories	Key observations and issues identified
TB containment laboratory (Controlled access, monitoring of negative pressure, standard safety equipment, appropriate PPE)	
Equipment (Installation, functionality, AMC and PM, backup, condemnation committee)	
Reagents (Procurement procedure, inspection on receiving, monitoring of consumption, storage)	
BMW management (Segregation of waste and disposal, BMW agency contract, training of lab staff in BMW management)	
Lab Management	
Training and Review meetings conducted by STDC	

III B. Workload, quality indicators and diagnostic algorithm: (Comments/recommendations based on analysis of Quantitative indicators in checklist)

Add columns if additional IRL/TB C&DST laboratory visited

	NRL Comments/key observations
Workload (NAAT, LPA, Liquid culture, and DST)	
Completion of diagnostic algorithm (gaps in FL LPA, SL LPA, PZA, extended DST)	

Quality indicators (Contamination rate in culture and DST, non-interpretable results in LPA, NAAT errors/ indeterminates, X200 and X400 errors etc.)	
TAT for all diagnostic technologies	

III C. Observations on Diagnostic technologies, recording, reporting and EQAS

Categories	Operational and technical issues
Diagnostic algorithm implementation in the lab	
Specimen collection, request forms and processing	
CBNAAT	
Truenat	
Sample processing	
Smear microscopy	
LPA (FL and SL)	
LC DST (First and Second Line)	
Recording and Reporting	
Quality assurance and EQAS (streamlining requirements as per NABL)	

III D. Supervision and Monitoring activities (only for IRLs)

Activities	Key observations
OSE visits conducted in last 4 quarters (Review the OSE reports and comment on the quality of OSE visits, quarterly reports communicated to NRL, review the action taken report received from districts/DTOs)	
Availability of panel slides as required by the NTEP EQA Program (Unstained panel slides kept as per their batch number and grading after validation)	

Trainings conducted by IRL in last 4 quarters					
Refresher trainings conducted by IRL in last 4 quarters					
Regularity of receiving annexure E and NAAT indicators from districts, sending same to NRL and feedback to districts					
Communication of IRLs and districts (Virtual monthly meetings to discuss issues related to annexures, indicators, sample quality, transportation etc.)					
Issues raised in last DTO review meeting (review the last DTO review meeting report)					
Monitoring of district indicators					
Evaluation of manufacture of panel slides at IRL and review of validation process	**Slide No.**	**Result of designated State-level lab technician**	**Result of National level laboratory**	**Staining AFB and background**	**Remarks (Including review of validation process)**

IV A- District(s) visited (Data from district to be collected before the visit for previous quarter through Ni-kshay/DTO)

(Add columns if more than one district visited)

	Details of District 1
District visited	
Reasons/criterion for selection (refer district indicators)	
Population	
Number of public health institutions	District/sub-district Hospital_____

	Details of District 1
	CHC_____HWC-PHCs_____HWC-SHC_____
Number of TUs	
Proportion of functional microscopy facilities (Functional/Total microscopy facilities)	
Proportion of functional NAAT sites (Functional/Total NAAT sites)	CBNAAT_____; Truenat_____
Number of STLS	
Presumptive TB examination rate (rate per lakh population)	
% of estimated target notification achieved (Source: Ni-kshay)	Private notification target- Achieved- Public notification target- Achieved- Total target notification- Achieved-
% of presumptive TB patients offered upfront NAAT (Presumptive TB offered NAAT (from NAAT indicators)/Total presumptive TB patients (from Annexure M) x100	
% of presumptive TB cases with known HIV status (Presumptive TB offered HIV testing/Total presumptive TB patients)x100	
Number of TB patients diagnosed in last quarter (Check for Bacteriology confirmed and clinically diagnosed Source: Ni-kshay)	
% UDST offered in last quarter (Source-Ni-kshay)	
Proportion of 'RR /MDR-TB' offered FL and SL LPA and results available in last quarter (Rif resistant offered FL LPA/Total RIF resistant) (Rif resistant offered SL LPA/Total RIF resistant)	
Proportion of 'Rif resistant not detected' offered FL LPA and results available in last quarter (Rif resistant not detected offered FL LPA/Total RIF resistant not detected)	

	Details of District 1
Proportion of 'INH resistant' offered SL LPA and results available in last quarter (INH resistant offered SL LPA/Total INH resistant)	
Number of DR-TB patients initiated on (shorter/ longer oral bedaquiline containing regimen/ H mono/poly DR-TB regimen) in last quarter	
Analysis of the data and comments	

IV B. Observations and issues identified during visit

	NRL Observations
Human resource/ Training LTs STLS	
Vacant posts	
Specimen transport mechanism	
Non-functional Microscopy facilities	
Microscopes and AMC	
Microscopy reagent preparation and QC	
EQA implementation and RBRC	
NGO PP partnership existing in the district	
Ni-kshay entry	

	NRL Observations
Provision of roadworthy vehicles for STLS/ SLS	
Monthly and quarterly review of the performance of the TB Unit	
Coordination activities TB-HIV, TB- diabetes mellitus (DM), TB-non communicable diseases (NCD) etc.	

IV C. Quantitative findings at NAAT site (Collect data from NAAT indicators for previous quarter and validate the same during onsite visit)

Quantitative Indicators	NAAT site 1	NAAT site 2
Total tests performed in last quarter		
Percent MTB positive patients whose specimen transported to TB C&DST lab for LPA/LC DST		
Percent specimen with unsuccessful results (errors, invalids, no result) for MTB detection		
Percent specimens with rifampicin indeterminate (RIF testing in NAAT)		
Number of days between specimen collection and results reported		
Score obtained in the most recent round of NAAT EQA		
Analysis of the data and comments		

IV D. Observations and issues identified during visit to NAAT sites

Qualitative indicators	NAAT site 1	NAAT site 2
NAAT site infrastructure		
Usage and downtime		
Sputum transport mechanism		

Qualitative indicators	NAAT site 1	NAAT site 2
Manpower and Training		
Maintenance of equipment		
Recording and Reporting		
BMW management		
SOP, diagnostic algorithm displayed and followed		
Lab register completion		
Storage of cartridges/chips and following of FEFO principle		
Availability of packing material for sample transportation		

IV E. Quantitative indicators from visited microscopy facility (Collect data for previous quarter before the visit)

Quantitative Indicators	Microscopy facility 1	Microscopy facility 2
Percent presumptive TB testing rate (out of total adult OPD)		
Percent smear positivity rate among presumptive TB patients		
Percent notified TB patients initiated on treatment		
Percent presumptive DR-TB patients offered NAAT/specimen transported to NAAT site		
Percent presumptive TB patient under key population (children, PLHIV, EPTB) offered upfront NAAT/ specimen transported to NAAT site		
Number of smear negative presumptive TB patients subjected to X-rays and found to be suggestive of TB		
If yes, how many sent for NAAT testing		
Analysis of the data and comments		

IV F. Observations and issues identified during visit to Microscopy facilities

	Microscopy Facility 1	Microscopy Facility 2
Infrastructure (Separate area for TB laboratory work, separate tables for specimen receipt/ smear preparation/ microscopy, ventilation, window for depositing the sample, benches/chairs for patients, power supply, running water etc.)		
Staff and training		
Staining reagents		
Microscope usage, maintenance, and AMC		
Registers, records, and reports (completion of TB bacteriology request form, registers, Ni-kshay entry etc.)		
Notification register		
Supervision by STLS		
Data triangulation		
Disposal of infectious material and BMW management		
Internal Quality control		

V. Report on panel testing of IRL and field staff done during on-site evaluation

	IRL staff/ Districts STLS/LT*	HFP	HFN	LFP	LFN	QE	Total number of errors	Corrective action recommended
Name of IRL								
Name of District 1								
Name of District 2								

*if required

VI. Overall remarks and recommendations

VI A. Good practices observed

VI B. Actions recommended by NRL based on quantitative indicators and observations/issues identified

Action recommended	Responsible person	Timeline
STDC/IRL		

District(s)		

VI C. Key points for state/STO/MDNHM:

1

2

3

4

5

VI D. Key points for CTD

1.

2.

3.

4.

Signature of the visiting NRL team leader with date

Signature of IRL Director with date

Signature of STO with date

Annexure III (i): Panel testing results of IRL/ TB C&DST laboratory and district staff using manufactured panel slides from NRL

To be entered by IRL/ TB C&DST/ field staff		For use by NRL LT		
Slide number	Result	Expected result	Error type	Remarks

Annexure III (ii): Rechecking of slides

	To be entered by NRL LT		For use by NRL LT		
Name of the microscopy facility	Slide number	Result of microscopy facility technician	Result of NRL technician	Error type	Remarks

Annexure 3.3: Quarterly report of NRL to CTD

Quarterly report of NRL to CTD

Name of NRL		
Quarterly report	Quarter_____	Year _____

Summary of activities

A. OSE visits conducted

IRLs and TB C&DST labs visited	Dates of visit	Name(s) of NRL Supervisor(s)	Date of submitting report to IRL, CTD and STO
1			
2			
3			
4			

B. Report on panel testing done during on-site evaluation (After rechecking of discordant slides)

STDC	Number of IRL-LT/STLS	HFP	HFN	LFP	LFN	QE	Total number of errors

C. Details of other visits (Assessment visits, EQA follow-up visits etc.)

S.No.	Date of meeting	Date of visit	Name(s) of NRL Supervisor(s)

D. Details of training /refresher trainings/workshops conducted

S.No.	Details of training/Refresher conducted/workshop (Name of training, duration, dates etc.)	At NRL/On-site/virtual	No. of participants

E. Other activities (Not mandatory)

Details of any operational research/other projects	
Details of publications if any	

F. Details of key issues identified during OSE visits/ coordination meeting/ monthly meetings and corrective action/possible solutions recommended

S. No.	IRL/ TB C&DST lab	Key issues	Possible solutions suggested and corrective actions taken

G. Annual panel cultures sent, and results received from IRLs

Name of IRL/ TB C&DST labs	Date of sending panel cultures by NRL	Date of receiving results for FL and SL LPA	Date of receiving results for MGIT I, II Line	Concordance for FL and SL LPA	Concordance for MGIT I and II Line

H. Details of any labs which applied for certification and their PT status

S. No.	Name of the lab	Status of retesting	Status of Panel testing

Signature of the Director, National Reference Laboratory

Annexure 3.4: On-Site Evaluation for IRL Personnel to TB C&DST laboratory

I. Summary of sites visited.

S.No.	Sites visited/Officials met	Details
1	Name of State	
2	Number of TB C&DST laboratory(ies)	
3	TB C&DST laboratory visited	
4	Date of Visit	
5	Details of TB C&DST laboratory staff	Microbiologist- LT- DEO- LA- Others-
6	Total number of districts linked with TB C&DST laboratory	
7	**Name of District 1 visited-**	
	Names of microscopy facilities visited	
	Names of CBNAAT sites visited	
	Names of Truenat sites visited	
	DTOs and other officials met	
8	**Name of District 2 visited-**	
	Names of microscopy facilities visited	
	Names of CBNAAT sites visited	
	Names of Truenat sites visited	
	DTOs and other officials met	
9	Visiting IRL staff details	

II. Action required as per the previous visit to TB C&DST laboratory:

Date of the previous visit:

Was action taken report (ATR) received: Yes/No **Date of receiving ATR--------**

(Highlight actions pending for long in red)

Actions recommended by IRL during previous OSE visit	Action taken by TB C&DST laboratory/Districts	Completed/Pending /Additional remarks by IRL

III A. Observations and issues identified at TB C&DST laboratory during visit on lab components (refer the guiding checklist):
Add columns if additional TB C&DST laboratory visited

Categories	Key observations and issues identified
Human resources and training (Manpower, trainings, records of educational and professional qualifications, competencies)	
Infrastructure (Floor plan, dedicated areas for different activities, all activities performed in same location/floor, power back up, communication systems)	
Biosafety (Trainings and handling of spills, access to the lab, surface and equipment cleaning, disinfection, certification of BSC, appropriate PPE and annual medical evaluations of lab staff)	
TB containment laboratory (Controlled access, monitoring of negative pressure, standard safety equipment, appropriate PPE)	
Equipment (Installation, functionality, AMC and PM, backup, condemnation committee)	
Reagents (Procurement procedure, inspection on receiving, monitoring of consumption, storage)	

Categories	Key observations and issues identified
BMW management (Segregation of waste and disposal, BMW agency contract, training of lab staff in BMW management)	
Lab management	

III B. Workload, quality indicators and diagnostic algorithm: (Comments/recommendations based on analysis of Quantitative indicators in checklist)

Add columns if additional TB C&DST laboratory visited

	IRL Comments/key observations
Workload (NAAT, LPA, Liquid culture, and DST)	
Completion of diagnostic algorithm (gaps in FL LPA, SL LPA, PZA, extended DST)	
Quality indicators (Contamination rate in culture and DST, non-interpretable results in LPA, NAAT errors/ indeterminates, X200 and X400 errors etc.)	
TAT for all diagnostic technologies	

III C. Observations on diagnostic technologies, recording, reporting and EQAS

Categories	Operational and technical issues
Diagnostic algorithm implementation in the lab	
Specimen collection, request forms and processing	
CBNAAT	
Truenat	
Sample processing	
Smear microscopy	
LPA (FL and SL)	
LC DST (First and Second Line)	
Recording and Reporting	
Quality assurance and EQAS (streamlining requirements as per NABL)	

IV A- District(s) visited (Data from district to be collected for previous quarter before the visit through Ni-kshay/DTO)

(Add columns if more than one district visited)

	Details of District 1
District visited	
Population	
Number of public health institutions	District/sub-district Hospital_____ CHC_____HWC-PHCs_____HWC-SHC_____
Number of TUs	
Proportion of functional microscopy facilities (Functional/Total microscopy facilities)	
Proportion of functional NAAT sites (Functional/Total NAAT sites)	CBNAAT_____; Truenat_____
Number of STLS	
Presumptive TB examination rate (rate per lakh population)	

% of estimated target notification achieved (Source: Ni-kshay)	Private notification target- Achieved- Public notification target- Achieved- Total target notification- Achieved-
% of presumptive TB patients offered upfront NAAT (Presumptive TB offered NAAT (from NAAT indicators)/Total presumptive TB patients (from Annexure M) x100	
% of presumptive TB cases with known HIV status (Presumptive TB offered HIV testing/Total presumptive TB patients)x100	
Number of TB patients diagnosed in last quarter (Check for Bacteriology confirmed and clinically diagnosed Source: Ni-kshay)	
% UDST offered in last quarter (Source-Ni-kshay)	
Proportion of 'RR /MDR TB' offered FL and SL LPA and results available in last quarter (Rif resistant offered FL LPA/Total RIF resistant) (Rif resistant offered SL LPA/Total RIF resistant)	
Proportion of 'Rif resistance not detected' offered FL LPA and results available in last quarter (Rif resistant not detected offered FL LPA/Total RIF resistant not detected)	
Proportion of 'INH resistant' offered SL LPA and results available in last quarter (INH resistant offered SL LPA/Total INH resistant)	
Number of patients initiated on (shorter/ longer oral bedaquiline containing regimen/ H mono/poly DR-TB regimen) in last quarter	

Analysis of the data and comments

IV B. Observations and issues identified during visit

	IRL Observations
Human resource/ Training LTs STLS	
Vacant posts	
Specimen transport mechanism	
Non-functional microscopy facilities	
Microscopes and AMC	
Microscopy reagent preparation and QC	
EQA implementation and RBRC	
NGO PP partnership existing in the district	
Ni-kshay entry	
Provision of roadworthy vehicles for STLS/STS	
Monthly and quarterly review of the performance of the TB Unit	

	IRL Observations
Coordination activities TB-HIV, TB- diabetes mellitus (DM), TB-non communicable diseases (NCD) etc.	

IV C. Assessment of EQA responsibilities of STLS

EQA activity of STLS	Number to be performed during the assessment period*	Number performed	Remarks
On-site evaluation			
Blinded Rechecking			

* Assessment period refers to the period from first day of the year till the current date

IV D. Blinded rechecking results (refer to reports)

Categories	Responses
What is the expected number of slides to be checked by all STLS during the month?	
How many have been checked? (in %)	
Type and number of errors detected	
If errors are detected, explain recommended actions	
Has corrective action been adequately implemented (check STLS reports)?	
If no, explain:	

IV E. Quantitative findings at NAAT site (Collect data from NAAT indicators and validate the same during onsite visit)

Quantitative Indicators	NAAT site1	NAAT site 2
Total tests performed in last quarter		
Percent MTB positive patients whose specimen transported to TB C&DST lab for LPA/LC DST		
Percent specimen with unsuccessful results (errors, invalids, no result) for MTB detection		
Percent specimens with rifampicin indeterminate (RIF testing in NAAT)		
Number of days between specimen collection and results reported		
Score obtained in the most recent round of NAAT EQA		
Analysis of the data and comments		

IV F. Observations and issues identified during visit to NAAT sites

Qualitative indicators	NAAT site 1	NAAT site 2
NAAT site infrastructure		
Usage and downtime		
Sputum transport mechanism		
Manpower and Training		
Maintenance of equipment		
Recording and Reporting		
BMW management		
SOP, diagnostic algorithm displayed and followed		
Lab register completion		
Storage of cartridges/chips and following of FEFO principle		
Availability of packing material for sample transportation		

IV G. Quantitative indicators from visited microscopy facilities (Collect data for previous quarter before the visit)

Quantitative Indicators	Microscopy facility 1	Microscopy facility 2
Percent presumptive TB testing rate (out of total adult OPD)		
Percent smear positivity rate among presumptive TB patients		
Percent notified TB patients initiated on treatment		
Percent presumptive DR-TB patients in the quarter offered NAAT/ specimens transported to NAAT site		
Percent presumptive TB patient under key population (children, PLHIV, EPTB) offered upfront NAAT/specimens transported to NAAT site		
Number of smear negative presumptive TB patients subjected to X-rays & found to be suggestive of TB		
Of above, how many sent for NAAT testing		
Analysis of the data and comments		

IV H. Observations and issues identified during visit to microscopy facilities

	Microscopy facility 1	Microscopy facility 1
Infrastructure (Separate area for TB laboratory work, separate tables for specimen receipt/ smear preparation/ microscopy, ventilation, window for depositing the sample, benches/chairs for patients, power supply, running water etc.)		

	Microscopy facility 1	Microscopy facility 1
Staff and training		
Staining reagents		
Microscope usage, maintenance, and AMC		
Registers, records, and reports (completion of TB bacteriology request form, registers, Ni-kshay entry etc.)		
Notification register		
Supervision by STLS		
Data triangulation		
Disposal of infectious material and BMW management		
Internal Quality control		

V. Report on panel testing of TB C&DST and field staff done during on-site evaluation

	TB C&DST staff$/ Districts STLS/LT*	HFP	HFN	LFP	LFN	QE	Total number of errors	Corrective action recommended
Name of TB C&DST laboratory								
Name of District 1								
Name of District 2								

$ optional (depending on panel testing conducted by NRL in the year), *if required

VI. Overall remarks and recommendations

VI A. Good practices observed

VI B. Actions recommended by IRL based on quantitative indicators and observations/issues identified

Action recommended	Responsible person	Timeline
TB C&DST laboratory		
District(s)		

VI C. Key points for state/STO

1

2

3

4

5

Signature of the visiting IRL team leader with date

Signature of TB C&DST lab in charge

Annexure V (i): Panel testing results of TB C&DST laboratory and district staff using manufactured panel slides from IRL

To be entered by TB C&DST/ field staff		For use by IRL LT		
Slide number	**Result**	**Expected result**	**Error type**	**Remarks**

Annexure V (ii): Rechecking of slides

	To be entered by IRL LT		For use by IRL LT		
Name of the microscopy facility	**Slide number**	**Result of microscopy facility technician**	**Result of IRL technician**	**Error type**	**Remarks**

Chapter 4

On-Site Evaluation of Districts and Sub-Districts Level TB Laboratories

Courtesy:
NRL National Tuberculosis Institute, Bangalore
NRL ICMR National JALMA Institute of Leprosy and Other Mycobacterial diseases, Agra

Chapter 4: On-site evaluation of Districts and Sub-districts level TB laboratories by IRLs

The NTEP has a large network of TB Detection Centres (TDCs; NAAT and Microscopy facilities) at the district and sub-district level, which plays an important role in early TB detection, UDST (for rifampicin), and laboratory-based monitoring of treatment response. Although, the testing modalities available at these laboratories are simple, they may face a variety of technical and operational challenges that impact on quality service delivery. To ensure accuracy, reliability and reproducibility of test results, NTEP has a comprehensive QA programme that includes performance indicator monitoring, panel testing or rechecking, on-site evaluation (OSE), timely feedback, corrective actions and follow-up.

OSE of TB laboratories is a critical component of QA program; and it should be planned at regular intervals to assess the on-ground situations like operational condition of laboratory services, laboratory practices and adherence to SOPs. The QA activities for all TB laboratories at district or sub-district level are carried out by STLSs of the district under the supervision of DTO. To ensure that these activities are being carried out effectively, IRL reviews available resources, available records (like supervisory visits by STLSs and DTO, action taken reports on recommended corrective actions and RBRC reports of routine slides) and conducts competency assessment of all STLSs (through on-site panel testing) during OSE. In addition, OSE is an opportunity to provide mentoring, technical updates, immediate troubleshooting advice and assess retraining needs if any or demonstrate best practices. According to supervision and monitoring strategy adopted in NTEP, the IRL (State level) should visit all linked districts (DTC and a selected TDCs) at least once in a year.

Key considerations when IRL plans to conduct an OSE are as follow

4.1. Planning district OSE visit

Planning for IRL-OSE visits should be an integral part of the annual/quarterly routine work-planning exercise. Planning should be data-driven; and it should indicate where to conduct the visit, when to conduct the visit and what are the activities to cover.

4.1.1. Where to conduct the visit?

A) Selection of district: Although OSE visit of a district is planned by IRLs at a regular interval (once in a year), any particular district can be prioritized based on following considerations:

- If it has been long time (> 1 year) since a district last visited.
- If there is opportunity to integrate the visit with another supervisory visit by STC/STDC.
- If repeated quality or performance issues reported in a particular district (based on routinely collected monthly reports including Annexure E, Annexure M and NAAT indicators e.g. high rates of MTB invalids/errors/RIF indeterminates or based on feedback received from any other NTEP supervisory visits to the same district).
- If samples received from the districts are not as per guidelines (high contamination rate, delayed transportation, poor packaging etc.)

B) Selection of health facilities/laboratories within a district

Although major activities of IRL-OSE take place at DTC, IRL should plan for visiting at least 20% of NAAT sites in the district. Following criteria may be considered for selecting the sites before the OSE visit:

- Sites where deficiencies have been documented by the district supervisor staff (STLS or DTO) and reported to IRL.
- Sites with minimum supervisory visit of STLS, District Coordinators and DTO.
- Poorly performing site based on
  - Annexure M, E or NAAT indicators- last quarter (e.g., high rate of errors/ invalid/ indeterminate, high/low testing load, poor referral of samples for reflex NAAT/LPA testing etc.)
  - Ni-kshay generated reports of district such as NTEP key performance indicators and laboratory specific performance reports - last quarter (in case of no access of Ni-kshay reports/data, IRL should request to the district well in advance for submission before OSE visit)
- Sites where major non-compliance observed during last OSE visit and no satisfactory corrective action taken by the district.

Visiting a few good performing laboratories is also important as it provide opportunity to gain insight on best practices and to explore the possibility to implement in other sites/districts. During OSE, it is possible that the initial assessment suggests visiting a site that was not previously planned. In this situation, there may be deviation between the sites planned for the visit and sites actually visited during the visit. However, IRL should visit at least two of the three health facilities as planned (before the OSE).

Note: *Refer chapter 6 for details on NTEP key performance indicators as well as indicators related to laboratory services. These indicators may be utilized for selecting a priority district and help focus on areas that need more attention during OSE visit.*

4.1.2. When to conduct the visit?

A) Periodicity and duration of visit:

Ideally, IRL should visit each linked districts **at least once in a year**. OSE can be conducted more than one time in a year when -

- It is deemed necessary to assess the lab's corrective action in response to a previous OSE.
- IRL observe significant deviation in monitoring indicators and/or suspect any systematic error or major non-compliance to the standard/national guidelines.

When planning on-site visits, sufficient time should be allocated, making sure to include travel time to the district as well as travel time to other sites within the district. Each OSE should be for at least 2 **days**. The visit may be planned or extended for an additional 1-2 days when the ground situation necessitates on-site refresher training, when TB C&DST laboratory located in the same district is also planned to visit, when planning for visiting additional sites (or visits to remote areas where travel requires time) or when strategic advocacy meetings with district health officials is needed.

Note: *Visiting all linked districts by IRL may be difficult particularly in states with large number of districts or due to unusual situations (like shortage of HR, or funds). No timely re-imbursement of travel allowance (TA)/ dearness allowance (DA) claim of IRL team members is another important factor demotivating them from carrying out the expected number of OSE visits. Therefore, planning at appropriate level should be done to ensure the continuity of OSE programme as well as to meet the target coverage (visit of all assigned districts within one year).*

B) Visiting Team:

The visiting team should consist of following members

- IRL Microbiologist

- Medical Officer (IRL/STDC; wherever possible)
- IRL Senior Lab Technician (SLT)

This team should be accompanied by WHO NTEP consultants and any other officer nominated by STDC or STC. During the site visit, DTO and all STLSs of the district should be available

IRL Microbiologists and SLT/LT should receive trainings on 'EQA programme under NTEP', 'comprehensive training on different TB testing procedures (including biosafety guidelines and TB diagnosis algorithm)'. IRL Microbiologist and MO should have additional training on 'Technical and Operational Guidelines (TOG): NTEP' as well as updated 'PMDT guidelines in India'.

IRL-OSE team members should be aware of

- the structural framework of the public health system as a whole, as well as the NTEP at the district, sub-district, and peripheral levels
- newer updates on TOG (laboratory aspect)
- role and job responsibilities of appointed individual consultant and contractual staff under NTEP [https://tbcindia.gov.in/showfile.php?lid=3617]
- specification of laboratory consumables/equipment and required facility design for TB laboratories (of different risk level) [https://tbcindia.gov.in/index1.php?lang=1&level=3&sublinkid=4340&lid=2984]
- services and performance of agencies contacted for specific services (e.g., specimen transportation, preventive maintenance of laboratory equipment) at state level
- norms and basis of costing for NTEP programme that guides states and districts in preparing annual action plan, budget, and incurring expenses [https://tbcindia.gov.in/showfile.php?lid=3384]

Note: *Covering at least 20% of NAAT sites for IRL-OSE may be difficult for some districts, and therefore a larger visiting team should be planned that can be divided into two or more. SLTs from IRL should be trained and competent to perform OSE at TDCs.*

C) Communication for District OSE visit:

IRL In-charge/Microbiologist should contact the district well in advance (at least 15-30 days) and finalize mutually agreeable dates for the OSE visit. This will help districts/DTOs in making the necessary arrangements for OSE visit. It is important to conduct the visit as planned and the team should obtain prior approval and reservation for travel and lodging. If the scheduled visit cannot take place , district should be informed in advance. It is important to monitor planned versus actual visits and record the reasons for not carrying out the visit as planned (e.g., lack of transport, competing priorities, etc.).

Once the date has been finalized, IRL should send a confirmation letter to the district, with copy to STC, STDC and WHO NTEP consultant/s. When communicating with district, IRL should consider the following:

i) Collection of data and reports:

Pre-visit data analysis is important activity that enables the supervisory team to become acquainted with a broad situation of laboratory services in the district, as well as to identify areas that need improvement and thus deserve special attention during the OSE.

Every district should send standard laboratory reports such as Annexure M, Annexure E, and NAAT indicators on a monthly/quarterly basis, and these reports should be thoroughly reviewed prior to an OSE visit

In addition to above, IRL should request the following information

- General information about NTEP resources in the district (population, staff, vacant positions, trainings, non-functional TDCs etc.)
- Last quarter Ni-kshay performance report- performance indicators related to TB notification, UDST, FL LPA report, SL LPA report, Treatment outcome/cure etc. (Refer Chapter 6 for more details)

  Ensure that the above data are submitted by the district at least one week before the scheduled date of OSE.

ii) Guidance for district's preparedness:

IRL should advise districts on the pre-requisites for an OSE visit, and districts should prepare accordingly. This may include

- Presence of all NTEP staff at their respective duty station during the OSE visit. On the first day of OSE visit, all STLSs should be available at DTC for panel testing activity (for sputum smear microscopy).
- Travel arrangement for field visits within the district
- Availability of
  - RBRC reports (last one year) and OSE visit reports.
  - TB lab register, staining and reagents preparation and lot testing records, quality control slides preparation records, TB notification register, TB C&DST register, specimen transportation register, stock register, and treatment card.
  - Annexure M, E, NAAT indicators and a copy of previous OSE visit and action-taken report.
  - Equipment breakdown and maintenance/ calibration records.

iii) Appointment for meeting with district health administration:

During OSE, IRL team may identify a variety of operational challenges impacting on laboratory services/NTEP performance indicator. Some of them require administrative interventions from higher level. Therefore, IRL should communicate to DTO for arranging a meeting with senior officials of district health administration [CMO/ DM] on the last day of OSE. This meeting should be utilized by the IRL team for conveying the key administrative/operational issues, its impact on patient services as well as suggesting appropriate strategy to address the issue.

4.1.3. What are the activities to cover?

The IRL team should have a clear understanding of all the activities to be performed during OSE. This includes comprehensive assessment of visited sites, panel testing and rechecking activities, assessing effectiveness of capacity building trainings provided by STLS to LTs and conducting need based on-site training (described in section 4.2).

Although it may not be possible to conduct a comprehensive assessment of all TB laboratories in the district during the annual OSE, IRL should collect all relevant information that provides a broad insight into the effectiveness of the NTEP program, with a focus on 'TB diagnosis services' at the district and sub-district levels. Furthermore, some data-driven information can be validated on-site by the IRL team through discussions with staff/patients and a review of physical records. Key monitoring indicators, their source, significance and suggested actions for improvement are described in detail in Chapter 6.

Before departing for an OSE visit IRL team should ensure to carry

- Key pre-visit observation recorded by analyzing the data/indicators/OSE reports received from the district.
- Adequate numbers of panel slides with appropriate packaging and coding.
- Comprehensive assessment checklist and reporting formats.
- Tools that may require for on-site demonstration/training during OSE.

4.2. Conducting district OSE visit

It is important that the IRL-team members are well trained on laboratory QA activities and have updated information and skills on issues related to laboratory diagnosis of TB. The IRL-OSE visit begins with an opening meeting with DTO and other NTEP staff. During this meeting, the IRL-team should provide a briefing about the activities to be performed with the overall goal of assessing the real situation and facilitating problem-solving rather than determining what is wrong.

4.2.1. Information collection

Assessment of TB services in the district or any particular laboratories visited are based on comprehensive information collected during the OSE. This information may be collected by

- Supervisory checklist assisted comprehensive physical assessment of laboratory
- Observing the LT while performing the tests
- Discussion with staff and laboratory/programme manager
- Reviewing the documents, records and recommendations from past visits.
- Patient interaction

For a standardize supervision system, it is important that the supervisory team uses a standard supervisory checklist. A set of updated OSE checklists (DTC, Microscopy facility, CBNAAT and Truenat facility) has been developed that covers all thematic areas of laboratory operation and has included all TB testing modalities available at district/sub-district level TB laboratories. During OSE, IRL should refer to these checklists as well as the reporting formats (Annexure 4.1). This checklist will help the IRL team to focus on and record priority aspects.
Although the checklist is comprehensive, it does not deter the IRL-team from recording and following up on other critical issues that they have observed but that are not included in the checklist.

Key considerations under different thematic areas of laboratory assessment by IRL are as follows:

Table 4.1. Key thematic areas and considerations for assessment

S.No.	Key points to be observed by IRL team
1.	**Human resource** (Training, competency and adequate number of HR)
	• All LTs should receive the training either by a trained STLS (on-site or at the DTC or by IRL/STDC). Assess the suitability of the infrastructure where district level trainings/refresher trainings are conducted. The training site should have sufficient space for seating as well as for demonstrating laboratory procedures, or assessing the competency of LTs. Review the records, and tools used for training by the STLS/ trainer. - *Review training records* • Competency assessment of LTs (for test procedures, biosafety precautions, equipment handling and maintenance, recording and reporting and troubleshooting) must be assessed by STLS before allowing them to conduct routine TB testing independently.

- *Observe the testing activities and ask few technical questions (to assess their competency), review the laboratory records and monthly indicators/ reports.*

- Number of LTs should be adequate to manage the testing load.
  - *Adequacy for number of LTs and optimal utilization of testing site can be assessed using following table that describes maximum number of tests that a full-time dedicated LT can perform.*

Test procedures	***Max. number of test/ technician/day (8 hour)****			
	Day	***Week***	***Month***	***Year***
Light microscopy	*25*	*125*	*500*	*5750*
Fluorescence microscopy	*50*	*250*	*1000*	*11500*
CBNAAT (4 module)	*16*	*80*	*320*	*3680*
Truenat (Duo)	*8*	*40*	*160*	*1920*

**workload is indicative and it depends on HR expertise, laboratory infrastructure, equipment and utilities like water and electricity*

- Number of STLSs in the district should be as per NTEP norms.
  - *One STLS for every 5-lakh population (one per 2.5 lakh population for tribal/ hilly /difficult areas).*

2. Laboratory infrastructure (Facility design ventilation and housekeeping)

- **Facility design:**
  - Key features for a Truenat and Microscopy facility include, separate laboratory work area from the public traffic (restricted access); ample space for the safe conduct of laboratory work and for cleaning and maintenance; sturdy, impervious and cluttered free workbench that can be decontaminated easily; smooth floors and walls; adequate storage space/furniture (without any cloth covering); proper illumination in the work area; adequate supply of water and electricity; dedicated sink for hand washing; separate area for smear preparation/sample processing for NAAT. For CBNAAT room, consider at least 10'X10'size securing space with glass/aluminum paneling, door closure and adequate sealing for effective air conditioning, 5KV UPS with rack for batteries to provide 2hr 30 min backup, split air-conditioner (AC) 1.5 ton, refrigerator (220-250 lt) with stabilizer.

- **Ventilation:**
  - Sample handling, smear microscopy, Truenat testing, and specimen preparation for CBNAAT should all be done in a naturally or mechanically ventilated laboratory room ensuring directional airflow *i.e.,* air flowing from clean areas to areas where aerosol may generate and then to outside.
  - While natural ventilation can easily achieve the requisite 6-12 air-exchange per hour (ACH) and air movement speed (0.5 meter/second), mechanical ventilation (exhaust fan) should be installed if the facility design poses certain obstacles to achieving requisite ACH and air-movement speed.

- **Laboratory housekeeping:**
  - Floors should be free of hazards and should be cleaned on daily basis with disinfectant (eg. lysol).
  - Workbench and floors should be clear of all material not being used. Workbench should be disinfected daily (freshly prepared 5% phenol for smear microscopy; and 1% Sodium hypochlorite for CBNAAT and Truenat) before and after work.
  - All reagents and chemicals used should be labeled properly (along with expiry date) and placed in the recommended environmental condition; hazardous chemicals (like HCl, H_2SO_4, phenol etc.) should not be placed above shoulder height; inflammables items (like alcohol, sprit) should be placed away from open flame sources/or any ignition.

- Instructions related to safety, good practices and testing procedure should be displayed at strategic locations.
  - *Most of the above visual observation points are important to minimize the biohazard risk in the laboratory and should be assessed accordingly.*
  - *Refer 'Biosafety Manual for TB Laboratories' to determine ACH*

3	**Equipment (**Repair, preventive maintenance and calibration)

- Key equipment (Microscope, CBNAAT, Truenat) should be covered by an AMC programme and kept in good working condition.
  - *Review the equipment calibration and maintenance records; check the microscope condition by observing a few stained slides; check functional status of CBNAAT and Truenat*
- LTs should be aware of recommended in-house maintenance activity of critical equipment and same should be done periodically.
  - *Ask LT about how the in-house maintenance activities are being carried out; review the in-house equipment maintenance logs.*
  - *Refer the following key activities related to in-house maintenance of critical equipment*

***Microscope**: At the end of work, lenses of the objectives, eyepieces and condenser, should be cleaned using lens tissue o a soft, clean cloth; When not in use the microscope should be kept covered (preferably in a box with silica gel).*
***CBNAAT:** Cleaning of work area and disinfect the equipment, cleaning of filter and plunger rods (at least monthly/more frequently as required)*
***Truenat:** Clean the work area (daily); disinfecting the instrument surface, clean the Truelab bays*

- In the event of an equipment breakdown, LT should be aware of the escalation system, and the equipment down-time period should be recorded.
  - *Review the records and inquire with the LT(s) about how they respond if a breakdown occurs.*
  - *Assess the contingency plan to ensure continuity of services in the event of any critical equipment fails.*
- Compliance with recommended installation requirements, placement, and operational environmental conditions is required. CBNAAT is highly sensitive equipment, and it should be placed in an air-conditioned room and machine should have sufficient power back-up (at least 2hr 30 min).
  - *Assess visually; review the types of errors encountered while testing with CBNAAT or Truenat during the last quarter year (manual records can be reviewed and verified with the machine records).*

4	**Biosafety**

- LTs should follow good microbiological practices. Safe practices should be followed to minimize the risk of aerosol generations such as
  - AFB smear microscopy: Use of disposable wooden applicator sticks (broom sticks), opening sample container and smear preparation in proximity to flame, air-drying of slides before heat/flame fixing, no immediate opening of specimen container and making the smear with a slow move, avoid any rapid motion when making the smear, disinfection of working area before and after smear preparation, immediate covering of sputum spills with disinfectant before cleaning up the area, use of foot operated discard bin containing disinfectant (5% phenol).
  - Truenat and CBNAAT: Careful shaking or transferring of liquid, gentle handling of pipette and placing the pipette against inner wall of container while transferring the infectious liquid
    - *Observe the testing practices followed by LTs and/or ask to demonstrate a few steps of testing activity.*
- LTs must wear appropriate PPE (lab coats and gloves of appropriate size) and adhere to standard donning and doffing procedures. Adequate quantity of PPE should be available at the laboratory.

If re-usable laboratory coat is used, it should be washed periodically. Lab coat should never be taken to home for laundry.

- *Review the PPE stock at the facility and observe the LT whether he/she is using the PPE correctly. Assess the practices followed for storage/ laundry of re-usable lab coat.*

- Although N-95 respirator is not essential PPE for TB testing procedures at TDCs sites, it may be required for LTs in especial situations (like bi-directional TB-COVID screening in which COVID-19 screening for all diagnosed TB patients and TB screening for all COVID positive patients are conducted). Therefore, LTs should know correct donning, doffing and storage (if re-used) of respirators. N95 respirator is not affected until three days of use (8h/day) and it can be stored in a paper bag with air holes (to allow moisture to evaporate) in a well-ventilated area.
  - *Observe how the LT uses and stores the N-95 mask.*
- LT should be aware of how to respond in the event of an infectious spill.
  - *Assess practices related to management of spills by interviewing the laboratory technicians and regarding the frequency of such incidence. Alternatively, pour a small amount of clean water on the bench/floor and ask LT to respond the spillage, considering it as specimen spillage and check if following is being practiced*
    1. *LT wears PPE (laboratory coat and gloves)*
    2. *Places paper towel over the spill area and liberally apply disinfectant solution (5% phenol for sputum specimen and 1% sodium hypochlorite for DNA spills)*
    3. *Leaves it covered for minimum 15 minutes*
    4. *Clean up the contaminated material and put into the waste container*
    5. *Clean with a final mop using 70% v/v alcohol followed by regular mopping*
    6. *Washes hands after the clean-up is complete*
- All BMW waste should be decontaminated (using appropriate disinfectant and for sufficient contact time) before disposal. Plastic sputum containers and wooden applicator sticks should be disinfected with 5% phenol and molecular testing items like cartridges, chips should be disinfected with 1% sodium hypochlorite. BMW should be segregated in color coded disposable plastic bags/bins before being transported for disposal/incineration. Sharps should be transported into puncture proof container. Bins should not be filled more than three quarters of their capacity.
  - *Gather the above information by visually inspecting the available disinfectants, biohazard bins and biohazard storage area at the site. Team can ask LT about the proper color-coded bin for a few BMW items ex. Sputum cups, pasture pipettes, Truenat and CBNAAT cartridges (into red bag/bin), infected cotton and tissue paper (into yellow bag/bin) etc.*
  - *Inquire about the biomedical agency that has been contracted and how frequently the waste is collected. If burial pits are used, inspect the site to see if it was built according to standard guidelines.*

5 Laboratory consumables

- Critical laboratory consumables (including sputum container, glass slides, reagents and kits) should meet the specification recommended under NTEP or as per manufacturer's instruction. Inventory for critical laboratory consumables should be maintained, monitored and FEFO principle should be followed.
  - *Review the inventory records, specification of a few consumables and assess the adequacy of buffer stock or stock-out event during last quarter year.*
  - *All reagent bottles should be clearly labeled along with expiry date.*
- Kits or reagents should be labeled and stored at recommended temperature. Refrigerator should be available at NAAT site (especially for CBNAAT cartridges).
  - *Open the refrigerator and check that the kits or reagents are placed orderly and that no food items and infectious materials (e.g., specimen) are stored in the refrigerator.*

6	Specimen collection, storage and transportation

- Locating the TB laboratory should be easier for patients. Children and anyone with impaired immune systems should be kept away from laboratory area or patient waiting areas. Triaging the patient who have cough should be considered.
  - *Assess by observing the overall health facility (including location of Outpatient Departments (OPD), TB laboratory, child-immunization clinic and ICTC or ART clinics.*
- Patients should be properly instructed on how to collect sputum correctly. Two sputum samples of adequate quality and quantity (spot and morning sample; in special circumstances, two spot samples at an interval of at least 1 hour) should be collected in a leak-proof, screw-capped plastic container. Spot specimens should be collected outside, in open area, rather than in the laboratory/closed spaces (toilets etc.).
  - *Assess the above through patient interaction or by asking the LT to demonstrate.*
- Specimen container should always handle with gloved hand and the exterior of container should be disinfected if visible contamination is detected. Specimen (spot/morning) should be labeled at least with two identifications (e.g. name, age/sex) along with lab ID and date of collection; and it should be processed on the same day. If required, the specimen should be stored in refrigerator (never with kits and reagents) or in a cool box.
  - *Observe the specimen container the space where it is stored.*
- When specimens need to be transported from one location to another, they must be packaged in a standard triple layer with a cool chain arrangement. Batching of specimens over several days should be avoided. A robust mechanism of specimen transportation should be in place to ensure safe transportation of specimen within 24 hr (intra-district) or 72 hr (inter-district).
  - *Observe the availability of packaging materials and assess the number of specimens ready or pending for transportation to another site (NAAT or TB C&DST laboratories). Evaluate the average TAT for specimen transportation as well as the system used to notify the specimen transportation agency to pick up the specimen at earliest.*
  - *Some of test request forms should be checked to assess if they are filled properly.*

7	AFB microscopy procedure

- LT should follow the SOPs for smear preparation, staining and microscopy examination. Wall instructions (steps of test procedure) should be displayed at strategic locations.
  - *Observe the facility and inspect the slides. The smears should not be too thick/ thin, over-heated during the heat fixing, over/less decolorized, stored in direct light (if stained with auramine).*
  - *A few slides may be cross-examined.*
- LT should test the QC slides, both positive and negative (provided by STLS) with every fresh batch of reagents. Before staining, it should be ensured that carbol-fuschin /auramine stains are filtered (to avoid possible artifacts in smear)
  - *Check the availability of QC slides at the site and the filtering the stain.*
- LT should store the slides for EQA activity (RBRC) and rechecking by STLS.
  - *Observe the facility and TB laboratory register to verify whether slides are being stored, and whether RBRC and rechecking are being done by STLS.*

8	CBNAAT testing procedure

- LT should adhere to SOPs that are easily accessible, with wall instructions displayed in strategic locations. Blood-stained sputum should be avoided.
  - *Observe the testing activities.*
  - *Assess the knowledge of LT about some of critical aspects like sample-reagent ratio, incubation time, correct handling of cartridge, precaution during adding correct volume (2ml) of the processed specimen in cartridges and timely insertion of cartridges into machine.*

- Some of extra-pulmonary specimens (e.g., large volume body fluid, tissue) may require special procedures and safety equipment (like BSC, safety centrifuge) and should be sent to linked IRL/TB C&DST laboratory.
    - *Assess what types of extra-pulmonary specimens are processed at the site visited, and whether or not LT follows proper procedure.*
- LT should be able to monitor the performance indicator and troubleshoot/ respond to the various errors flagged by the machines.
    - *Review the CBNAAT indicator as well as types of errors recorded during last quarter year (this can be accessed through Xpert software).*
- The site should participate in annual PT programme (dried tube specimens PT panels) under NTEP.
    - *Review the score of last PT of site.*

9	Truenat testing procedure

- LT should adhere to SOPs (should be readily accessible), with wall instructions displayed at strategic locations.
    - *Observe the laboratory and practices followed by the technician. Following Do's and Don'ts should be considered*
    - *Do's: Placement of devices in a dust free environment, daily cleaning and maintenance activity, replacement of cartridge holder tray (Trueprep) in case of a spillage in the device, running flushing protocol (if Trueprep device is kept idle for more than 10 days), ensuring that the elute is loaded in the center of the reaction well (Truelab) and chips are hold by edges only, good lab practices while handling pipettes and taking all precautions to avoid carry over contamination.*
    - *Don'ts: Cartridge or chips are left inside the device (after completing the test), used materials are kept on the device, device is tilted/moved while test is in progress and that nozzle of buffer bottles are touched while adding.*
- Because aerosol-generating procedures are used in the processing of some extra-pulmonary specimens (e.g., tissue and large volume body fluid), they should be referred/transported to a linked *TB C&DST* / IRL for testing.
    - *Assess the linkages and types of extra-pulmonary specimens tested at the site visited.*
- LT should be able to monitor the performance indicator and troubleshoot/ respond to the various errors flagged by the machines.
    - *Review the Truenat indicator as well as type of errors, and rates of invalids/indeterminates during last quarter year.*
- Positive and negative controls should be setup after every 50 tests and whenever a new shipment of Truenat TB test kits is received and for each new tests kit lot.
    - *Review the records of last QC tests conducted.*
- LT should be aware regarding replacement of pipettes after every 6 months by Molbio and maintain records for same
    - *Review the records to see when the pipettes were replaced and check if LT has the contact details of Molbio personnel in case of any issues to be discussed*

10	Recording and reporting

- The laboratory should ensure that the patient receives the test results correctly, completely and timely. LT should maintain the standard TB laboratory register and notification register neatly completely. All smear-positive (including scanty) results should be recorded in red ink in the TB laboratory register. In addition, LT should update the test result on Ni-kshay promptly.
    - *Review the Notification register, lab register and treatment cards (data triangulation): the information entered in one or more records should be checked for consistency. E.g., results of sputum examination in lab register, treatment card and TB notification register.*

11 Turn-around time

- Patient TAT that includes pre-lab, lab and post-lab TAT is important to be closely monitored for all TUs by MO-TC and DTO.
  - *Review TB notification register (or Ni-kshay report) to assess the patient TAT, identify the gap areas (if found) and suggest appropriate corrective actions.*
  - *The NTEP defined timeline for patient TAT is as follow*

Test	Pre-lab TAT* (in days)	Lab TAT ** (in days)	Post-lab TAT*** (in days)	Total Patient TAT (in days)
NAAT	1-2	1-2	2-3	4-7
LPA	1-3	2-3	2-3	5-9
LC DST#	NA	Time till LPA testing – 5-7 days + 22-48 days (in most cases 30 days)	2-3	29-58 (in most cases 40 days)
LC for follow up		8-42 days	1-2	11-45

Remarks:
* Pre lab TAT for NAAT includes time from patient identification, counselling, collection and transport of 2 specimens to NAAT facility. Pre lab TAT for LPA & LC DST includes time from collection to NAAT and further transport of second specimen to TB C&DST labs.
** Lab TAT includes the time from specimen receipt to results by technology.
***Post lab TAT included time from accessing test results, pre-treatment evaluation to treatment initiation.
For Z DST additional 7 days will be needed.

12 Compliance to diagnostic algorithm

- TB laboratory should adhere to NTEP TB diagnostic algorithm and follow-up testing.

Discuss with LT and STLS/STS to assess whether

- *Presumptive TB cases among key population (such as people living with HIV- PLHIV, children, extra-pulmonary TB- EPTB, smear negative/not available with chest X-ray suggestive of TB), presumptive DR-TB patients, contact of DR- TB patients and other vulnerable groups are offered upfront NAAT rather than AFB microscopy.*
- *Microscopy facility sends two specimens to a linked NAAT site for UDST for every AFB-positive TB patient.*
- *MO recommends chest X-ray for smear-negative patients.*
- *Two specimens from smear negative but chest symptomatic patients are sent to NAAT site for TB detection (and UDST).*
- *If TB is detected (R resistant detected or not detected), the other specimen is packaged and transported in cool chain through courier/ speed post to the linked TB C&DST laboratory for cascade testing as per diagnostic algorithm.*
- *AFB positive but MTB not detected in NAAT are considered as presumptive Nontuberculous mycobacteria (NTM) and samples are sent directly to IRL/NRL for confirmation.*
- *Follow-up sputum examinations (AFB microscopy) for drug sensitive TB patients are carried out at the end of intensive phase and continuation phase of treatment as well as long term follow up to 2 years (at 6 months, 12, 18, 24 months).*

13 Supervision and monitoring

- Supervisory visits by STLS and DTO:
  - STLS should visit all microscopy centers in the jurisdiction of all the assigned TUs at least once a month. He/she should review laboratory records, stocks of reagents and consumable, collect slides for RBRC and conducts re-testing of few slides (at least 5 positive & 5 negatives- incase positive slides are less than 5 then all positives need to be

cross checked), inspect sputum collection centers and TDCs including that of private/NGO and other sectors.
  - All TDCs in the district should also be inspected properly by DTO at least once in a quarter.
  - In-addition to this, IRL/NRL team should also visit each district annually.
    - *Discuss with DTO and STLS about their supervisory visits and availability of vehicle and funds for fuel. Review the issues flagged during past supervisory visits and status of corrective action taken.*
- Each TB laboratory should prepare the relevant monthly reports and send them to the DTC for compilation, review, and further communication to the IRL.
- Laboratory testing related issues and performance indicators should be reviewed during monthly review meeting by DTO.
  - *Review the minutes of monthly review meeting and the compiled laboratory related reports of last month at DTC.*
  - *Key reports include, NAAT indicators, Annexure E, M, F and OSE visit by STLS.*

14	TB-HIV / TB-Diabetes

- HIV and diabetes are key risk factors for TB and poor treatment result. Therefore, it is important to identify these co-morbidities in people diagnosed with TB in order to ensure early diagnosis and improve co-management. It is preferable that all TB testing facilities also have facility of HIV and diabetes testing. Offering HIV testing should be made available even to all presumptive TB patients (not just to notified TB patients).
  - *Assess the kits and consumable availability (for HIV and diabetes testing) and review the records whether HIV and diabetes status of all diagnosed TB patients is known.*

15	Patient interactions

- Observing the interaction between health staff and patients is crucial for understanding how the programme is functioning and the areas that require improvement.
  - *Observing the interactions during various activities like sputum collection, patient counselling during treatment initiation or drugs dispensing etc. to assess whether complete information is provided to the patients.*
- OSE visits are a good chance to interact with the patients and understand the quality of health service delivery. The idea is to concentrate on public health action linking the diagnosis and treatment of patients and programmatic support extended to the patients in a holistic approach.
  - *While interacting, the patient should not feel that he/she is being interviewed. It should be a general talk in the local language to make the person comfortable. The discussion can start with have they been explained how to produce a good quality specimen, whether home visits were conducted (for screening of household contacts and counseling of patients and family members), whether patient is informed about adherence to daily doses and treatment duration, and whether they have been linked or are getting benefits of nutritional support scheme (like Ni-kshay Poshan Yojna).*
  - *Patient health seeking behavior should also be assessed because to identify the gaps (if any) in referral of presumptive case /TB notification in public/ private health care system.*

16	Discussion with staff and DTO

The following points can be analyzed and discussed with district level laboratory staff, MO or DTO. Based on the analysis appropriate feedback can be communicated

- Any major deviation in % RIF resistant cases (very high/low) as compared to state/ national average or as compared to last quarter. If yes, reasons for the same.
- Gaps in completion of cascade testing as per diagnostic algorithm.
- Are pediatric samples, samples of PLHIV and EPTB being subjected to CBNAAT?
- High rates of errors/invalids/indeterminates from sites (if any) and discussion regarding troubleshooting.

- Assess the issues discussed in monthly meetings (e.g., any pending LPA reports of patients awaited by districts, timely treatment initiation of all patients detected MTB positive)
- Linking of additional microscopy facilities to NAAT sites with less workload
- Is there backlog of samples at any of the NAAT site? If yes, discuss reasons for the same.
- Are there any sites with near expiry cartridges which need to be shifted?
- Training requirement for NAAT sites, if any.
- Reasons and solutions of non-functional sites or sites where services interrupted frequently.
- Discussion regarding discordance resolution among new cases with very low MTB detected with RIF resistance.
- Adequacy of services related to smear microscopy-based treatment follow-up and initiation of treatment timely and correctly.
- Adequacy on existing specimen transportation mechanism. *(Specimen pick-up coverage both public and private health facility; transportation turn-around time)*.
- Discussion on gaps area and suggestion for improving Presumptive TB examination rate and TB notification from both public and private sectors.

4.2.2. Panel testing:

Panel testing of slides is the laboratory method used to evaluate the competency of an individual to perform AFB smear microscopy. These methods, broadly, involve comparing test results from district/sub-district level laboratories to those from higher level laboratories (IRL/NRL).

In brief, a panel consists of a batch of unstained pre-fixed smear slides are provided by IRL (during onsite IRL-OSE) to all STLSs of the district for staining, reading, and reporting of results. When conducting panel testing, the following points should be considered:

- Unstained pre-fixed slides for panel testing should be manufactured by trained LTs at IRL. The composition of slides should be known only to the Microbiologist / MO of the team.
- Each STLS in the district should receive a panel of 5 slides with different grades. A different panel should be used for each STLS.
- Standardized forms for recording and reporting the results should be provided by IRL team for the panel test exercise.
- An approximate time of 5 minutes per slide should be allowed for the panel test conducted.
- Ensure that each STLS has completed the exercise independently.
- The results should be made available to the IRL- Microbiologist within the specified time frame so that discordant test panel slides can be re-read by IRL Microbiologist with individual STLS(s).

Note: *IRLs should monitor RBRC during OSE visit as per NTEP guidelines till any further changes recommended.*

Presently some states have replaced smear microscopy with upfront NAAT. The smear microscopy is performed only for follow up samples. In this situation, the technicians shall read a positive slide daily before reporting the smears of the FU patients to maintain skill and proficiency. This practice shall be documented and monitored. IRL to conduct panel testing for all Microscopy centers once in every quarter.

4.2.3. Need based on-site training/ demonstration

IRL team should be prepared and equipped with tool (e.g., slide or video presentation, demonstration of activity, sharing reference document) that may be required for on-site refresher training during the OSE visit. When, a major training gap in testing activity is observed, IRL should recommended the

concerned staff for a comprehensive training preferably at IRL/STDC. Some of key areas that the IRL should be prepared are as follow:

- Newer technical update in the program
- Correct and complete filling of 'Test request form'
- Quality determination of specimen container and correct specimen packaging
- Good microbiological technique and quality control procedures
- Biosafety and infection control and prevention measure
- Testing procedure and troubleshoot activities during NAAT or AFB microscopy testing.
- Patient counseling

4.2.4. Suggesting corrective action and feedback sharing

Based on above activities, IRL should identify the problems (and not the individuals) and then initiate the problem-solving activities. A systematic way of problem-solving activity should be followed by IRL to suggest an appropriate corrective action or feedback to the district. The steps are as follow:

- Describe the problem (and not the individual) and its impact
    - All key thematic areas of laboratory services should be under the scope.
    - Wherever possible the problem should be backed up with facts/data rather than judgment alone.
    - Classify the problem as major (that lead to interruption of testing services or affect the quality test report to the patient) or minor.
- Identify the reason of problem:
    - Once the problem is identified, try to identify the cause of problem (by asking "why" repeatedly).
    - If the problem is found to be individual specific, assess whether the problem is due to training/knowledge gap or any external factor that prevents the laboratory personnel from doing the assigned job.
    - Explain the impact (long-term/short term) impact
- Corrective action and its monitoring
    - An appropriate and feasible corrective action should be suggested clearly that what needs to be done and by whom (along with tentative timeline).
    - Corrective action that can be taken immediately should be prioritized to implement first.
    - It is important to follow-up on progress time-to time.

IRL should prepare a supervisory report in a standard format (Annexure 4.2) and should be submitted to the DTO on the last day of visit. The report should include all major observation by IRL along with suggestions for appropriate corrective action and timelines. Some operational challenges (like coordination between different health programs, funds, infrastructure, HR roster etc.) that have an impact of patient's diagnosis care services and key performance indicators and require administrative support from higher officials should be listed and discussed with district health administration (CMO/DM).

4.3. Post visits follow up

The IRL-OSE visit does not end with conducted visit. IRL should plan for follow-up, which should include the following-

- Acting on the issues or technical support that IRL team agreed to work on.
- Discussion of issues with STC/STDC, particularly those requiring state intervention.
- Establishing regular communication with district to see the progress on corrective actions recommended during the on-site visit.
- Reviewing of action taken report submitted by the district and regular monitoring of indicators/reports for expected improvement.
- Assess the situation, if the district needs an early on-site follow-up visit.

Note: *As per diagnostic algorithm, TB specimens are transported from the district (NAAT sites) to the TB C& DST and/or the IRL for DST and culture-based treatment follow-up. To ensure seamless coordination between laboratories, IRL should hold monthly/quarterly coordination meetings with all districts and TB C&DST laboratories within their geography. A review of the district's progress on action taken in response to the IRL-OSE visit report should also be included as one of the agenda items for the coordination meeting. This provides opportunity to discuss training requirements of any newly recruited staff, functionality of NAAT machines and comprehensive maintenance contract (CMC) status, relocation of instrument, gaps in filling of monthly indicators, completion of sequential testing as per NTEP Diagnostic algorithm, discussing data about upfront NAAT for presumptive TB patients, issues identified during OSE visit, outcomes and impact.*

4.4. Quarterly reporting to NRL

A quarterly report summarizing the below mentioned areas should be communicated from IRL to NRL (Annexure 4.3). This report helps NRL in monitoring the supervision activities carried out by respective IRLs as well as understanding state-specific issues in which the IRLs require assistance. The report covers:

- Details of supervisory visits, district specific issues and possible solutions
- Summary of panel testing results
- Trainings conducted
- Coordination meetings conducted

Annexure 4.1: OSE checklist for Districts (for use by NRLs/IRLs)

4.1.1. OSE Checklist for District TB Center

Following particulars (serial number 1-20) need to be discussed with DTO instead of questioning.

S.No.	Particulars to be assessed	Responses
Human resource and training		
1	Training of DTO, MO-DTC, MOTCs and District Coordinators in NTEP guidelines.	
2	Vacant position in the district and steps taken to fill the same or managing the workload	
3	Training status of staff in assigned duties (especially, LT and STLS). Is there any STLS who are engaged in the routine testing or the STLS job assigned to an STS (if yes, discuss reasons).	
4	Adequacy of the infrastructure and tools for conducting district level/ToT training to the staff. Availability of training records	
5	Competency of laboratory staff (LT/STLS) in Ni-kshay and access of recording tools (tablets, laptop, computer)	
Operationalization and linkages of services		
6	Number of non-functional Microscopy facility , their reasons and the corrective action taken	
7	Number of non-functional NAAT sites, their reasons and the corrective action taken	
8	Linkages established for X-ray, NAAT and pre-treatment evaluation.	
9	Linkages/ co-ordination with other national programs- Diabetes, NACO, Tobacco cessation, Reproductive and Child Health (RCH) and other programs	
10	Frequency of samples transported to NAAT lab or TB C&DST Lab/IRL (Daily/weekly/SOS). Mechanism of specimen transportation (Human carrier/NGO/patient referred/other).	
11	Decentralization of sample transportation and availability of packing material at all TDCs. Any TDCs with issues related to sample transportation?	
Laboratory equipment, kits and consumables		
12	AMC coverage for all microscopes, Truenat and CBNAAT machines	
13	Laboratory reagents, kits and consumables (including specimen container and packaging materials) are procured as per standard specification (NTEP) and in sufficient quantity to supply all the TDCs sites.	

Health facility mapping			
14	Mapping status of all the public health facilities (including HWCs, ESI, Railways, Steel, CGHS, Coal, Mines, etc.) as well as private health facilities.		
15	Availability of PPSA agency. If not, is the available mechanism for private sector engagement (both formal and informal; clinics, hospital, testing lab and chemist) adequate.		
16	Strengthening activities done for HWCs - availability of test request form, sample container and training to CHOs		
Supervision and monitoring			
17	Frequency of review meetings with MOTC, District Coordinators, STS and STLS. Is the Laboratory performance as well as SLTS-OSE monitored and discussed? *(Review the agenda and minutes of meeting as well as data/indicators discussed in the last review meeting)*		
18	Availability, maintenance and fuel status for vehicles used for supervisory visits by DTO, STLS and STS.		
19	Coverage of OSE visits by DTO (in last quarter) and by STLSs (in last month) against the expected visits. *(Review the records/reports related to OSE)*		
		Yes/No	Remarks
20	Do all the STLS submit their TU-OSE checklist to the DTO every month? *(Review whether checklists for all TDCs are available for the last month)*	Yes No	
21	Are the RBRC being carried out as per standard protocol available? *(Review the monthly slides collected for RBRC, procedures followed for slides blinding and coding, and relevant records/ Annexure)*	Yes No	
22	Were there any Microscopy facility that reported major errors in random blinded cross checking in the current year/previous year?	Yes No	
23	Were the corrective actions taken and adequate to improve the situation in Microscopy facility (with major errors identified in RBRC or rechecking)?	Yes No	
24	Has the district sent the Annexure F to IRL? *(Review the latest annexure F and comment)*	Yes No	
25	Is functional equipment required for reagent preparation (weighing balance, water bath) available?	Yes No	
26	Are reagents checked with positive and negative control slides before being supplied? Check registers and records	Yes No	

27	Are the key data/indicators for last month available and displayed? Are these data stratified TU-wise/facility wise?	Yes No	

The following data may be collected from the district prior to OSE visit.

I. Population_____

II. Number of District and Sub-District Hospitals_____Community Health Centres_____ Health and Wellness Centre- PHCs_____ Health and Wellness Centre- SHCs_____

III. Number of TUs_____

IV. Number of total Microscopy facility_____Proportion of functional Microscopy facility_____

V. Number of total NAAT sites_____Proportion of functional NAAT sites_____

VI. Number of STLS_____

VII. Presumptive TB examination rate (rate per lakh population) _____

VIII. Percent target notification achieved (till date): Public _____ Private_____

IX. Percent presumptive TB patients offered upfront NAAT _____

X. Percent presumptive TB cases with known HIV status _____

XI. Percent bacteriologically confirmed TB patient_____

XII. Percent UDST offered _____

XIII. Proportion of 'RR /MDR-TB' offered FL and SL LPA and results available in last quarter (Rif resistant offered FL LPA/Total RIF resistant) (Rif resistant offered SL LPA/Total RIF resistant)

a. _____

XIV. Proportion of 'Rif resistant not detected' offered FL LPA and results available in last quarter. (Rif resistant not detected offered FL LPA/Total RIF resistant not detected).

a. _____

XV. Proportion of 'INH resistant' offered SL LPA and results available in last quarter (INH resistant offered SL LPA/Total INH resistant).

_____

XVI. Number of DR-TB patients initiated on (shorter/ longer oral bedaquiline containing regimen/ H mono/poly DR-TB regimen) in last quarter_____

Consider analyzing previous quarter data for questions IX to XVI

4.1.2. OSE Checklist for Microscopy facility

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
Laboratory access and patient counselling			
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
2	Are patients counselled appropriately for sputum collection? *(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)*	Yes No	

Infrastructure and facility			
3	Is separate area, adequate space and ventilation available for TB laboratory work? *(Separate workspace, directional airflow, adequate space for working and storage)*	Yes No	
4	Is power supply and running water available? *(Reliable electricity and sink)*	Yes No	
5	Is the furniture fit for purpose and are there separate workbenches for specimen receipt, smear preparation, and microscopy? *(Sturdy and cluttered free workbenches; ergonomic chairs; furniture without cloth covering; adequate storage cabinet)*	Yes No	
6	Is the laboratory's wall and floor clean and smooth, and is proper housekeeping in place? *(Slip-resistant floor, walls without damp, laboratory well organized and tidy)*	Yes No	
Human resource and training			
7	Is the LT available full time on all working days? *(Backup arrangement in the absence LT)*	Yes No	
8	Is the LT trained in sputum microscopy and has his/her competency been evaluated before assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
Equipment, reagents and consumables			
9	Is the microscope functional and well maintained (BM/FM)? *(Physical condition, annual maintenance contract or in-house maintenance record)*	Yes No	
10	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
11	Are the adequate supplies of reagents, slides and other consumables available for the next one-month? *(Slide, lens paper, filter paper, spirit lamp, Immersion oil, disinfectant-phenol, staining racks, loops/sticks and slide boxes)*	Yes No	
12	Are the staining reagents properly labelled (with expiry date) and stored appropriately? *(1% carbol fuschin, 0.1% methylene blue, 25% sulphuric acid or 0.1% auramine, 0.5% acid alcohol and 0.5% potassium permanganate)*	Yes No	
Safe practices, standard operating procedures and quality control			
13	Does the LT follow standard laboratory practices and safe technique to minimize aerosol generation? *(Use of appropriate PPE, avoiding eating/drinking inside the laboratory, protecting documents and personnel*	Yes No	

	belonging from contamination, proper handwashing, use of disposable loop/wooden stick, disinfection of workbench before and after the work and if spill incidence occurred, opening of sample container in proximity to flame, slow move when making smear, air-drying of slides before heat/flame fixing, etc.)		
14	Is the standard operating procedure accessible to LT or displayed at strategic locations? *(Preparation of smear, staining, grading chart as well as safety precautions/instructions)*	Yes No	
15	Is the quality of the smear prepared by LT appropriate? *(Smear thickness, evenness, size and staining; slide labelling)*	Yes No	
16	Is the LT examining quality control slides (supplied by STLS) with each fresh batch of reagents? *(Availability of QC slides)*	Yes No	
17	Is the LT proficient in examining and grading the smear slides in accordance with standard grading chart? *(Rechecking randomly selected positive and negative slides)*	Yes No	
18	Is the LT preserving slides properly for external quality assurance protocol (RBRC and rechecking)? *(Conduct rechecking of slides and collect required number of slides for RBRC)*	Yes No	
Specimen packaging and transportation			
19	Is the available sample collection and transportation mechanism (for NAAT testing) efficient? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely)*	Yes No	
20	Is the LT efficient enough to properly label the sample, correctly and completely fill the test request form and securely pack the sample container for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes No	
Biomedical waste management			
21	Does the LT disinfect the infectious waste (such as wooden stick, sputum cup with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
22	Is the biomedical waste segregated before final disposal as per BMW rule, Govt. of India? *(Color coded bins and bags; timely and securely removal from laboratory; disposal of waste preferably by an authorized agency)*	Yes No	
Recording and reporting			
23	Is the TB laboratory register filled correctly, completely and legibly?	Yes No	

	(TB laboratory register)		
24	Does the lab register have the summary/abstract at the end of each month? *(TB laboratory register)*	Yes No	
25	Is the lab register consistent with the TB notification register and treatment cards? *(Timely notification, co-morbidity testing and treatment initiation)*	Yes No	
26	Are treatment follow-up samples collected and tested from all pulmonary TB patients at each recommended months during and after TB treatment? *(TB notification register and Treatment card)*	Yes No	
27	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
28	Is the laboratory visited by STLS (monthly) and OSE observation report available? *(STLS-OSE report/ register)*	Yes No	

Laboratory indicators

Following indicators should be verified during the visit. Collect the information for last quarter and assess the areas of improvement.
Period_____

I. Number tested slides: Diagnosis_____; Follow up_____
II. Percent presumptive TB testing rate (out of total adult OPD) _____%
III. Percent smear positivity rate among presumptive TB patients_____%
IV. Lab turnaround time_____days
V. Percent presumptive TB patient under key population offered upfront NAAT (or sample transported to NAAT site)_____%
VI. Percent presumptive DR-TB patients offered NAAT (or sample transported to NAAT site)_____%
VII. Percent presumptive TB patients tested for HIV _____%
VIII. Percent notified patients tested for HIV _____%
IX. Percent notified patients tested for diabetes _____%
X. Percent notified TB patients initiated on treatment_____%

4.1.3 OSE Checklist for Truenat facility

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
Laboratory access and patient counselling			
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
2	Are patients counselled appropriately for sputum collection?	Yes No	

	(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)		
Infrastructure and facility			
3	Is the laboratory physically secure and does it have enough space for receiving and processing specimens? *(Lockable doors and secure windows; separate area for sample receiving and processing)*	Yes No	
4	Is specimen processing area well ventilated?	Yes No	
5	Is there separate and sufficient workbench space for the Truelab instruments, ancillary equipment and specimen processing? *(Sturdy, clutter-free and spacious workbench; placement of machine away from direct sunlight and other radiating and heating equipment,)*	Yes No	
6	Is the laboratory well-lit (enough light), has multiple power outlets, and an adequate power supply to conduct Truenat testing and battery charging?	Yes No	
7	Is the laboratory environmental condition optimal?	Yes No	
8	Is the laboratory's wall and floor clean and smooth, and is proper housekeeping in place? *(Slip-resistant floor, walls without damp, laboratory well organized and tidy)*	Yes No	
Human resource and training			
9	Is dedicated LT available full time on all working days?	Yes No	
10	Is the LT trained in Truenat testing and has his/her competency been evaluated before assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
Equipment, reagents and consumables			
11	Are routine maintenance (daily, weekly, and monthly) procedures and calibration performed and recorded for existing Truenat machine? *(Review maintenance log as well as machine down-time log)*	Yes No	
12	Are pipettes being replaced/calibrated after every six months?	Yes No	
13	Are kits and consumables for Truenat (MTB and Rif testing) available for next one month and are they stored appropriately? *(Verification of physical stock, stock register and storge condition)*	Yes No	

14	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
15	*Is adequate stock of disinfectant available and used appropriately by LT?* *(Sodium Hypochlorite)*	Yes No	
Standard operating procedures and quality control			
16	Is suitable personal protective equipment (PPE) provided at the testing site and is LT trained in its correct use?	Yes No	
17	Is the standard operating procedure accessible and followed by the LT?	Yes No	
18	Is the LT document, monitor and troubleshoot the different alerts/error flagged by the machine? *(Test register)*	Yes No	
19	Is repeat testing done in the event of error, invalid or indeterminate test result? *(Check the test register and monthly indicators)*	Yes No	
20	Are all samples tested and reported within 24 hours after they arrive at the laboratory? *(Average turn-around time)*	Yes No	
21	Is the lab running quality controls after every 50 tests and replacing the glass slide after every 200 tests?	Yes No	
Biomedical waste management			
22	Does the LT disinfect the infectious waste (such as sputum container with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
23	Are the biomedical waste segregated before final disposal as per BMW rule, Govt. of India *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	

Specimen packaging and transportation			
24	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes No	
25	Is the available sample collection and transportation mechanism efficient to meet the timely reflex testing (NAAT, LPA and Culture DST) as per current diagnosis algorithm? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely; Truenat indicator)*	Yes No	
Recording and reporting			
26	Is PMDT TB C&DST registers available and maintained?	Yes No	
27	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
28	Are monthly Truenat indicators report correctly prepared and shared with DTC and IRL on time?	Yes No	
29	Is the laboratory visited by STLS (monthly) and OSE observation report available? *(STLS-OSE report/ register)*	Yes No	

Laboratory indicators

Following indicators should be verified during the visit. Collect the information for last quarter and assess the areas of improvement.

Period_____

I. Number of total tests done: _____MTB positive ____%; Rif resistance____ %
II. Percent specimen for which DNA extraction was unsuccessful (Trueprep)_____%
III. Percent specimen with unsuccessful results (errors, invalids, no result) for MTB detection - Truenat TB _____%
IV. Percent specimen with unsuccessful results (errors, invalids, no result) for MTB-RIF Dx - _____%
V. Percent specimens with rifampicin indeterminate_____%
VI. Percent MTB positive patients whose specimen transported to TB C&DST lab for LPA/LC DST _____%
VII. Lab turnaround time_____days

4.1.4. OSE Checklist for CBNAAT facility

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
Laboratory access and patient counselling			
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
2	Are patients counselled appropriately for sputum collection? *(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)*	Yes No	
Infrastructure and facility			
3	Is the laboratory physically secure and does it have separate space for sample receiving, sample processing and machine operation?	Yes No	
4	Is specimen processing area well ventilated?	Yes No	
5	Is the laboratory environment, bench space, and power supply appropriate for the placement and operation of the CBNAAT machine? *(Functional Air conditioner, placement of machine away from direct air-conditioning vent, window or sunlight, stable surface, clearance surrounding the machine, grounded power supply, UPS with power backup of at least 2hr 30min)*	Yes No	
6	Is the laboratory environment monitored and the workbench cleaned on a regular basis?	Yes No	
Human resource and training			
7	Is dedicated LT available full time on all working days?	Yes No	
8	Is the LT trained to provide CBNAAT services, and has his/her competency been assessed prior to assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
Equipment, reagents and consumables			
9	Is the CBNAAT machine equipped with a dedicated desktop or laptop with E-connectivity?	Yes No	
10	Are routine maintenance (daily, weekly, and monthly) activities for the CBNAAT machine performed and recorded? *(Cleaning of fan filters, instrument surface, plunger; periodic data backup; maintenance log)*	Yes No	
11	Is the machine calibrated and is the down-time of machine/individual module monitored? *(Review calibration due date; equipment down-time log)*	Yes No	
12	Are cartridges and consumables for CBNAAT available for next one month and are they stored in appropriately?	Yes No	

	(Verification of physical stock, stock register and refrigerator)		
13	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
14	*Is adequate stock of disinfectant available and used appropriately by LT?* *(Freshly prepared 1% hypochlorite solution)*	Yes No	
Standard operating procedures and quality control			
15	Is suitable personal protective equipment (PPE) provided at the testing site and is LT trained in its correct use?	Yes No	
16	Is the standard operating procedure accessible and followed by the LT?	Yes No	
17	Is the LT document, monitor and troubleshoot the different alerts/error flagged by the machine? *(Test register/ machine software/ CBNAAT indicator)*	Yes No	
18	Is repeat testing done in the event of error, invalid or indeterminate test result? *(Check the test register and monthly indicators)*	Yes No	
19	Are all samples tested and reported within 24 hours after they arrive at the laboratory? *(Average turn-around time)*	Yes No	
20	Has the laboratory participated in the EQA programme and achieved the desired concordance?	Yes No	
Biomedical waste management			
21	Does the LT disinfect the infectious waste (such as sputum container with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
22	Are the biomedical waste segregated before final disposal as per BMW rule, Govt. of India *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	
Specimen packaging and transportation			
23	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes No	

24	Is the available sample collection and transportation mechanism efficient to meet the timely reflex testing (NAAT, LPA and Culture DST) as per current diagnosis algorithm? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely; Truenat indicator)*	Yes No	
Recording and reporting			
25	Is PMDT TB C&DST registers available and maintained?	Yes No	
26	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
27	Are monthly CBNAAT indicators report correctly prepared and shared with DTC and IRL on time?	Yes No	
28	Is the laboratory visited by STLS (monthly) and OSE observation report available? *(STLS-OSE report/ register)*	Yes No	

Laboratory Indicators

Following indicators should be verified during the visit. Collect the information for last quarter and assess the areas of improvement.

Period_____

I. Number of total tests done: _____MTB positive ____%; Rif resistance____ %
II. Percent specimen with unsuccessful results (errors, invalids, no result) _____%
III. Percent specimens with rifampicin indeterminate_____%
IV. Percent MTB positive patients whose specimen transported to C&DST lab for LPA/LC DST _____%
V. Lab turnaround time_____days

Annexure 4.2: On-Site Evaluation of District Level Laboratory by IRL

I. General Information and visit summary

<table>
<tr><th></th><th colspan="3">Details</th></tr>
<tr><td>District (DTC)</td><td colspan="3"></td></tr>
<tr><td>State</td><td colspan="3"></td></tr>
<tr><td>Number of TUs</td><td colspan="3"></td></tr>
<tr><td>Number of TDCs</td><td colspan="3">Microscopy facilities:_____
Truenat sites:_____
CBNAAT sites:_____</td></tr>
<tr><td>TDCs visited (briefly mention criterion of selection)</td><td colspan="3">Microscopy facilities visited:

CBNAAT sites visited:

Truenat sites visited:</td></tr>
<tr><td>Date of visit</td><td colspan="3"></td></tr>
<tr><td rowspan="11">Total number of staff and vacant positions</td><td>Position</td><td>In-place</td><td>Vacant</td></tr>
<tr><td>LT</td><td></td><td></td></tr>
<tr><td>STLS</td><td></td><td></td></tr>
<tr><td>TB-HV</td><td></td><td></td></tr>
<tr><td>STS</td><td></td><td></td></tr>
<tr><td>DEO</td><td></td><td></td></tr>
<tr><td>Accountant</td><td></td><td></td></tr>
<tr><td>DPPMC</td><td></td><td></td></tr>
<tr><td>District DR-TB & HIV-TB Coordinator</td><td></td><td></td></tr>
<tr><td>DPC</td><td></td><td></td></tr>
<tr><td>DTC-Medical Officer</td><td></td><td></td></tr>
<tr><td>Name and qualifications of current staff: (Separate sheet to be attached indicating information for each of STLS, if it is different from the previous report)</td><td colspan="3"></td></tr>
<tr><td>Officials met during OSE visit</td><td colspan="3"></td></tr>
<tr><td>Visiting IRL staff details:</td><td colspan="3"></td></tr>
</table>

II. Action required as per the previous visit to District:

Observations in previous visit	Action taken	Remarks (Pending/Completed/any other)

III A. District(s) visited (Data from district to be collected before the visit for previous quarter through Ni-kshay/DTO)

	Details of District
District visited	
Population	
Number of public health institutions	District/sub-district Hospital_____ CHC_____HWC-PHCs____HWC-SHC_____
Proportion of functional Microscopy facilities (Functional/Total Microscopy facilities)	
Proportion of functional NAAT sites (Functional/Total NAAT sites)	CBNAAT_____;Truenat_____
Presumptive TB examination rate (rate per lakh population)	
% of estimated target notification achieved (Source: Ni-kshay dashboard)	Private notification target- Achieved- Public notification target- Achieved- Total target notification- Achieved-
% of presumptive TB patients offered upfront NAAT (Presumptive TB offered NAAT (from NAAT indicators) /Total presumptive TB patients (from Annexure M) x100	

	Details of District
% of presumptive TB cases with known HIV status (Presumptive TB offered HIV testing/Total presumptive TB patients) x100	
Number of TB patients diagnosed in last quarter (Check for bacteriology confirmed and clinically diagnosed Source: Ni-kshay)	
% UDST offered in last quarter (Source-Ni-kshay)	
Proportion of 'RR/MDR-TB' offered FL and SL LPA and results available in last quarter (Rif resistant offered FL LPA/Total RIF resistant) (Rif resistant offered SL LPA/Total RIF resistant)	
Proportion of 'Rif resistance not detected' offered FL LPA and results available in last quarter (Rif resistant not detected offered FL LPA/Total RIF resistant not detected)	
Proportion of 'INH resistant' offered SL LPA and results available in last quarter (INH resistant offered SL LPA/Total INH resistant)	
Number of DR-TB patients initiated on (shorter/ longer oral bedaquiline containing regimen/ H mono/poly DR-TB regimen) in last quarter	
Analysis of the data and comments	

III B. Observations and issues identified during visit

	Key observations
Human resource/ Training and competency LTs STLSs	

	Key observations
Vacant posts	
Specimen transport mechanism	
Non-functional Microscopy facilities	
Microscopes and AMC	
Microscopy reagent preparation and QC	
EQA implementation and RBRC	
NGO PP partnership existing in the district	
Ni-kshay entry	
Provision of roadworthy vehicles for STLS/ SLS	
Monthly and quarterly review of the performance of the TB Unit	
Coordination activities TB-HIV, TB- diabetes mellitus (DM), TB-non communicable diseases (NCD) etc.	

III C. Assessment of EQA responsibilities of STLS

EQA activity of STLS	Number to be performed during the assessment period*	Number performed	Remarks
On-site evaluation			
Blinded Rechecking			

* Assessment period refers to the period from first day of the year till the current date

III D. Blinded rechecking results (refer to reports)

Categories	Responses
What is the expected number of slides to be checked by all STLS during the month?	
How many have been checked? (in %)	
Type and number of errors detected	
If errors are detected, explain recommended actions	
Has corrective action been adequately implemented (check STLS reports)?	
If no, explain:	

III E. Quantitative findings at NAAT site (Collect data from NAAT indicators and validate the same during onsite visit)

Quantitative Indicators	NAAT site1	NAAT site 2
Total tests performed in last quarter		
Percent MTB positive patients whose specimen transported to TB C&DST lab for LPA/LC DST		
Percent specimen with unsuccessful results (errors, invalids, no result) for MTB detection		
Percent specimens with rifampicin indeterminate (RIF testing in NAAT)		
Number of days between specimen collection and results reported		
Score obtained in the most recent round of NAAT EQA		
Analysis of the data and comments		

III F. Observations and issues identified during visit to NAAT sites

Qualitative indicators	NAAT site 1	NAAT site 2
NAAT site infrastructure		
Usage and downtime		
Sputum transport mechanism		
Manpower and training		
Maintenance of equipment		
Recording and reporting		
BMW management		
SOP, diagnostic algorithm displayed and followed		
Number (%) and types of errors/invalid/indeterminate result in the last quarter		
Lab registers completion		
Storage of cartridges/chips and following of FEFO principle		
Availability of packing material for sample transportation		

IIIG. Quantitative indicators from visited Microscopy facilities (Collect data for previous quarter before the visit)

Quantitative Indicators	Microscopy facility 1	Microscopy facility 2
Percent presumptive TB testing rate (out of total adult OPD)		
Percent smear positivity rate among presumptive TB patients		
Percent notified TB patients initiated on treatment		
Percent presumptive DR-TB patients in the last quarter offered NAAT/specimens transported to NAAT sites		
Percent presumptive TB patient under key population (children, PLHIV, EPTB) offered upfront NAAT/specimens transported to NAAT site		

Quantitative Indicators	Microscopy facility 1	Microscopy facility 2
Number of smear negative presumptive TB patients subjected to X-rays and found to be suggestive of TB		
Out of above, how many sent for NAAT testing		
Analysis of the data and comments		

III H. Observations and issues identified during visit to Microscopy facility

	Microscopy facility 1	Microscopy facility 2
Infrastructure (Separate area for TB laboratory work, separate tables for specimen receipt/ smear preparation/ microscopy, ventilation, window for depositing the sample, benches/chairs for patients, power supply, running water etc.)		
Staff and training		
Staining reagents		
Microscope usage, maintenance, and AMC		
Registers, records, and reports (completion of TB bacteriology request form, register, Ni-kshay entry etc.)		

	Microscopy facility 1	Microscopy facility 2
Notification register		
Supervision by STLS		
Data triangulation		
Disposal of infectious material and BMW management		
Internal quality control		

IV. Report on panel testing of STLS during on-site evaluation

District	STLS/LTs*	HFP	HFN	LFP	LFN	QE	Total number of errors	Corrective action recommended

*if required

V. Overall remarks and recommendations

V A. Good practices observed

1.

2.

3.

4.

5.

V B. Actions recommended by IRL based on quantitative indicators and observations/issues identified at DTC/TDCs

Action recommended	Responsible person	Timeline
DTC		
Microscopy facilites		
NAAT sites		

Key points for DTO

1.
2.
3.
4.
5.

Signature of DTO with date

Signature of IRL team leader with date

Annexure VI (i): Panel testing results

To be entered by STLS		For use by IRL LT		
Slide number	Result	Expected result	Error type	Remarks

Annexure VI (ii): Rechecking of slides

To be entered by IRL LT		For use by IRL LT		
Slide number	Result of technician	Result of IRL technician	Error type	Remarks

Annexure 4.3: IRL OSE and quarterly reports

Quarterly report of IRLs to NRLs

Name of IRL:		
Quarterly Report	Quarter_____	Year_____

A. OSE visits conducted to Districts and TB C&DST lab

S.No.	Name of the District /TB C&DST lab	Dates of visit	Name(s) of IRL supervisor(s)	Date of submitting report to STO and NRL

B. Report on panel testing done during on-site evaluation: (After rechecking of discordant slides)

TB C&DST laboratory/District	Number of LT/STLS	HFP	HFN	LFP	LFN	QE	Total number of errors

C. Details of training conducted

S.No.	Details of training conducted with dates	At IRL/On- site/ virtual	No. of participants

D. Details of meetings with district level lab staff

S.No.	Details of meetings conducted	Date	Number of participants

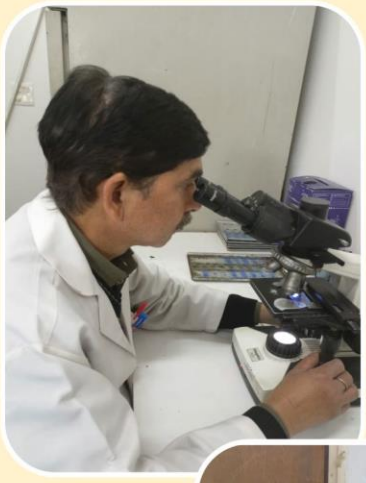
S.No.	Details of meetings conducted	Date	Number of participants

E. Details of major issues identified during OSE, monthly meetings, possible solutions recommended, and corrective actions taken

District	Issues identified at TB C&DST/DTC/TDC/ monthly meetings	Recommended corrective actions/ corrective actions taken	Remarks

F. Any other remarks

Signature of Director, IRL



Courtesy:
NRL National Institute of TB and Respiratory Diseases, New Delhi

Chapter 5

On-site evaluation of TDCs by Senior TB Laboratory Supervisors (STLSs) and District TB Officers (DTOs)

Chapter 5: On-site evaluation of TDCs by Senior TB Laboratory Supervisors (STLSs) and District TB Officers (DTOs)

NTEP has decentralized the rapid diagnosis of TB and Rifampicin resistance by equipping the district and sub-district level TB laboratories with the rapid nucleic acid amplification test (NAAT; *i.e.,* CBNAAT and/or Truenat). The programme is moving at a faster pace towards phasing out smear microscopy and offering upfront NAAT to all presumptive TB patients. The importance of smear microscopy will still remain in monitoring treatment follow-up.

Accurate, timely, and reliable testing services at Tuberculosis Diagnostic Centers (TDCs)are crucial for TB control programs, and these laboratories are supervised and monitored by STLSs with the support of the DTO. STLS is a full-time, dedicated NTEP staff member assigned to each 5 lakh population. They conduct an OSE visit to each assigned TDCs (including sample collection sites) once a month. A single STLS may have multiple TDCs in his/her jurisdiction to identify the technical and programmatic issues related to laboratory testing services and resolve them with the support of MO-IC and DTO. Under the NTEP supervision and monitoring framework, the DTO and/or delegated staff (such as MO, DPC) should also visit each TDCs at least once in a quarter. During their visit, all aspects of NTEP services are assessed, including TB diagnosis services.

5.1. On-site evaluation by STLS

Monthly OSE visit of TDCs by STLS includes a comprehensive assessment of the laboratory practices, testing procedures, reporting, conditions of the equipment, adequacy of laboratory supplies, specimen packaging and transportation mechanism, adherence to diagnostic algorithm and biosafety including BMW management. In addition, STLS also conducts EQA activities for smear microscopy (rechecking of slides and supporting RBRC activity) as per available NTEP guidelines.

5.1.1. Planning the OSE visit

STLS should visit every assigned TDCs once in a month. An advance OSE visit calendar should be prepared and shared with the DTO and the laboratories to be visited. STLS should meticulously review the last month data/ indicators to decide on priority supervision sites. Common criteria for selecting a priority laboratory may include very high/low test loads, a high rate of error/invalid/indeterminate result (NAAT), frequent equipment breakdown or stock problems, poor compliance to the diagnostic algorithm, poor performance in EQA and laboratory indicators, and pending action taken against major non-compliance observed during the last OSE visit. Some laboratories may require more attention, support, and frequent visits depending on the situation, such as a new laboratory, new staff, new test service or any other major changes in existing lab services.

When setting-up an OSE, STLS need to ensure that

- The last month data/ monitoring indicator reports (such as Annexure-M, Truenat, CBNAAT indicators and RBRC report) of laboratory have been reviewed and analyzed.
- Keep the data or report driven pre-visit observation during OSE visit.
- Review the OSE report of last visit and status report of action taken.
- Keep OSE checklists as well as tools and job aids that may require for on-site demonstration/training (on test procedures, diagnostic algorithm, monitoring indicators, recording and reporting, etc.).

5.1.2. Conducting OSE visit

STLS should allot sufficient time for the OSE visit to carefully observe all the testing activities. In order to assist STLS and to standardize the supervision system, three checklists (separate for smear microscopy, Truenat and CBNAAT) are developed. These checklists allow for consistent data collection, analysis and subsequent monitoring. STLS can simply enter a 'Yes or No' response to each question and note significant remarks, if any, based on visual observations, document/record review, and discussion with LT. The checklist also includes quick reference points (specific items to look for) as well as assessment guidance notes to specific questions. Checklists without guidance notes (annexed at the end of chapter) may be handy, and those may be used by STLS once they are well versed.

OSE should be conducted in a friendly and non-authoritarian way, with a focus on using OSE as an opportunity to improve the knowledge and skills of staff as well as carry out problem-solving activities jointly with the LT. For each identified issue, it is important to discuss with LT the cause, impact, and possible solution to be implemented. When required, STLS should properly demonstrate the process and subsequently assess the competency of LTs. It is the responsibility of STLS that LT is competent to do assigned job.

STLSs are expected to track the progress of each laboratory under their supervision. This is usually done by reviewing and analyzing the monitoring indicators/reports shared by the laboratory on monthly basis. During OSE, any indicator with a poor score or significant deviation from the expected trend/score should be investigated, validated and considered for root cause analysis and suggesting appropriate corrective actions. Important monitoring indicators (that can be filled prior to OSE visit) for Microscopy facility, Truenat and CBNAAT sites are provided below, along with OSE checklists.

5.1.2.1. STLS-OSE checklist and monitoring indicators for Microscopy facility (Refer OSE checklist for Microscopy facility (Annexure 5.1))

Checklist: On-site evaluation of Microscopy facility			
General information			
Name of Microscopy facility:_____; TB Unit:_____; District:_____ Name of LT/(s):_____ Date of visit: _____; Name of visiting STLS_____			
S.No.	**Particulars to be assessed**	**Response (Adequate/ acceptable)**	**Remarks**
Laboratory access and patient counselling			
1	Is the laboratory easily identifiable and accessible to the patients? *(Information Education Communication (IEC) material; laboratory timing; LT availability)*	Yes No	
	Guidance notes: *Observe the IEC material in the health facility, laboratory timing (preferably be displayed) and availability of trained LT/(s) on all working days. Laboratory testing area should be restricted to only authorized personnel. To avoid entry of patient into laboratory, separate counter/windows for receiving the sample should be available.*		
2	Are patients counselled appropriately for sputum collection?	Yes No	

	(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)		
	Guidance notes: *Observe the LT when counselling the patient and assess whether or not all key messages were conveyed. Alternatively, an exit interview with at least 2 patients may be conducted. The information to be communicated by LT to the patients include i) general cough etiquettes (such as covering the mouth); ii) number of sputum samples (two); iii) timing of sample collection (preferably spot and morning); iv) appropriate place for sputum collection (open area away from people); v) quality of sputum (preferable mucopurulent, not salivary or blood stained); vi) use of sputum container (open the screw-capped container only for a short period of time, avoiding smearing over the container, and securely capping the container); vii) safe and timely transportation of sputum.*		
Infrastructure and facility			
3	Is separate area, adequate space and ventilation available for TB laboratory work? *(Separate work space, directional airflow, adequate space for working and storage)*	Yes No	
	Guidance notes: *When dedicated room is not possible, smear microscopy can be performed in laboratory room that conducts general testing. TB testing area, however, should be separated with adequate space for working and storage as well as well-ventilated allowing directional airflow (from clean to dirty area and then outside the building). Where the facility design or laboratory arrangement does not allow for directional airflow, mechanical ventilation (exhaust fan) would be required.*		
4	Is power supply and running water available? *(Reliable electricity and sink)*	Yes No	
	Guidance notes: *Reliable electricity source, arrangement of power backup and availability of overhead water tank should be ensured to avoid any service delay/interruption. Ideally, two sinks should be available, one for hand-washing (near the existing door) and another for staining slides.*		
5	Is the furniture fit for purpose and are there separate workbenches for specimen receipt, smear preparation, and microscopy? *(Sturdy and cluttered free workbenches; ergonomic chairs; furniture without cloth covering; adequate storage cabinet)*	Yes No	
	Guidance notes: *Workbench for low-risk activity (like paperwork) should be separated from the higher risk activities (e.g., Smear preparation). This arrangement minimizes the possibility of contaminating the clean area/activity. Workbenches should be sturdy and resistant to chemical/disinfects as well as moderate heat. Only necessary furniture should be present in the laboratory, and cloth curtains or cloth covering on table should be avoided. Chairs with adjustable height should be preferred especially for microscopic examination. To keep the laboratory well-organized and workbenches clutter-free, there should be enough storage space for both short-term and long-term storage of laboratory items.*		
6	Is the laboratory's wall and floor clean and smooth, and is proper housekeeping in place? *(Slip-resistant floor, walls without damp, laboratory well organized and tidy)*	Yes No	
	Guidance notes: *Floors should be slip resistant, free of hazards and should be cleaned on daily basis with disinfectant (e.g., lysol). Walls should be smooth and without any damp/seepage.*		
Human resource and training			
7	Is the LT available full time on all working days?	Yes No	
	Guidance notes: *Assess how the services continue when the deputed LT is not available and whether the number of LT is adequate for the assigned workload.*		
8	Is the LT trained in sputum microscopy and has his/her competency been evaluated assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	

	Guidance notes: *LT must receive comprehensive training in smear microscopy (including the TB diagnosis algorithm, laboratory biosafety, use and maintenance of equipment, use of safe laboratory technique, recording, and reporting). The STLS must assess the competency of the LT before assigning them patient services. LT should undergo periodic retraining (every two years).*		
Equipment, reagents and consumables			
9	Is the microscope functional and well maintained (BM/FM)? *(Physical condition, AMC or in-house maintenance record)*	Yes No	
	Guidance notes: *Observe the microscope condition when the 'rechecking of slides' activity is performed. Check the due date of equipment maintenance (by AMC provider agency). Silica gel (dehydrated) and bulb should be present inside microscope storage box to avoid moisture.*		
10	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
	Guidance notes: *Observe falcon tube and packaging materials are per available specification/ recommendation by NTEP. Updated test request forms as well as facility to pre-chill the ice gel pack should be available.*		
11	Are the adequate supplies of reagents, slides and other consumables available for the next one-month? *(Slide, lens paper, filter paper, spirit lamp, Immersion oil, disinfectant-phenol, staining racks, sticks and slide boxes)*	Yes No	
	Guidance notes: *Verify the quantity and quality of laboratory materials physically. Glass slides should never be reused.*		
12	Are the staining reagents are properly labelled (with expiry date) and stored appropriately? *(1% carbol fuschin, 0.1% methylene blue, 25% sulphuric acid or 0.1% auramine, 0.5% Acid alcohol and 0.5%Potassium permanganate)*	Yes No	
	Guidance notes: *Review the expiry date of reagents in use and assess whether or not they are stored in appropriate environmental conditions (e.g., storage of chemicals in ventilated place, auramine reagent in amber bottle, alcohols away from fire source etc.). All staining reagents may be used for three months from the date of preparation except for Auramine which can be used only for 3 weeks.*		
Safe practices, standard operating procedures and quality control			
13	Does the LT follow standard laboratory practices and safe technique to minimize aerosol generation? *(Use of appropriate PPE, avoiding eating/drinking inside the laboratory, protecting documents and personnel belonging from contamination, proper handwashing, use of disposable loop, disinfection of workbench before and after the work and if spill incidence occurred, opening of sample container in proximity to flame, slow move when making smear, air-drying of slides before heat/flame fixing, etc.)*	Yes No	
	Guidance notes: *Observe practices when LT is performing the test.*		
14	Is the SOP accessible to LT or displayed at strategic locations? *(Preparation of smear, staining, grading chart as well as safety precautions/instructions)*	Yes No	
	Guidance notes: *Review the availability of SOPs and wall instructions.*		

15	Is the quality of the smear prepared by LT appropriate? *(Smear thickness, evenness, size and staining; slide labelling)*	Yes No	
	Guidance notes: *Observe the prepared/stored slides. Smears should not be too thick/thin, large/small, over-heated during heat fixing, over/less decolorized, or stored in direct light (if stained with auramine).*		
16	Is the LT examining quality control slides (supplied by STLS) with each fresh batch of reagents? *(Availability of QC slides)*	Yes No	
	Guidance notes: *Review available QC slides and reagent batch testing records*		
17	Is the LT proficient in examine and grading the smear slides in accordance to standard grading chart? *(Rechecking randomly selected positive and negative slides)*	Yes No	
	Guidance notes: Observe LT while preparing and stating smears. *Recheck slides at least 5 positive & 5 negatives- if positive slides are less than 5 then all positive need to cross check. NRLs/IRLs may cross check few slides.*		
18	Is the LT preserving slides properly for EQA protocol (RBRC and rechecking)? *(Conduct rechecking of slides and collect required number of slides for RBRC. Check if the slides are stored till the RBRC is completed and feedback communicated)*	Yes No	
	Guidance notes: *Review the storage condition of slides stored for EQA (RBRC and rechecking) purpose and collect slides as per standard EQA protocol recommended by NTEP.*		
Specimen packaging and transportation			
19	Is the available sample collection and transportation mechanism (for NAAT testing) efficient? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely)*	Yes No	
	Guidance notes: *A robust sample transportation mechanism should be available that allows pick up of samples from the health facility same day when sample collected/submitted. Assess the transportation TAT to the NAAT sites and whether it is acceptable or not.*		
20	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample container for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; standard triple layer packaging)*	Yes No	
	Guidance notes: *Carefully inspect the packaged specimen ready to be transported for appropriate labelling of samples, completely filled test requisition forms as well as appropriate packaging.*		
Biomedical waste management			
21	Does the LT disinfect the infectious waste (such as broom stick, sputum cup with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
	Guidance notes: *Review how frequently 5% phenol is prepared by the LT and how he/she disinfects the infectious waste. When disinfecting the sputum cup, leftover sputum and wooden stick, ensure that the sputum cup is open and fully submerged in the phenol solution, and after a sufficient contact period (overnight), drain off the disinfectant and leave the sputum cup and wooden stick in biohazard bag for final disposal.*		

22	Are the BMW segregated before final disposal as per BMW rule, Govt. of India? *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	
	Guidance notes: *The laboratory should be aware of state/local BMW norms and must also acquaint themselves with amendments made from time-to-time in the BMW management rules. As general rule, all BMW is disinfected and segregated before final disposal. Most suitable disinfectant for TB laboratory is 5% Phenol or 1% freshly prepared Sodium hypochlorite in NAAT labs. Laboratory should have different color-coded bins (red, yellow, blue, black) for appropriate segregation of BMW (Refer to Biosafety Manual for more details). Bins shouldn't be more than two thirds full, and the area where they are temporarily stored needs to be secured.* *Waste generated in TB laboratories should not be disposed in a landfill even after decontamination. If facilities for waste collection are not available, all soiled/ contaminated gloves/sputum cups/soiled paper are wrapped in autoclavable red/ yellow /blue bags and buried in the pit in an isolated area, identified for the purpose*.		
Recording and reporting			
23	Is the TB laboratory register filled correctly, completely and legibly? *(TB laboratory register)*	Yes No	
	Guidance notes: *Review the TB laboratory register. Laboratory serial number should be entered correctly, starting with 1 on 1st Jan of the year continuing until 31 December. All the columns should be filled correctly and legibly. Positive test result (scanty, 1+, 2+ or 3+) should be marked/highlighted in red.*		
24	Does the Lab register have the summary/abstract at the end of each month? *(TB laboratory register)*	Yes No	
	Guidance notes: *Review monthly test summary (as per standard format) that should include information related to number of patients tested for diagnosis and treatment follow-up purpose (including any repeat examination), number of positive patients as well as total number of positive and negative slides examined.*		
25	Is the lab register consistent with the TB notification register and treatment cards? *(Timely notification, co-morbidity testing and treatment initiation)*	Yes No	
	Guidance notes: *Check information for at least 4-6 randomly selected new smear positive patients. Verify that all patients who tested positive have been entered into TB notification register, that their co-morbidity testing status (HIV and diabetes testing) has been updated, and that their treatment card, which indicates prompt treatment initiation, is available.*		
26	Are treatment follow-up samples collected and tested from all pulmonary TB patients at each recommended months during and after TB treatment? *(TB notification register and Treatment card)*	Yes No	
	Guidance notes: *Review the notification register and treatment cards. Pulmonary Drug Susceptible TB (DS-TB) patient should be followed-up at the end of IP and end of treatment. In addition to this, long term follow up should be done at 6, 12, 18 and 24 months after completion of treatment. Smear and or Culture is recommended for patients on DR-TB regimen (refer PMDT guideline for follow-up schedule under different DR-TB regimen)*		
27	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
	Guidance notes: *Verify that the information in register is updated timely in Ni-kshay and that there is no deviation*		

Quantitative indicators- Microscopy facility			
S.No.	**Indicator**	**Method to derive**	**Score**
1	Percent presumptive TB testing rate *(Source: OPD and TB lab register; Annexure M)*	Numerator: Number of presumptive TB patient identified and tested Denominator: Total new adult outpatients (include OPD of linked PHI/HWC expected to refer patients)	____%
2	Percent smear positivity rate among presumptive TB patients *(Source: TB lab register; Annexure M)*	Numerator: Number of smear positive patient Denominator: Total number of presumptive TB patient tested	____%
3	Lab TAT *(Source: TB lab register)*	The average time (in days) elapsed between date samples were received in the lab and date smear result reported.	____days
4	Percent smear positive TB patients offered NAAT (or specimens transported to NAAT site) *(Source: TB lab register)*	Numerator: Number of smear positive patients who were tested by NAAT Denominator: Total Number of smear positive patients	____%
5	Percent presumptive TB patient under key population offered upfront NAAT (or specimens transported to NAAT site) *(Source: TB lab register)*	Numerator: Number of presumptive TB patients tested upfront by NAAT Denominator: Total number of presumptive TB patients (smear negative chest X-ray positive patient + pediatric patients + presumptive extra-pulmonary TB patient + PLHIV + other vulnerable group)	____%
6	Percent presumptive DR-TB patients offered NAAT (or specimens transported to NAAT site) *(Source: TB lab register)*	Numerator: Number of presumptive DR-TB patients tested by NAAT Denominator: Total number of presumptive DR-TB patients (smear positive TB patients + DR-TB contact person + previously treated patients + Non responders to DS-TB treatment regimen)	____%
7	Percent presumptive TB patients tested for HIV *(Source: TB lab register)*	Numerator: Number of presumptive TB patients tested for HIV Denominator: Total number of presumptive TB patients	____%
8	Percent notified patients tested for HIV *(Source: TB notification register)*	Numerator: Number of notified TB patients tested for HIV Denominator: Total number of notified TB patients	____%
9	Percent notified patients tested for diabetes *(Source: TB notification register)*	Numerator: Number of notified TB patients tested for diabetes Denominator: Total number of notified TB patients	____%
10	Percent notified TB patients initiated on treatment *(Source: TB notification register)*	Numerator: Number of notified TB patient initiated on appropriate treatment regimen Denominator: Total number of notified patients (microbiologically confirmed + clinically diagnosed	____%

5.1.2.2. OSE checklist and monitoring indicators for Truenat site (Refer OSE checklist for Truenat, Annexure 5.2)

OSE Checklist for Truenat site

General information

Name of Truenat site:_____; Facility Type: _____(Public / Private)

TB Unit:_____; District:_____;

Name of LT/(s):_____;

Date of visit:_____; Name of visiting STLS_____

Equipment Details

	Machine 1	Machine 2	Machine 3
Type of Module	Uno/Duo/Quatro	Uno/Duo/Quatro	Uno/Duo/Quatro
Number of machines			
Date of installation			
Due date for next calibration			
Functional Status			
Number of TDCs linked			

Action required as per the previous visit

Current visit particulars

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
Laboratory access and patient counselling			
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
	Guidance notes: *Observe the IEC material in the health facility, laboratory timing (preferably be displayed) and availability of trained LT/(s) on all working days. Laboratory testing area should be restricted to only authorize personnel. Separate counters or windows for receiving samples, as well as chairs in the waiting area, should be available to prevent patient entry into the laboratory.*		
2	Are patients counselled appropriately for sputum collection?	Yes No	

	(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)		
	Guidance notes: *Observe the LT when counselling the patient and assess whether or not all key messages were conveyed. Alternatively, an exit interview with at least 2 patients may be conducted. The information to be communicated by LT to the patients include i) general cough etiquettes (such as covering the mouth); ii) number of sputum samples (two; one for Truenat and another for LPA, if M. tuberculosis detected in Truenat); iii) timing of sample collection (preferably one spot and one morning sample; alternatively two spot samples); iv) appropriate place for sputum collection (open area away from people); v) quality of sputum (preferable mucopurulent- not salivary or blood stained); vi) use of sputum container (opening and closing the container securely; opening only for a short period of time; clean exterior of container without any smearing); vii) safe and timely transportation of sputum.*		
Infrastructure and facility			
3	Is the laboratory physically secure and does it have enough space for receiving and processing specimens? *(Lockable doors and secure windows; separate area for sample receiving and processing)*	Yes No	
	Guidance notes: *In context to biosecurity, the laboratory should have lockable doors (that can be locked when un-occupied) and secure windows.* If different activities are being performed within the same laboratory, low risk activities should be performed near the entry door and comparatively higher risk activities should be performed at the farthest end of the laboratory. It is preferable to have separate areas for sample receiving and sample processing.		
4	Is specimen processing area well ventilated?	Yes No	
	Guidance notes: *Specimen processing area should be well ventilated allowing directional airflow (from clean to dirty area and then outside the building).*		
5	Is there separate and sufficient workbench space for the Truelab instruments, ancillary equipment, and specimen processing? (Sturdy, clutter-free and spacious workbench; placement of machine away from direct sunlight and other radiating and heating equipment,)	Yes No	
	Guidance notes: *Assess the area where machine installed. Separate and adequate workbench space should be allotted for Truenat machine as well specimen processing activity. Bench should be flat, sturdy, without any cloth coverings and it should be resistant to commonly used disinfectant (1% Sodium hypochlorite).* *Micro-PCR instruments should be placed at least one meter away from other equipment (especially radiating or heating equipment apparatus). Avoid direct sunlight to the equipment. For efficient operations, workbench should be clean and well organized.*		
6	Is the laboratory well-lit (enough light), has multiple power outlets, and an adequate power supply to conduct Truenat testing and battery charging?	Yes No	
	Guidance notes: *For sites that would rely on Truelab equipment in-built batteries, up to 10 hours of electricity is required to recharge the batteries, in order to be able to run tests for 8 hours. Enough light should be there to correctly add small volumes to truant chips.*		
7	Is the laboratory environmental condition optimal?	Yes No	
	Guidance notes: *Truenat is a robust equipment and does not require a conditioned environment. However, operation of machine in optimal environmental condition (Temp: 15^0C to 40^0C; Humidity: 10-80%; dust free) should be considered.*		

8	Is the laboratory's wall and floor clean and smooth, and is proper housekeeping in place? *(Slip-resistant floor, walls without damp, laboratory well organized and tidy)*	Yes No	
	Guidance notes: *Floors should be slip resistant, free of hazards and should be cleaned on daily basis with disinfectant (e.g., lysol). Walls should be smooth and without any dampness/seepage.*		
Human resource and training			
9	Is dedicated LT available full time on all working days?	Yes No	
	Guidance notes: *Assess how the services continue when the deputed LT is not available and whether the number of LT is adequate for the assigned workload.*		
10	Is the LT trained in Truenat testing and has his/her competency been evaluated before assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
	Guidance notes: *The Truenat TB test procedures require multiple hands-on steps as well as precision micro-pipetting. Laboratory technicians should be properly trained on all procedures and in Good Molecular Biology practices. LT must receive Truenat testing training (on-site by Molbio/STLS; or at district/IRL). STLS should ensure that LT is competent in performing the test, referral of sample as per TB diagnosis algorithm, laboratory biosafety, use and maintenance of equipment, recording and reporting activities). LT should undergo periodic retraining (every two years).*		
Equipment, reagents and consumables			
11	Are routine maintenance (daily, weekly, and monthly) procedures and calibration of Truenat machine performed and recorded? ? Is the record of equipment breakdowns maintained? *(Review maintenance log as well as machine down-time log)*	Yes No	
	Guidance notes: *LT must be trained in conducting the in-house maintenance activity. In-house maintenance as well as service and calibration by authorized service engineer should be recorded (log sheet) and reviewed during OSE visit. In addition, breakdown escalation system should also be assessed by reviewing the down-time log.*		
12	Are pipettes being replaced/changed after every six months?	Yes No	
	Guidance notes: *Inspect the pipette and/or the relevant records.*		
13	Are kits and consumables for Truenat (MTB and Rif testing) available for next one month? Are they stored appropriately and used as per FEFO principle? *(Verification of physical stock, stock register and storage condition)*	Yes No	
	Guidance notes: *The storage area should be well-organized and secure, with an adequate supply of kits and consumables. at the recommended storage condition for Truenat chips 2°C–30°C and for sample pretreatment pack and prep kit is 2°C–40°C. If geographies with higher temperature, chips and reagents should be stored in refrigerator. Review the stock-register to assess whether or not FEFO (first expiry first out) principle followed.*		
14	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm,*	Yes No	

	absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)		
	Guidance notes: *Review the stocks physically.*		
15	*Is adequate stock of disinfectant available and used appropriately by LT?* *(Sodium Hypochlorite)*	Yes No	
	Guidance notes: *The work area should be cleaned regularly with freshly prepared 1% Sodium hypochlorite followed by 70% alcohol/distilled water. LT should know to dilute any concentration stock to required concentration. 5% phenol should be used to discard sputum/ sample cups.*		
Standard operating procedures and quality control			
16	Is suitable PPE provided at the testing site and is LT trained in its correct use?	Yes No	
	Guidance notes: *Minimum PPE for conducting the test includes lab coat and gloves. LT should wash their hands properly after removing the gloves. Although N-95 respirator is not essential PPE for TB testing procedures at TDCs, it may be required for LTs in especial situations (like bi-directional TB-COVID screening in which COVID-19 screening for all diagnosed TB patients and TB screening for all COVID positive patients are conducted). Therefore, LTs should know correct donning, doffing and storage (if re-used) of respirators. N95 respirator is not affected until three days of use (8 hrs./day) and it can be stored in a paper bag with air holes (to allow moisture to evaporate) in a well-ventilated area*		
17	Is the SOP accessible and followed by the LT?	Yes No	
	Guidance notes: *Review whether SOP and safety precautions are displayed at strategic locations. Observe/discuss the different steps involved in the Truenat testing.* *Assess that the LT consider to i) reject the sputum with pan masala, gutkha, tobacco, any food particle or blood stained sputum; ii) extend incubation for 5 min if sputum could not liquified after 10 min; iii) transfer entire volume of elute from elute chamber and discard pipette in 1% freshly prepared Sodium hypochlorite solution; iv) replace cartridge holder tray (Trueprep) in case of a spillage in the device; v) running flushing protocol (if Trueprep device is kept idle for more than 10 days) vi) ensure that the elute is loaded in the center of the reaction well (Truelab); vii) chips are hold by edges only; viii) perform RIF testing only after confirming MTB by MTB chips.* *LT must avoid that cartridge or chips are left inside the device (after completing the test), used materials are kept on the device, device is tilted/moved while test is in progress and that nozzle of buffer bottles are touched.*		
18	Does the LT document, monitor and troubleshoot the different alerts/error flagged by the machine? *(Test register)*	Yes No	
	Guidance notes: *Review the Truenat indicator and assess type and frequency of errors encountered during last month. Documentation of error enable the user to troubleshoot the issue effectively.*		
19	Is repeat testing done in the event of error, invalid or indeterminate test result? *(Check the test register and monthly indicators)*	Yes No	
	Guidance notes: *Review the test register and monthly indicator of last month. In situations where both specimens are used by the NAAT site, assess repeat samples are taken from the eligible patients for reflex LPA/C&DST testing.*		
20	Are all samples tested and reported within 24 hours after they arrive at the laboratory? *(Average turn-around time)*	Yes No	
	Guidance notes: *Review the C&DST lab register to assess the average laboratory turn-around time. In case of significant delay (TAT), investigate the reasons and suggest appropriate corrective actions.*		
21	Is the lab running quality controls after every 50 tests and replacing the glass slide after every 200 tests?	Yes No	
	Guidance notes: *Review the quality control records.*		

Biomedical waste management			
22	Does the LT disinfect the infectious waste (such as sputum container with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
	Guidance notes: *Review how frequently 5% phenol is prepared by the LT and how he/she disinfect the infectious waste. When disinfecting the sputum cup and leftover sputum, ensure that the sputum cup is fully submerged in the phenol solution, and after a sufficient contact period (overnight), drain off the disinfectant and collect the sputum cup in biohazard bag for final disposal.*		
23	Are the BMW segregated before final disposal as per BMW rule, Govt. of India *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	
	Guidance notes: *The laboratory should be aware of state/local BMW norms and must also acquaint themselves with amendments made from time-to-time in the BMW management rules. As general rule, all BMW is disinfected and segregated before final disposal. Most suitable disinfectant for TB laboratory is 5% Phenol or 1% Sodium hypochlorite. Laboratory should have different color-coded bins (red, yellow, blue, black) for appropriate segregation of BMW (Refer Biosafety manual for further details). Bins shouldn't be more than two thirds full, and the area where they are temporarily stored needs to be secured. Chips and cartridges should be considered as infected plastic waste and should be disposed accordingly.* *Waste generated in TB laboratories should not be disposed in a landfill even after decontamination. If facilities for waste collection are not available, all soiled/ contaminated gloves/sputum cups/soiled paper are wrapped in autoclavable red/ yellow /blue bags and buried in the pit in an isolated area, identified for the purpose*.		
Specimen packaging and transportation			
24	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes No	
	Guidance notes: *Carefully inspect the packaged specimen ready for transportation. Asses that the samples are labelled appropriately, test request forms are filled completely and correctly, samples are packed in triple layer along with pre-chilled ice gel packs (cool chain transportation) as per NTEP guidelines.*		
25	Is the available sample collection and transportation mechanism efficient to meet the timely reflex testing (NAAT, LPA and Culture DST) as per current diagnosis algorithm? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely; Truenat indicator)*	Yes No	
	Guidance notes: *A robust sample transportation mechanism that allows samples to be picked up and delivered within the specified time frame should be available. Two sputum samples are collected from patients or linked microscopy facility by the NAAT facility. If MTB is detected in one sample, another is sent to the IRL/linked C&DST laboratory for cascade testing as per Diagnostic algorithm [LPA (FL/SL)/culture and DST]. Samples should be picked up from the Truenat facility the same day that the MTB and rifampicin test results are available.* *Review the Truenat indicator report of last month to assess the proportion of eligible patients (as per current diagnosis algorithm) whose samples were not sent to IRL/C&DST laboratory for LPA/Culture and DST. Some of EPTB specimens (e.g., tissue or large volume body fluid) are also sent to higher*		

	laboratories since the specimen processing require special equipment (e.g., safety centrifuge, biosafety cabinet).		
Recording and reporting			
26	Is PMDT TB C&DST registers available and maintained?	Yes No	
	Guidance notes: *Check for details of all columns and also if LT knows the importance of repeat testing in invalids, errors, indeterminates, cfu/ml values and mentioning the same in register.*		
27	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
	Guidance notes: *Verify that the information in C&DST lab register is updated timely in Ni-kshay.*		
28	Are monthly Truenat indicators report correctly prepared and shared with DTC and IRL on time?	Yes No	
	Guidance notes: *Review Truenat indicator report of last month and verify them with available physical records. Discuss with LT, if any significant observation (e.g., high rate of errors) noticed and suggest appropriate corrective actions.*		

	Recommended Corrective Action	Timeline
I		
II		
III		
IV		
V		

Signature of LT **Signature of visiting STLS** **Signature of MO-IC**

Quantitative indicators (Previous month)- Truenat facility			
S.No.	**Indicators**	**Method to derive**	**Score**
1	Percent testing capacity utilized? *(Source: TB lab register; monthly Truenat indicator report)*	Numerator: Number of total tests performed; Denominator: Expected number of tests to be done	_____%
2	Percent presumptive TB patients offered upfront NAAT *(Source: OPD and TB lab register; Annexure M)*	Numerator: Number of presumptive TB patient tested upfront by NAAT; Denominator: Total number of presumptive TB patients	_____%
3	Percent presumptive TB (among key population)/DR-TB patient offered upfront NAAT *(Source: TB lab register; TB notification register; Truenat indicator)*	Numerator: Number of presumptive TB (among key population)/DR-TB patients tested upfront by NAAT; Denominator: Total number of presumptive TB (among key population) and DR-TB patients identified	_____%
4	Percent samples with MTB detected	Numerator: Number of samples with MTB detected result in Truenat;	

	(Source: TB lab register; monthly Truenat indicator report)	Denominator: Total number of samples tested	_____%
5	Percent samples with Rif resistant detected *(Source: TB lab register; monthly Truenat indicator report)*	Numerator: Number of samples with Rif resistance detected in Truenat; Denominator: Total number of MTB detected in Truenat	_____%
6	Percent specimen for which Deoxyribonucleic acid (DNA) extraction was unsuccessful (Trueprep) *(Source: TB lab register; monthly Truenat indicator report)*	Numerator: Number of specimens for which DNA could not be extracted; Denominator: Total number of DNA extractions performed	_____%
7	Percent specimen with unsuccessful results (errors, invalids, no result) for MTB detection - Truenat TB *(Source: TB lab register; monthly Truenat indicator report)*	Numerator: Number of specimens with unsuccessful result; Denominator: Total number of specimens tested with MTB chips	_____%
8	Percent specimens with rifampicin indeterminate *(Source: TB lab register; monthly Truenat indicator report)*	Numerator: Number of specimens with rifampicin indeterminate; Denominator: Total number of specimens tested for rifampicin resistance	_____%
9	Percent MTB positive patients whose specimen transported to C&DST lab for LPA/LC DST	Numerator: Number of patients whose specimens sent to TB C&DST laboratory; Denominator: Total number of patients with MTB detected result in NAAT	_____%
10	Lab TAT *Source: TB lab register*	The average time (in days) elapsed between date samples were received in the lab and date Truenat test result reported	_____days

5.1.2.2. OSE Checklist and monitoring indicators for CBNAAT facility (Refer OSE checklist for CBNAAT (Annexure 5.3))

Checklist: On-site evaluation of CBNAAT facility
General information
Name of CBNAAT facility:_____; Facility Type: _____(Public / Private) TB Unit:_____; District:_____; Name of LT/(s):_____; Date of visit:_____; Name of visiting STLS_____

Equipment Details		
	Machine 1	**Machine 2**
Type of Module		
Number of machines		
Date of installation		
Due date for next calibration		
Functional Status		

Action required as per the previous visit

Current visit particulars

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
	Laboratory access and patient counselling		
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
	Guidance notes: *Observe the IEC material in the health facility, laboratory timing (preferably be displayed) and availability of trained LT/(s) on all working days. Laboratory testing area should be restricted to only authorized personnel. Separate counters or windows for receiving samples, as well as chairs in the waiting area, should be available to prevent patient entry into the laboratory.*		
2	Are patients counselled appropriately for sputum collection? *(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)*	Yes No	
	Guidance notes: *Observe the LT when counselling the patient and assess whether or not all key messages were conveyed. Alternatively, an exit interview with at least 2 patients may be conducted.* *The information to be communicated by STLS to the patients include i) general cough etiquettes (such as covering the mouth); ii) number of sputum samples (two; one for CBNAAT and another for LPA, if MTB detected in Truenat); iii) timing of sample collection (preferably one spot and one morning); iv) appropriate place for sputum collection (open area away from people); v) quality of sputum (preferable mucopurulent- not salivary or blood stained); vi) use of sputum container (open the screw-capped container only for a short period of time, avoiding smearing over the container, and securely capping the container); vii) safe and timely transportation of sputum.*		
	Infrastructure and facility		
3	Is the laboratory physically secure and does it have separate space for sample receiving, sample processing and machine operation?	Yes No	

	Guidance notes: *In context to biosecurity, the laboratory should have lockable doors (that can be locked when un-occupied) and secure windows. It is preferable to have separate areas for sample receiving, sample processing and machine operation.*		
4	Is specimen processing area well ventilated?	Yes No	
	Guidance remarks: *Specimen processing should be done separately in a naturally or mechanically ventilated area ensuring directional airflow i.e., air flowing from clean areas to potentially contaminated area and then to outside.*		
5	Is the laboratory environment, bench space, and power supply appropriate for the placement and operation of the CBNAAT machine? *(Functional air-conditioner, placement of machine away from direct air-conditioning vent, window or sunlight, stable surface, clearance surrounding the machine, grounded power supply, UPS with power backup >2hrs.)*	Yes No	
	Guidance notes: *CBNAAT is sensitive to environmental condition and therefore equipment should be placed in dust free and temperature (15-30^{0}C) controlled environment. There rooms should be equipped with an AC, and it should be ensured that machine is not directly under an AC vent or a window and in no direct sunlight. Machine should be place on a sturdy, impervious and cluttered free workbench (e.g. granite/title fitted concrete slab) that can be decontaminated easily. A 5-10 cm of clearance surrounding the instrument from the walls or other instruments should be considered. Power should be well-grounded, and the power socket should be near the equipment. CBNAAT must be connected to a UPS that provides at least 2 hours of power backup.*		
6	Is the laboratory environment monitored and the workbench cleaned on a regular basis?	Yes No	
	Guidance notes: *LT should monitor the room temperature and humidity (using a hygrometer) and maintain the log. Since, dusty environment can impact on machine operation, the workbench and room should be cleaned on regular basis.*		
Human resource and training			
7	Is dedicated LT available full time on all working days?	Yes No	
	Guidance notes: *Assess how the services continue when the deputed LT is not available and whether the number of LT is adequate for the assigned workload.*		
8	Is the LT trained to provide CBNAAT services, and has his/her competency been assessed prior to assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
	Guidance notes: *LT must receive CBNAAT testing training (on-site by STLS; or at district/IRL). STLS should ensure that LT is competent in performing the test, referral of sample as per TB diagnosis algorithm, laboratory biosafety, use and maintenance of equipment, recording and reporting activities. LT should undergo periodic retraining (every two years).*		
Equipment, reagents and consumables			
9	Is the CBNAAT machine equipped with a dedicated desktop or laptop with E- connectivity?	Yes No	
10	Are routine maintenance (daily, weekly, and monthly) activities for the CBNAAT machine performed and recorded?	Yes No	

	(Cleaning of fan filters, instrument surface, plunger; periodic data backup; maintenance log)		
	Guidance notes: *LT must be trained in conducting the in-house maintenance activity. In-house maintenance activity includes cleaning of dust on equipment and on the bench (daily), cleaning of fan filter and plunger rods (at least monthly/more frequently as required). To avoid loss of testing data, the data backup should be done periodically. Maintenance-log should be maintained, and it should be reviewed by the assessor during OSE visit.*		
11	Is the machine calibrated and is the downtime of machine/individual module monitored? *(Review calibration due date; equipment down-time log)*	Yes No	
	Guidance notes: *The CBNAAT machine should be calibrated at least once a year, or every 2,000 tests or modules, whichever comes first. Down-time of equipment/ each module should be recorded (down-time log) and an efficient breakdown escalation system should be in place.*		
12	Are cartridges and consumables for CBNAAT available for next one month? Are they stored appropriately and used as per FEFO principle? *(Verification of physical stock, stock register and refrigerator)*	Yes No	
	Guidance notes: *The cartridges should be stored in refrigerator (recommended temperature range (2-28°C). Review the stock-register as well as physical stocks to assess whether or not FEFO principle followed.*		
13	Does the laboratory have sputum container/falcon tubes, test requisition form and packaging material for sample transport at least for a quarter? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
	Guidance notes: *Review the stocks physically.*		
14	*Is adequate stock of disinfectant available and used appropriately by LT?* *(Freshly prepared 1% Sodium hypochlorite solution)*	Yes No	
	Guidance notes: *The work area and device should be cleaned regularly with freshly prepared 1% Sodium hypochlorite followed by 70% alcohol/distilled water.*		
Standard operating procedures and quality control			
15	Is suitable PPE provided at the testing site and is LT trained in its correct use?	Yes No	
	Guidance notes: *Minimum PPE for conducting the test includes lab coat and gloves. LT should wash their hands properly after removing the gloves. Stock register may be reviewed to assess the stocks.*		
16	Is the SOP accessible and followed by the LT?	Yes No	
	Guidance notes: *Review whether SOP and safety precautions are displayed at strategic locations. Observe/discuss the different steps involved in the Truenat testing.* *Assess that the LT consider correct sample-reagent ratio, incubation time, correct handling of cartridge, precaution during adding correct volume (2ml) of the processed specimen in cartridges and timely insertion of cartridges into machine.*		
17	Is the LT document, monitor and troubleshoot the different alerts/error flagged by the machine? *(Test register/ machine software/ CBNAAT indicator)*	Yes No	
	Guidance notes: *Review the CBNAAT indicator/test register or machine software to determine the type of error and its frequency during the previous month. If a significant number of errors (>3% of total test done) or no result (>1% of total test done) are observed, discuss the corrective action.*		

18	Is repeat testing done in the event of error, invalid or indeterminate test result? *(Check the test register and monthly indicators)*	Yes No	
	Guidance notes: *Review the test register and monthly indicator of last month. Some-time repeat testing on second sample is required. In this situation, the MTB positive patient should be asked to provide a fresh sample for LPA/Culture-DST testing.*		
19	Are all samples tested and reported within 24 hours after they arrive at the laboratory? *(Average turn-around time)*	Yes No	
	Guidance notes: *Review the C&DST lab register to assess the average laboratory turn-around time. In case of significant delay (TAT), investigate the reasons and suggest appropriate corrective actions.*		
20	Has the laboratory participated in the EQA programme and achieved the desired concordance? *(If not, identify the root cause and suggest the corrective action/s)*	Yes No	
Biomedical waste management			
21	Does the LT disinfect the infectious waste (such as sputum container with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
	Guidance notes: *Review how frequently 5% phenol is prepared by the LT and how he/she disinfect the infectious waste. When disinfecting the sputum cup and leftover sputum, ensure that the sputum cup is fully submerged in the phenol solution, and after a sufficient contact period /overnight), drain off the disinfectant and collect the sputum cup in biohazard bag for final disposal.*		
22	Are the BMW segregated before final disposal as per BMW rule, Govt. of India? *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	
	Guidance notes: *As general rule, all BMW is disinfected and segregated before final disposal. Most suitable disinfectant for TB laboratory is 5% Phenol or 1% Sodium hypochlorite. Laboratory should have different color-coded bags and bins (red, yellow, blue, black) for appropriate segregation of BMW. Bins shouldn't be more than two thirds full, and the area where they are temporarily stored needs to be secured. Cartridges should be considered as infected plastic waste and should be disposed accordingly. Waste generated in TB laboratories should not be disposed in a landfill even after decontamination. If facilities for waste collection are not available, all soiled/ contaminated gloves/sputum cups/soiled paper are wrapped in autoclavable red/ yellow /blue bags and buried in the pit in an isolated area, identified for the purpose. The laboratory should be aware of state/local BMW norms.*		
Specimen packaging and transportation			
23	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes No	
	Guidance notes: *Carefully inspect the packaged specimen ready for transportation. Asses that the samples are labelled appropriately, test request forms are filled completely and correctly, samples are*		

	packed in triple layer along with pre-chilled ice gel packs (cool chain transportation) as per NTEP guidelines.		
24	Is the available sample collection and transportation mechanism efficient to meet the timely reflex testing (NAAT, LPA and Culture DST) as per current diagnosis algorithm? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely; Truenat indicator)*	Yes No	
	Guidance notes: *A robust sample transportation mechanism that allows samples to be picked up and delivered within the specified time frame should be available. CBNAAT facility receives two sputum samples either from the patients or received through linked microscopy facility. If MTB is detected in one sample, another should be sent to the IRL/linked C&DST laboratory for cascade testing as per NTEP diagnostic algorithm. Ideally, samples should be picked up from the CBNAAT facility the same day that the MTB positive test result is available.* *Review the CBNAAT indicator report of last month to assess the proportion of eligible patients (as per current diagnosis algorithm) whose samples were not sent to IRL/C&DST laboratory for LPA/Culture and DST. Some of extrapulmonary specimens (e.g., tissue or large volume body fuild) are also sent to higher laboratories since the specimen processing require special equipment (e.g., safety centrifuge, biosafety cabinet). Review records.*		
Recording and reporting			
25	Is PMDT TB C&DST registers available and maintained?	Yes No	
	Guidance notes: *Check for details of all columns and also if LT knows the importance of repeat testing in invalids, errors, indeterminates, cfu/ml values and mentioning the same in register.*		
26	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
	Guidance notes: *Verify that the information in C&DST lab register is updated timely in Ni-kshay.*		
27	Are monthly CBNAAT indicators report correctly prepared and shared with DTC and IRL on time?	Yes No	
	Guidance notes: *Review Truenat indicator report of last month and verify them with available physical records. If any significant observation (e.g., high rate of errors) is noticed, it should be discussed with LT and appropriate corrective actions should be suggested.*		

Key recommendations

S. No.	Recommended corrective actions	Timeline
I		
II		
III		
IV		
V		

Signature of STLS **Signature of LT** **Signature of MO-IC**

Quantitative indicators (Previous month)- CBNAAT site			
S.No.	**Indicators**	**Method to derive**	**Score**
1	Percent testing capacity utilized? *(Source: TB lab register; monthly CBNAAT indicator report)*	Numerator: Number of total tests performed; Denominator: Expected number of tests to be done	_____%
2	Percent samples with MTB detected *(Source: TB lab register; CBNAAT indicator report)*	Numerator: Number of samples with MTB detected result in CBNAAT; Denominator: Total number of samples tested	_____%
3	Percent samples with Rif resistance detected *(Source: TB lab register; CBNAAT indicator report)*	Numerator: Number of samples with Rif resistance detected in CBNAAT; Denominator: Total number of samples with MTB detected	_____%
4	Percent specimen with unsuccessful results (errors, invalids, no result) *(Source: TB lab register; CBNAAT indicator report)*	Numerator: Number of specimens with unsuccessful result; Denominator: Total number of specimens tested	_____%
5	Percent specimens with rifampicin indeterminate *(Source: TB lab register; CBNAAT indicator report)*	Numerator: Number of specimens with rifampicin indeterminate Denominator: Total number of specimens with MTB detected tested	_____%
6	Percent MTB positive patients whose specimen transported to C&DST lab for LPA/LC DST	Numerator: Number of patients with MTB detected whose specimens sent to C&DST laboratory; Denominator: Total number of patients with MTB detected result in CBNAAT.	_____%
7	Lab TAT *Source: TB lab register*	The average time (in days) elapsed between date samples were received in the lab and date Truenat test result reported	____days

5.1.3. Sharing of feedback/reports:

After completing the OSE, STLS should discuss the findings and corrective actions with LT and MO-IC and obtain their signature on the filled checklist. STLS should document the summary of 'action required' in the Supervision Register before leaving the visited laboratory. After OSE visit STLS should act on programmatic issues (with support of DTO) that he/she agreed to work on.

STLS should submit the summary report of visited TDCs to DTO on a monthly basis so that reports from all laboratories can be compiled, analyzed and discussed (for pending corrective action) during monthly review meeting at DTC. STLS should maintain separate files for checklists including summary reports of each TDC under his/her jurisdiction. These records should be available for review by DTO/IRL/NRL during an OSE visit. Every quarter, DTO should submit the key recommendation and action taken report for each TDCs to CMO/DM and IRL.

5.2. On-site evaluation by DTO:

In addition to the monthly OSE visit by STLS, the DTO who is administratively and technically in charge of the STLS, also conducts OSE to assess overall NTEP services, (Diagnostic centers once a quarter and TU and NAAT labs once in a month). Regular visits by the DTO allow for a review of the STLS's written recommendations as well as the formulation of a corrective action plan for the issue at hand.

When planning the OSE visit, DTO should review the key performance indicators, Annexure M, CBNAAT/Truenat indicator reports, as well as monthly OSE reports submitted by the STLS for the TU/TDC to be visited. A standard checklist for DTO is already available covering all aspect of NTEP services at PHI/TU. However, for assessing the laboratory services, DTO may refer the following updated checklist.

DTO Checklist: On-site evaluation of Microscopy/Truenat/CBNAAT facility **(Refer OSE checklist for DTO (Annexure 5.4))**

General information

Name of facility:_____; Type of facility: __Microscopy/Truenat/CBNAAT____;

TB Unit:_____; District:_____;

Name of MO-IC_____; Name of LT:_____;

Date of visit:_____; Name of visiting officer_____

S.No.	Particulars to be evaluated	Response	Remarks
1	% of adult OPD referred for laboratory testing (sputum microscopy and/or upfront NAAT) in the last quarter *(Referral of about 3-5% adult OPD)*	_____%	
	Guidance notes: *Review the records for assessing the proportion of adult OPD are being referred for sputum microscopy or upfront NAAT. Considering TB elimination goal, MO should aim to refer about 5% of adult OPD for TB testing.*		
2	Are IEC/ Advocacy Communication and Social Mobilization (ACSM) activities and case finding efforts undertaken by the MO?	Yes No	
	Guidance notes: *Observe for visible IEC wall paper/ Banners etc. in the PHI and its vicinity. Enquire about the ACSM activities (like School health programs, Village health sanitation & nutrition meetings, community orientation meetings, etc.,) undertaken. Assess the case-finding efforts undertaken, such as organizing health camps, sensitization of HWCs and private health facilities, as well as active/intensified case-finding activities.*		
3	Are the Medical Officers at visiting health facility trained in NTEP (TB diagnosis and management).	Yes No	
	Guidance notes: *During interaction with MO, assess their knowledge on available diagnostic tools, TB diagnosis algorithm, essential public health actions (such as co-morbidity testing, UDST, contact tracing, chemoprophylaxis, and Ni-kshay Poshan Yojana) and newer updates in treatment regimens.*		
4	Is the LT trained in the TB testing services offered at the facility, and has their competency been assessed? *(Date of last training/refresher training)*	Yes No	

	Guidance notes: *Assess LT's knowledge on the test procedure being performed or review the monthly OSE report of STLS. LT must receive the Smear microscopy/Truenat/CBNAAT training on-site by STLS or at district/IRL. STLS should ensure that LT is competent in performing the test, referral of sample as per NTEP diagnostic algorithm, laboratory biosafety, use and maintenance of equipment, recording and reporting activities. LT should undergo periodic retraining (every two years).*		
5	Are the sputum samples tested as soon as the patient is referred for TB testing? *(LT availability and laboratory timing)*	Yes No	
	Guidance notes: *Observe the presence of trained LT during working hours on all working days. Assess the backup arrangement in the cases that LT is absent.*		
6	Is the laboratory clean and well-organized, and does it have the necessary infrastructure for testing? - General: *Continuous water and electrical supply; adequate ventilation; sturdy workbench; chairs; storage space/almirah; handwashing sink; biohazard bins* - CBNAAT: *Air-conditioned room; UPS with >2hr power back-up* - CBNAAT & Truenat: Separate workbench/area for sputum processing	Yes No	
	Guidance notes: *Inspect the laboratory facility, paying special attention to the points listed above.*		
7	Are equipment functional, preventive maintenance/calibration being done periodically ? *(Microscope /Truenat/CBNAAT; down-time log)*	Yes No	
	Guidance notes: *Review the TB laboratory register, equipment records (including equipment breakdown records) and observe the maintenance condition of the equipment physically.*		
8	Are the stocks of laboratory materials adequate and stored appropriately? *(Slides and reagents for microscopy; NAAT chips/cartridges; sample container and packaging material; forms and register; PPE; disinfectant solution etc.)*	Yes No	
	Guidance notes: *Inspect the laboratory stock, storage space and environment condition. Laboratory having CBNAAT facility should have refrigerator/(s) for the storage of kits, storage condition for Truenat chips 2°C–30°C and for sample pretreatment pack and prep kit is 2°C–40°C. If geographies with higher temperature, chips and reagents should be stored in refrigerator. Review the stock-register to assess whether or not FEFO (first expiry first out) principle followed.* *Reagent should be properly labeled and light sensitive reagent (auramine) should be away from direct sun-light.*		
9	Is the BMW disposal mechanism in place? *(BMW management agency; burial pits)*	Yes No	
	Guidance notes: *Ideally, laboratory waste should be collected (after disinfection) by an authorized BMW management agency. If facilities for waste collection are not available, all soiled/ contaminated gloves/sputum cups/soiled paper are wrapped in autoclavable red/ yellow /blue bags and buried in the pit in an isolated area, identified for the purpose.*		
10	*Is a robust sample transportation mechanism in place?* *(Timely pickup and delivery of sample)*	Yes No	
	Guidance notes: *Assess how frequently packed samples are picked up and the time taken to delivered the sample to the NAAT laboratory or to the linked C&DST laboratory.* *Accumulation of samples for multiple days and transporting them in batches should not be practiced. LT should document and monitor the date sample collected, date of sample received, date sample tested, and date sample dispatched.*		

	• *Microscopy facility: Two fresh sputum samples from smear-positive patients must be sent to the NAAT site on the same day that the LT received them from the patient* • *At Truenat/CBNAAT facility: Of the two samples received from the patients or linked microscopy facility, one sample is tested at the NAAT facility and another is shipped to the Culture DST laboratory (for LPA / C&DST), preferably on the same day that MTB is detected in NAAT.*		
11	Is the testing capacity of the visited laboratory optimally utilized?	Yes No	
	Guidance notes: *Assess the daily testing load and compare with existing testing capacity. Expected testing capacity per day for Light microscope, LED fluorescent microscope, Truenat (duo) and CBNAAT (4 module) are 25, 50, 8 and 16, respectively.* When determining the precise testing capacity of a laboratory, the workload and skill of staff, adequate supplies, maintained equipment, and necessary facility infrastructure should always be taken into account.		
12	Is the patient turn-around time within the expected time frame? (*Date from identification of presumptive TB to date treatment initiated or changed; combining Pre-lab, lab and post-lab turn-around time)*	Yes No	
	Guidance notes: *Patient turn-around time for smear microscopy, NAAT, LPA, LC DST, LC (follow-up) are 2-3 days, 4-7 days, 5-9 days, and 29-58 days, respectively. If laboratory could not achieve the standard TAT, investigate the reasons of delay (by analyzing the pre-lab, lab and post-lab TAT separately.)*		
13	Is the STLS reviewing slides preserved by the LT during the OSE?	Yes No	
	Guidance notes: *Check the slides stored and review the register/report indicating slides are rechecked or collected for RBRC by the STLS.*		
14	Are the reports of OSE done by STLS available in the laboratory and have any pending action to be taken? (last month STLS-OSE report)	Yes No	
	Guidance notes: *Review the last month report of OSE by STLS; Discuss pending action taken, if any, with the Medical Officer and concerned staff.*		
15	Quantitative indicators (last quarter) • Average patient turn-around time • Percent smear negative presumptive TB patients who were offered chest x-ray? • Percent presumptive TB patients offered HIV testing. • Percent notified TB patients offered HIV testing. • Percent notified TB patients offered diabetes testing. • Percent notified patients (with MTB positive in NAAT) whose specimens were sent to the culture-DST laboratory for LPA/LC DST	_____days _____% _____% _____% _____% _____%	
	Guidance notes: *Review the above indicators and validate them by selecting a few patients randomly.*		

Annexure 5.1: STLS-OSE checklist for Microscopy facility

(to be used by STLS during the assessment)

General information
Name of Microscopy facility:_____; TB Unit:_____; District:_____; Name and qualification of LT/(s):_____; Date of visit:_____; Name of visiting STLS_____

Current visit particulars

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
Laboratory access and patient counselling			
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
2	Are patients counselled appropriately for sputum collection? *(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)*	Yes No	
Infrastructure and facility			
3	Is separate area, adequate space and ventilation available for TB laboratory work? *(Separate workspace, directional airflow, adequate space for working and storage)*	Yes No	
4	Is power supply and running water available? *(Reliable electricity and sink)*	Yes No	
5	Is the furniture fit for purpose and are there separate workbenches for specimen receipt, smear preparation, and microscopy? *(Sturdy and cluttered free workbenches; ergonomic chairs; furniture without cloth covering; adequate storage cabinet)*	Yes No	
6	Is the laboratory's wall and floor clean and smooth, and is proper housekeeping in place? *(Slip-resistant floor, walls without damp, laboratory well organized and tidy)*	Yes No	
Human resource and training			
7	Is the LT available full time on all working days?	Yes No	
8	Is the LT trained in sputum microscopy and has his/her competency been evaluated assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
Equipment, reagents and consumables			
9	Is the microscope functional and well maintained (BM/FM)?	Yes No	

	(Physical condition, annual maintenance contract or in-house maintenance record)		
10	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
11	Are the adequate supplies of reagents, slides and other consumables available for the next one-month? *(Slide, lens paper, filter paper, spirit lamp, Immersion oil, disinfectant-phenol, staining racks, loops/sticks and slide boxes)*	Yes No	
12	Are the staining reagents properly labelled (with expiry date) and stored appropriately? *(1% carbol fuschin, 0.1% methylene blue, 25% sulphuric acid or 0.1% auramine, 0.5% Acid alcohol and 0.5%Potassium permanganate)*	Yes No	
Safe practices, standard operating procedures and quality control			
13	Is the LT following standard laboratory practices and safe technique to minimize aerosol generation? *(Use of appropriate PPE, avoiding eating/drinking inside the laboratory, protecting documents and personnel belonging from contamination, proper handwashing, use of disposable loop, disinfection of workbench before and after the work and if spill incidence occurred, opening of sample container in proximity to flame, slow move when making smear, air-drying of slides before heat/flame fixing, etc.)*	Yes No	
14	Is the standard operating procedure accessible to LT or displayed at strategic locations? *(Preparation of smear, staining, grading chart as well as safety precautions/instructions)*	Yes No	
15	Is the quality of the smear prepared by LT appropriate? *(Smear thickness, evenness, size and staining; slide labelling)*	Yes No	
16	Is the LT examining quality control slides (supplied by STLS) with each fresh batch of reagents? *(Availability of QC slides)*	Yes No	
17	Is the LT proficient in examine and grading the smear slides in accordance to standard grading chart? *(Rechecking randomly selected positive and negative slides)*	Yes No	
18	Is the LT preserving slides properly for external quality assurance protocol (RBRC and rechecking)? *(Conduct rechecking of slides and collect required number of slides for RBRC)*	Yes No	
Specimen packaging and transportation			
19	Is the available sample collection and transportation mechanism (for NAAT testing) efficient? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely)*	Yes No	
20	Is the LT efficient to properly label the sample, correctly and completely fill the test request form	Yes No	

	and securely pack the sample container for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*		
Recording and reporting			
21	Is the TB laboratory register filled correctly, completely and legibly? *(TB laboratory register)*	Yes No	
22	Does the Lab register have the summary/abstract at the end of each month? *(TB laboratory register)*	Yes No	
23	Is the lab register consistent with the TB notification register and treatment cards? *(Timely notification, co-morbidity testing and treatment initiation)*	Yes No	
24	Are treatment follow-up samples collected and tested from all pulmonary TB patients at each recommended months during and after TB treatment? *(TB notification register and Treatment card)*	Yes No	
25	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
Biomedical waste management			
26	Does the LT disinfect the infectious waste (such as broom stick, sputum cup with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
27	Is the biomedical waste segregated before final disposal as per BMW rule, Govt. of India? *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	

Quantitative indicators (last month)

Following indicators of last month should be analyzed by STLS and discussed with LT and MOTC/MO-IC of the health facility.

Period_____

I. Number tested slides: Diagnosis_____; Follow up_____
II. Percent presumptive TB testing rate (out of total adult OPD) _____%
III. Percent smear positivity rate among presumptive TB patients_____%
IV. Lab turnaround time_____days
V. Percent smear positivity TB patients offered UDST/NAAT (or sample transported to NAAT site) _____%
VI. Percent presumptive TB patient under key population offered upfront NAAT (or sample transported to NAAT site)_____%
VII. Percent presumptive DR-TB patients offered NAAT (or sample transported to NAAT site)_____%
VIII. Percent presumptive TB patients tested for HIV _____%
IX. Percent notified patients tested for HIV _____%
X. Percent notified patients tested for diabetes _____%
XI. Percent notified TB patients initiated on treatment_____%

Annexure 5.2: STLS-OSE checklist for Truenat facility

General information

Name of Truenat facility:_____; Facility Type: _____(Public / Private)

TB Unit:_____; District:_____;

Name and qualification of LT/(s):_____;

Date of visit:_____; Name of visiting STLS_____

Equipment Details

	Machine 1	Machine 2
Type of Module	Uno/Duo/Quatro	Uno/Duo/Quatro
Number of machines		
Date of installation		
Due date for next calibration		
Functional Status		

Action required as per the previous visit

Current visit particulars

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
	Laboratory access and patient counselling		
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
2	Are patients counselled appropriately for sputum collection? *(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)*	Yes No	
	Infrastructure and facility		
3	Is the laboratory physically secure and does it have enough space for receiving and processing specimens?	Yes No	

	(Lockable doors and secure windows; separate area for sample receiving and processing)		
4	Is specimen processing area well ventilated?	Yes No	
5	Is there separate and sufficient workbench space for the Truelab instruments, ancillary equipment and specimen processing? (Sturdy, clutter-free and spacious workbench; placement of machine away from direct sunlight and other radiating and heating equipment,)	Yes No	
6	Is the laboratory well-lit (enough light), has multiple power outlets, and an adequate power supply to conduct Truenat testing and battery charging?	Yes No	
7	Is the laboratory environmental condition optimal?	Yes No	
8	Is the laboratory's wall and floor clean and smooth, and is proper housekeeping in place? *(Slip-resistant floor, walls without damp, laboratory well organized and tidy)*	Yes No	
Human resource and training			
9	Is dedicated LT available full time on all working days?	Yes No	
10	Is the LT trained in Truenat testing and has his/her competency been evaluated before assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes No	
Equipment, reagents and consumables			
11	Are routine maintenance (daily, weekly, and monthly) procedures and calibration of Truenat machine performed and recorded? Is the record of equipment breakdown maintained? *(Review maintenance log as well as machine down-time log)*	Yes No	
12	Are pipettes being replaced/calibrated after every six months?	Yes No	
13	Are kits and consumables for Truenat (MTB and Rif testing) available for next one month? Are they stored appropriately and used as per FEFO principle? *(Verification of physical stock, stock register and storge condition)*	Yes No	
14	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes No	
15	*Is adequate stock of disinfectant available and used appropriately by LT?* *(Hypochlorite)*	Yes No	

Standard operating procedures and quality control			
16	Is suitable personal protective equipment (PPE) provided at the testing site and is LT trained in its correct use?		
17	Is the standard operating procedure accessible and followed by the LT?	Yes No	
18	Is the LT document, monitor and troubleshoot the different alerts/error flagged by the machine? *(Test register)*	Yes No	
19	Is repeat testing done in the event of error, invalid or indeterminate test result? *(Check the test register and monthly indicators)*	Yes No	
20	Are all samples tested and reported within 24 hours after they arrive at the laboratory? *(Average turn-around time)*	Yes No	
21	Is the lab running quality controls after every 50 tests and replacing the glass slide after every 200 tests?	Yes No	
Biomedical waste management			
22	Does the LT disinfect the infectious waste (such as sputum container with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes No	
23	Are the biomedical waste segregated before final disposal as per BMW rule, Govt. of India *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes No	
Specimen packaging and transportation			
24	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes No	
25	Is the available sample collection and transportation mechanism efficient to meet the timely reflex testing (NAAT, LPA and Culture DST) as per current diagnosis algorithm? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely; Truenat indicator)*	Yes No	
Recording and reporting			
26	Is PMDT TB C&DST registers available and maintained?	Yes No	
27	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes No	
28	Are monthly Truenat indicators report correctly prepared and shared with DTC and IRL on time?	Yes No	

Quantitative Indicators (last month)
Following indicators of last month should be analyzed by STLS and discussed with LT and MOTC/MO-IC of the health facility. Period_____ I. Number of total tests done: _____MTB positive ____%; Rif resistance____ % II. Percent presumptive TB patients offered upfront NAAT_____% III. Percent specimen for which DNA extraction was unsuccessful (Trueprep)_____% IV. Percent specimen with unsuccessful results (errors, invalids, no result) for MTB detection - Truenat TB _____% V. Percent specimen with unsuccessful results (errors, invalids, no result) for MTB-RIF Dx - _____% VI. Percent specimens with rifampicin indeterminate_____% VII. Percent MTB positive patients whose specimen transported to C&DST lab for LPA/LC DST _____% VIII. Lab turnaround time_____days

	Recommended Corrective Action	Timeline
I		
II		
III		
IV		
V		

Signature of STLS **Signature of MO-IC**

Remarks by DTO:

Signature of DTO

Annexure 5.3: STLS-OSE checklist for CBNAAT

General information

Name of CBNAAT site:_____; Facility Type: _____(Public / Private)

TB Unit:_____; District:_____;

Name and qualification of LT/(s):_____;

Date of visit:_____; Name of visiting STLS_____

Equipment Details

	Machine 1	Machine 2
Type of Module		
Number of machines		
Date of installation		
Due date for next calibration		
Functional Status		

Action required as per the previous visit

Current visit particulars

S.No.	Particulars to be assessed	Response (Adequate/ acceptable)	Remarks
	Laboratory access and patient counselling		
1	Is the laboratory easily identifiable and accessible to the patients? *(IEC material; laboratory timing; LT availability)*	Yes No	
2	Are patients counselled appropriately for sputum collection? *(Cough etiquettes; number of sputum samples; when and where to collect sputum; quality of sputum; correct use of container; timely and safely submission)*	Yes No	
	Infrastructure and facility		
3	Is the laboratory physically secure and does it have separate space for sample receiving, sample processing and machine operation?	Yes No	

4	Is specimen processing area well ventilated?	Yes	No	
5	Is the laboratory environment, bench space, and power supply appropriate for the placement and operation of the CBNAAT machine? *(Functional Air conditioner, placement of machine away from direct air-conditioning vent, window or sunlight, stable surface, clearance surrounding the machine, grounded power supply, UPS with power backup >2hrs.)*	Yes	No	
6	Is the laboratory environment monitored and the workbench cleaned on a regular basis?	Yes	No	
Human resource and training				
7	Is dedicated LT available full time on all working days?	Yes	No	
8	Is the LT trained to provide CBNAAT services, and has his/her competency been assessed prior to assigning patient diagnosis services? *(Any change in LT since last supervisory visit; participation in refresher training in past 2 years)*	Yes	No	
Equipment, reagents and consumables				
9	Is the CBNAAT machine equipped with a dedicated desktop or laptop with updated antivirus software and internet access?	Yes	No	
10	Are routine maintenance (daily, weekly, and monthly) activities for the CBNAAT machine performed and recorded? *(Cleaning of fan filters, instrument surface, plunger; periodic data backup; maintenance log)*	Yes	No	
11	Is the machine calibrated and is the down-time of machine/individual module monitored? *(Review calibration due date; equipment down-time log)*	Yes	No	
12	Are cartridges and consumables for CBNAAT available for next one month? Are they stored appropriately and used as per FEFO principle? *(Verification of physical stock, stock register and refrigerator)*	Yes	No	
13	Does the laboratory have sufficient sputum container/falcon tubes, test requisition form and packaging material for sample transport? *(Falcon tubes, thermocol box, ice gel pack and facility to chill, adhesive tape, biohazard signage, parafilm, absorbent paper/cotton, rubber bands, zip polybags, scissor, permanent marker)*	Yes	No	
14	*Is adequate stock of disinfectant available and used appropriately by LT?* *(Freshly prepared 1% hypochlorite solution)*	Yes	No	
Standard operating procedures and quality control				
15	Is suitable personal protective equipment (PPE) provided at the testing site and is LT trained in its correct use?	Yes	No	
16	Is the standard operating procedure accessible and followed by the LT?	Yes	No	

17	Is the LT document, monitor and troubleshoot the different alerts/error flagged by the machine? *(Test register/ machine software/ CBNAAT indicator)*	Yes	No	
18	Is repeat testing done in the event of error, invalid or indeterminate test result? *(Check the test register and monthly indicators)*	Yes	No	
19	Are all samples tested and reported within 24 hours after they arrive at the laboratory? *(Average turn-around time)*	Yes	No	
20	Has the laboratory participated in the EQA programme and achieved the desired concordance?	Yes	No	
Biomedical waste management				
21	Does the LT disinfect the infectious waste (such as sputum container with lids removed) by putting them into foot operated bucket containing 5% phenol?	Yes	No	
22	Are the biomedical waste segregated before final disposal as per BMW rule, Govt. of India *(Color coded bins and bags; timely and securely removal from laboratory preferably by an authorized agency)*	Yes	No	
Specimen packaging and transportation				
23	Is the LT efficient to properly label the sample, correctly and completely fill the test request form and securely pack the sample for transportation? *(Specimen container- labelled with at least two identifiers; filled test request form- Ni-kshay ID, patient demographic information, key population, reason of testing, selection of test, available test result; Packaging- standard triple layer packaging)*	Yes	No	
24	Is the available sample collection and transportation mechanism efficient to meet the timely reflex testing (NAAT, LPA and Culture DST) as per current diagnosis algorithm? *(Frequency of visit to pick up the specimen; time taken to deliver the specimen safely; Truenat indicator)*	Yes	No	
Recording and reporting				
25	Is PMDT TB C&DST registers available and maintained?	Yes	No	
26	Is the data/information in Ni-kshay updated? *(Log on to Ni-kshay and verify)*	Yes	No	
27	Are monthly CBNAAT indicators report correctly prepared and shared with DTC and IRL on time?	Yes	No	

Quantitative indicators

Following indicators of last month should be analyzed by STLS and discussed with LT and MOTC/MO-IC of the health facility.

Period_____

I. Number of total tests done: _____MTB positive ____%; Rif resistance____ %
II. Percent specimen with unsuccessful results (errors, invalids, no result) _____%
III. Percent specimens with rifampicin indeterminate_____%

IV. Percent MTB positive patients whose specimen transported to C&DST lab for LPA/LC DST _____%

V. Lab turnaround time_____days

Key recommendations

S.No.	Recommended corrective actions	Timeline
I		
II		
III		
IV		
V		

Signature of STLS **Signature of MO-IC**

Remarks by DTO:

Signature of DTO

Annexure 5.4: DTO-OSE checklist for Microscopy/Truenat/ CBNAAT facility

General information
Name of facility:_____; Type of facility: ____Microscopy/Truenat/CBNAAT_____; TB Unit:_____; District:_____; Name of MO-IC_____; Name of LT:_____; Date of visit:_____; Name of visiting officer_____

S.No.	Particulars to be evaluated	Response	Remarks
1	% of adult OPD referred for laboratory testing (sputum microscopy and/or upfront NAAT) in the last quarter *(Referral of about 3-5% adult OPD)*	_____%	
2	Are IEC/ACSM activities undertaken by the MO and the case-finding effort adequate?	Yes No	
3	Are the Medical Officers at visiting health facility trained in NTEP (TB diagnosis and management).	Yes No	
4	Is the LT trained in the TB testing services offered at the facility, and has their competency been assessed? *(Date of last training/refresher training)*	Yes No	
5	Are the sputum samples tested as soon as the patient is referred for TB testing? *(LT availability and laboratory timing)*	Yes No	
6	Is the laboratory clean and well-organized, and does it have the necessary infrastructure for testing? - General: *Continuous water and electrical supply; adequate ventilation; sturdy workbench; chairs; storage space/almirah; handwashing sink; biohazard bins* - CBNAAT: *Air-conditioned room; UPS with >2hr power back-up* - CBNAAT & Truenat: Separate workbench/area for sputum processing	Yes No	
7	Are equipment functional, preventive maintenance/calibration being done periodically ? *(Microscope /Truenat/CBNAAT; down-time log)*	Yes No	
8	Are the stocks of laboratory materials adequate and stored appropriately? *(Slides and reagents for microscopy; NAAT chips/cartridges; sample container and packaging material; forms and register; PPE; disinfectant solution etc.)*	Yes No	

9	Is the biomedical waste disposal mechanism in place? *(BMW management agency; burial pits)*	Yes No	
10	*Is a robust sample transportation mechanism in place?* *(Timely pickup and delivery of sample)*	Yes No	
11	Is the testing capacity of the visited laboratory optimally utilized?	Yes No	
12	Is the patient turn-around time within the expected time frame? (*Date from identification of presumptive TB to date treatment initiated or changed; combining Pre-lab, lab and post-lab turn-around time*)	Yes No	
13	Is the STLS reviewing slides preserved by the LT during the on-site evaluation?	Yes No	
14	Are the reports of OSE done by STLS available in the laboratory and have any pending action to be taken? *(Last month STLS-OSE report)*	Yes No	
15	Quantitative indicators (last quarter) • Average patient turn-around time. • Percent smear negative presumptive TB patients who were offered chest x-ray? • Percent presumptive TB patients offered HIV testing. • Percent notified TB patients offered HIV testing. • Percent notified TB patients offered diabetes testing. • Percent notified patients (with MTB positive in NAAT) whose samples were sent to the culture-DST laboratory for LPA/C&DST?	_____days _____% _____% _____% _____% _____%	

Key recommendations

	Recommended corrective actions	Timeline
I		
II		
III		
IV		
V		

Signature of DTO **Signature of MO-IC**

Chapter 6

Monitoring Indicators

Chapter 6: Monitoring Indicators

NTEP has a robust recording and reporting system in place along with multiple internal/external checks to ensure good quality data generation which forms the basis for existing NTEP supervision and monitoring strategy. In NTEP, almost all patient services are digitally recorded on the Ni-kshay web portal/ mobile application, and Ni-kshay dashboard enables programme managers to monitor the programme at sub-district, district and state levels. Ni-kshay provides real-time monitoring of the programme performance as well as access to variety of downloadable line-lists (both aggregate and patient-wise) similar to previously maintained physical registers. Authorized users can download these line-lists by logging in to https://reports.nikshay.in/. Users can strategically select a cohort for data analysis desired i) Geography (State, district or TU); ii) Duration (year/month/days; quarterly/monthly); iii) Patient type (Public or Private); and other options based on the types of report.

NTEP has selected a range of indicators (input, process, output and outcome/impact) from various thematic areas of program. Some of them are key performance indicators (KPIs) that are utilized to measure the performance of programme as well as calculate the TB index (a composite score based on performance in KPIs) of each district and state. Using a KPI-based scoring system fosters a positive competition among districts/states towards TB elimination, while also enabling the programme managers to pinpoint areas that require guidance or corrective action to overcome challenges.
The following section discusses the KPIs as well as other monitoring indicators relevant to laboratory services (including case finding and TB diagnosis).

6.1. NTEP Key Performance Indicators

<table>
<tr><th>S.No.</th><th>Thematic area and Score</th><th>Key performance indicator</th><th colspan="2">Calculation</th></tr>
<tr><td rowspan="4">1</td><td rowspan="3">TB Notification</td><td rowspan="3">Proportion of TB cases notified against the target estimated

Data Source: Ni-kshay</td><td>Numerator</td><td>Number of TB patients notified/ diagnosed</td></tr>
<tr><td>Denominator</td><td>Target number of TB patients estimated to be notified</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
<tr><td colspan="4">Description:
India is believed to have more than a million ‘missing’ cases every year that are not notified, and a significant proportion of these cases remain undiagnosed or receive inadequate diagnosis and treatment care in the private sector. To address this challenge, Govt. of India issued a Govt. order on 7th May 2012, which made it compulsory for all healthcare providers (Public and Private; including testing laboratories, pharmacists, chemists and druggists) to notify every diagnosed or under-treatment TB cases to the local authorities. Amendment in this Govt. order was made on 21st July 2015 for including a set of public health actions. Mandatory TB notification has been strengthened through Gazette notification (Gazette of India on 19th March 2018) with provision of penal action under the law if failure to notify the TB patient. To motivate private health providers and community volunteers to notify or refer the patient, NTEP has initiated following two incentive schemes
i) Private Provider Incentives – Rs. 500 for notification and Rs. 500 for reporting of treatment outcome have been initiated for private practitioners</td></tr>
</table>

<table>
<tr><td></td><td colspan="4">ii) Informant Incentives – To encourage referrals from private sector and community volunteers, Rs. 500 are being provided for each referral of patient who is diagnosed as TB in public sector

Every year, the CTD projects a TB notification target both for public and private sector for each state and district. TB notification target is estimated using various data sources such as TB prevalence survey data, TB notification data, standard factors to address under-reporting and the insights of experts.
Some of key strategies to improve the indicator are as follows
• Mapping, sensitization and effective engagement of all healthcare providers both from public and private sector for TB notification. These include
• Public sector:
- Primary health care- HWC-PHCs and HWC-SCs
- Secondary and Tertiary health care – CHC's, Rural hospitals, district hospitals, specialty hospitals and teaching hospitals
- Health insurance schemes providing healthcare – Employee State Insurance (ESI), Central Government Health Scheme (CGHS)
- Other agencies: Defence services, Railways, Public sector units.
• Private Sector:
- Private hospitals, nursing homes, polyclinics etc.
- General practitioner
- Testing laboratory and Chemist
• In view of TB elimination goal, about 3-5% of new adult OPD should be referred for TB examination.
• Engagement of providers from indigenous system of medicines (Ayurveda, Unani, Homeopathy etc.) as well as informal providers as informant.
• Timely payment of incentive to private providers (for TB notification and successful treatment outcome) or informant.
• Scale-up and maximum utilization of rapid NAAT services to the patients, both in the public and private sectors.
• Strengthening of specimen transport mechanisms. Improving access to services of specimen collection from extra-pulmonary sites.
• Need based implementation of PPSA to facilitate TB notification and public health action for patients under private sector.
• Conduct systematic screening of high-risk / vulnerable groups through outreach and community-based approaches (Active case finding).
• Intensify contact tracing/investigation using community-based and other approaches to cover households, proximal contacts and workplace settings and follow up.
• Conducting the active case finding campaign periodically and strategically.</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">HIV testing</td><td rowspan="2">Proportion of notified TB patients with known HIV status (Positive/ Negative/Un-known)

Data Source: Ni-kshay</td><td>Numerator</td><td>Number of notified TB patients with known HIV status</td></tr>
<tr><td>Denominator</td><td>Total notified TB patients</td></tr>
<tr><td></td><td colspan="3">Multiplier</td><td>100</td></tr>
<tr><td></td><td colspan="4">Description:
TB is one of the most common causes of morbidity and leading cause of mortality in PLHIV. HIV is also a risk factor for TB which not only increases the risk of reactivating latent TB infection but also increases the risk of rapid TB progression soon after the TB infection or reinfection. TB in PLHIV is very difficult to diagnose (paucibacillary) and treat owing to</td></tr>
</table>

<table>
<tr><td></td><td colspan="4">challenges related to co-morbidity, pill burden, co-toxicity and drug interactions. India accounts for the highest burden of TB-HIV co-infected cases.
To mitigate the effect of the dual burden of HIV and TB co-infection, the National AIDS Control programme (NACP) and NTEP have been working together in accordance with the National Framework for HIV TB collaborative activities since 2001. Collaborative mechanisms have been put in place at the National, State and District levels; and to further strengthen the TB-HIV collaborative activities DTOs have also been nominated as District AIDS control officers.
Following key activities are performed under TB-HIV collaborative framework
The following components are part of the single window services approach:
• Four-symptom (4S) screening for TB in PLHIV and fast-tracking of all PLHIV with presumptive TB
• Provision of rapid NAAT for all PLHIV to ensure early TB diagnosis and identification of drug resistance
• Provision of anti-TB treatment (ATT) for all HIV-TB co-infected patients at ART centres
• Provision of TB preventive treatment (TPT) for PLHIV to prevent TB as primary and secondary prophylaxis
• Airborne Infection Control (AIC) measures to reduce TB transmission at HIV care setting
To improve the indicator (TB patient with known HIV status), programme manager should consider following steps
• Improve availability of HIV test kits to enhance HIV test uptake (at all TDCs and ICTCs).
• Ensure that laboratory technicians are available at TDCs and are well aware and trained in HIV testing for all notified TB patients.
• Sensitization of private providers about HIV testing of TB patients (one of public health action mandated for all notified TB patient- Gazette of India on 19th March 2018).</td></tr>
<tr><td rowspan="2">3</td><td rowspan="3">Universal DST</td><td rowspan="3">Proportion of notified TB patients with UDST tested

Data Source: Ni-kshay</td><td>Numerator</td><td>Number of notified TB patients with UDST tested.</td></tr>
<tr><td>Denominator</td><td>Total TB patient notified*</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
<tr><td colspan="4">Description:
India has highest DR-TB which accounts for about one fourth of global DR-TB burden. Treatment for DR-TB, especially Multidrug-resistant TB (MDR) and Extensively Drug-Resistant TB (XDR-TB) are long and difficult with lower success rate. The first National DR-TB survey (2016) reported that 28% of TB patients are resistant to anyone drugs (22% among new and 36.8 % among previously treated) and 6.2 % have multi-drug resistant-TB (2.84% among new and 11.62% among previously treated).
Timely detection and treatment initiation is key to address the menace of DR-TB and its transmission. In 2017, NTEP introduced UDST in phase manner under which all notified TB patients are offered DST for at least rifampicin drug using rapid NAAT. Currently, NTEP is also providing upfront TB testing to presumptive TB case under key vulnerable population and moving gradually towards NAAT as initial test for TB. To support this activity, NTEP has expanded and continues to expand the network of rapid NAAT labs throughout the country. In addition to offering UDST, NTEP has also taken a decision to offer FL and SL LPA (as per diagnosis algorithm) for additional drug resistance detection (H, E, Z, FQ and SLI) for all notified TB patients.</td></tr>
</table>

<table>
<tr><td></td><td colspan="4">Recently, the programmatic definition of UDST is updated as “Universal access to rapid DST for at least rifampicin, and further DST for at least fluoroquinolones among all TB patients with rifampicin resistance (preferably before initiation of treatment to maximum within 15 days of diagnosis). Rapid method for detecting fluroquinolones resistance includes SL LPA and Xpert MTB/XDR.

Some of key steps required for improving UDST indicator include
• Establishing a robust sample transportation system that collects specimens both from public and private health facilities and transports it to mapped NAAT and LPA laboratories. The state may consider any of the sample transport mechanisms like hub and spoke, PPP, postal services, courier, human carrier etc.
• Enhancing the testing capacity (NAAT as well as LPA) to meet the anticipated testing demand. This can be achieved by ensuring there is an adequate number of trained staff, equipment as well as enough kits and consumables required for conducting NAAT and LPA (both direct and indirect LPA).
• Ensuring that two specimens are transported to NAAT sites (one for NAAT testing and another for LPA testing at TB C&DST laboratories) and all potential health facilities (both from public and private sector) have specimen container and packaging materials.
• The state may do flexible mapping of catchment area of the NAAT laboratory and manage LT and logistics accordingly.
• Critical monitoring for timely specimen collection, transportation, testing and reporting of test result.
Please review for any latest change in the denominator</td></tr>
<tr><td rowspan="4">4</td><td rowspan="4">Treatment Success</td><td rowspan="4">Proportion of TB patient with successful treatment outcome (treatment completed + cured)

Data Source: Ni-kshay</td><td>Numerator</td><td>Number of TB patients with successful treatment outcome</td></tr>
<tr><td>Denominator</td><td>Total TB patient notified</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
<tr><td colspan="4">Description:
Treatment success affected by several factors such as the severity of disease (often associated with delay in start of appropriate treatment), HIV infection, drug resistance, malnutrition and the adherence support provided to the patient to complete their treatment. Even where treatment is of high quality, delayed recording/reporting of information into Ni-kshay leads to poor performance score in treatment success rate. As per PMDT 2021, treatment outcome of a TB patient can be declared as treatment failed, cured, treatment completed, died, loss to follow-up and not evaluated. Patients who either completed their treatment or declared as cured are considered successful treatment.
If any district/state has lower treatment success rates, the cause of the problem can only be identified by determining which of the unfavorable treatment outcomes is most common. NTEP is aiming to ensure treatment success rate >90% for drug sensitive TB patient.
Key steps towards improving treatment success are
• Timely conducting the follow-up test (smear/culture) so that non-responder can be detected earlier, or treatment outcome can be assigned timely.
• Frequent follow-up for treatment adherence by concerned health staff (STS/TB-HV/Treatment supporter).
• Ensuring timely DBT to patients (Ni-kshay Poshan Yojna)
• Timely detection and management of Adverse drug reaction (ADR)
• Timely updating the treatment outcome in Ni-kshay</td></tr>
</table>

<table>
<tr><td></td><td colspan="4">• Periodic Continuing Medical Education (CME) for private doctors on newer updates on TB treatment and management.</td></tr>
<tr><td rowspan="4">5</td><td rowspan="3">Ni-kshay Poshan Yojana Implementation</td><td rowspan="3">Proportion of eligible beneficiaries paid at least once under Ni-kshay Poshan Yojana
Data Source: Ni-kshay and Public Finance Management System (PFMS)</td><td>Numerator</td><td>Number of eligible beneficiaries paid at least once</td></tr>
<tr><td>Denominator</td><td>Total eligible beneficiaries</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
<tr><td colspan="4">Description:
Malnutrition is one of the risk factors for developing TB as well as poor treatment outcome. To address this issue, NTEP has launched Ni-kshay Poshan Yojna (NPY) under which all notified TB patients are provided incentive of Rs 500 per month during anti-TB treatment for Nutritional support in cash or in-kind support through DBT. The first payment (Rs. 1000) to be paid at the time of Notification as advance and is not conditional to initiating treatment. Advance payment is required to be settled at the time of outcome declaration. Processing payments involves two key steps i) Beneficiary registration (Bank account and Aadhaar seeding) and ii) Benefit processing (making payment). Ni-kshay auto-generates benefit to eligible patient and prompt to staff to process the benefit through PFMS. Benefit processing involves verification of generated benefits at maker level (TU), approver of benefit (at DTO level), sending approved benefit to PFMS for acceptance and further payment to eligible beneficiaries' account.

DBT-NPY indicators can be improved by
• Ensuring funds availability (district/state)
• Seeding bank account details for all eligible beneficiaries (TB patients both from public and private sector). Some patients may require assistance from NTEP staff for opening their bank accounts.
• Improving co-ordination between NTEP accountant and District Account manager
• Active monitoring of process and status by DTO/CMO
• Use of digital signatures to obviate the need for physical PPA (print payment advice) and further reconciliation.
Recently, MoHFW New Delhi has implemented the "Community Support to TB patients - Pradhan Mantri TB Mukt Bharat Abhiyaan" to provide additional support to the patients, augment the community involvement and to leverage Corporate Social Responsibility (activities) in the path towards ending TB in India. In this scheme, Ni-Kshay Mitra (Donor) is identified which may include co-operative societies, corporates, elected representatives, individuals, institutions, non-governmental organizations, political parties and partners who can support by adopting health facilities, blocks/urban wards/districts/states. The type of additional assistance that may be provided by the Ni-Kshay Mitra to on-treatment TB patients includes nutritional support, additional investigations for the diagnosed TB patients, vocational support and additional nutritional supplements.</td></tr>
<tr><td rowspan="3">6</td><td rowspan="3">DR-TB treatment initiation</td><td rowspan="3">Proportion of DR-TB* cases initiated on treatment among diagnosed

*(H mono/ RR-TB/Pre-XDR/ XDR)
Data Source: Ni-kshay</td><td>Numerator</td><td>Number of DR- TB* notified patients initiated on respective treatment regimen</td></tr>
<tr><td>Denominator</td><td>Total notified DR-TB patients</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
</table>

Description:

PMDT services were rolled-out in 2007 and complete geographic coverage achieved by 2013. Under PMDT services, there is a massive expansion of diagnostic network of laboratories, availability of new drugs, shorter regimen, decentralized treatment services, improved drug logistics management facilitated expansion of services.

Selection of appropriate DR-TB regimen is based on DST results, history of previous treatment and adverse reaction to drugs. NTEP provides simplified regimen for various types of oral DR-TB regimen including H-mono/poly regimen, shorter oral Bedaquiline-containing MDR/RR-TB regimen and longer oral M/XDR-TB regimen based on DST/DRT results with scope in difficult patients to extend Bedaquiline (Bdq) beyond 6 months, combined use of Bdq and delamanid (Dlm) and Bdq use in pregnancy. Use of BPaL regimen consisting of Bdq, pretomanid (Pa) & linezolid (Lzd) are ongoing in selected group of patients on a research mode. Key DR-TB treatment regimens and corresponding drug resistance pattern are described below

S. No.	Treatment regimen	DST profile	Remarks
1	H mono/ poly regimen	Only H resistance detected in FL LPA	R resistance not detected in NAAT/FL LPA; SL LPA need to be conducted for detecting FQ resistance; If additional FQ resistance is detected, LC DST need to be conducted for Moxifloxacin-high dose (Mfx^h), Z, Lzd and Clofazimine (Cfz)
2	Shorter oral Bedaquiline containing MDR/ RR-TB regimen	R resistance detected (with or without H resistance) in NAAT/ FL LPA	Patients with only InhA or only katG mutations (but not both) will be eligible for the shorter oral. SL LPA and LC DST (for Mfx^h, Z, Lzd & Cfz) is needed
3	Longer oral M/XDR-TB regimen with Bdq	Resistance to R detected (with or without and resistance to H and FQ) in NAAT/FL LPA/SL LPA	This regimen applicable to M/XDR-TB patient who are not eligible for shorter Bdq containing regimen. SL LPA and LC DST (for Mfx^h, Z, Lzd & Cfz) is needed

Correct and timely initiation of treatment regimen is crucial for DR-TB management and following steps could be ensured for improving this indicator

- Operationalize district level DR-TB centers
- Pre-treatment investigation available free of cost at district level
- Ensure travel support to DR-TB patients
- Establish linkages of DR-TB patients diagnosed in private sector to DR-TB centers
- Availability of drugs

7	**Expenditure**	Proportion of utilized budget against allotted budget (approved ROP) *Data Source: Ni-kshay*	Numerator	Utilized budget amount
			Denominator	Total allotted budget (ROP)
			Multiplier	100

Description:

As with other components of NHM, financial support to NTEP is provided through the PIP mechanism of the NHM. NTEP / NHM follow a bottom-up approach for planning and budgeting. The process begins at the district level by NTEP preparing the district PIP at the DTC which gets incorporated into the IDHAP which is further sent to the state level to form the State PIP. The State PIPs are then approved by the Union Secretary of Health and

<table>
<tr><td></td><td colspan="4">Family Welfare based on appraisal by the NPCC which is chaired by the Mission Director and includes representatives of the State, Technical and Programme Divisions of the MoHFW, other Departments and Ministries, as required. The approved ROP includes Central as well as State share and includes cash as well as commodity component.
The expenditure indicator is a proxy for whether or not the Programme is running as planned. The following points should be taken in account to improve this indicator.
Careful preparation PIP (State/district) covering all aspects of routine programme activities as well as newly planned activities for improved patient care.
• Expedite release of funds from treasury to State NHM
• Expedite release of funds to districts
• Streamline the procurement mechanism (along with ensuring the availability of specification of items or tender/contract document for services etc.)
• Monitor line time wise expenditure at all levels</td></tr>
<tr><td rowspan="6">8</td><td rowspan="6">TB infection management</td><td rowspan="3">Proportion of house-hold children <5 years given TB preventive treatment (TPT)
Data Source: Ni-kshay</td><td>Numerator</td><td>Number of household children given TPT</td></tr>
<tr><td>Denominator</td><td>Total number of household children</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
<tr><td rowspan="3">Proportion of PLHIV given isoniazid preventive treatment (IPT)

Data Source: NACP</td><td>Numerator</td><td>Number of newly enrolled PLHIV who are offered IPT</td></tr>
<tr><td>Denominator</td><td>Total newly enrolled PLHIV who are screened as negative for TB</td></tr>
<tr><td>Multiplier</td><td>100</td></tr>
<tr><td colspan="4">Description: Isoniazid is the most effective bactericidal, anti-TB drug available at currently and it is globally recommended for prevention of incident TB. Preventive treatment helps in preventing the reactivation (TB infection to TB disease).
• Preventive treatment to children: Children are more prone for severe disseminated form of TB. Children aged 5 years or less who are close contact with all forms of drug-sensitive TB patient are given isoniazid prophylaxis treatment (IPT) after ruling-out active TB by pediatrician or medical officer. It is given irrespective of BCG/nutritional status of child.
The steps to improve TB preventive treatment among children include
○ Ensure home-visit of all TB patients by STS/TB-HV for contact investigation
○ Sensitize all Medical Officers to get contacts' history about symptoms and record in treatment card at time of treatment initiation.
○ Sensitize private practitioners about chemoprophylaxis and make the drugs easily accessible to all eligible in private sector
○ Ensure smooth supply of INH to all health centers to provide preventive treatment
• Preventive treatment to PLHIVs: The risk of contracting TB is high among PLHIVs and therefore, all newly enrolled PLHIVs are screened for TB symptoms. If PLHIVs are unlikely to have active TB and they are offered IPT. (Note: TB is screened regularly among PLHIVs regardless of whether the PLHIV is receiving IPT or ART).
In order to improve the indicator of TB preventive treatment among eligible PLHIVs, following steps may be considered
○ Joint monitoring by State AIDS Control Societies (SACS) and STC
○ Bi-directional information flow and frequent co-ordination meetings
○ Ensure availability and supply of INH and pyridoxine at all ART centers
○ Robust laboratory linkages with ART centers for ruling out TB disease.</td></tr>
</table>

6.2. NTEP indicators related to case finding, TB diagnosis and laboratory services

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
Increase efforts to ensure optimal TB testing resources, as well as to improve its access and utilisation.				
1	Proportion of TB Detection Centres (TDCs) operationalized	Number of operational microscopy facilities	Total number of approved /expected microscopy facilities X100	• Microscopy services have been expanded to Peripheral Health Institutes based on availability of infrastructure and human resource, and not restricted to 1 per 100,000 population norms. This has resulted in scaling up of microscopy facility from 13657 in 2014 to 23,038 across the country currently (Figures as per Annual TB report 2023). • Non-availability of LTs or medical officers (who refer presumptive TB patients for testing), as well as microscope breakdown, are common causes of non-functional microscopy facility.
		Number of NAAT machines functional/ operational	Total NAAT machines available X100	• NAAT machines include CBNAAT and Truenat • Non-availability of LT, UPS breakdown, module failure, stock-out of kits/ consumables or machine engagement in COVID testing are the key reasons of non-operational NAAT sites
		Number of TDCs where LTs are available (at all working days)	Total number of approved TDCs X100	• Trained and motivated LTs in sufficient numbers are critical for smooth and high throughput laboratory services. • Ideally, each TDC should have one full-time LT (either from NTEP or from the general health system). Additional LTs may be needed depending on the workload and range of tests performed.
		Number of microscopy facilities with at least one functional microscope	Total number of microscopy facilities	• Despite the fact that smear microscopy is being replaced by NAAT, smear microscopy services will continue to be used for treatment follow-up.

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
		(light or fluorescent)		• NAAT, a highly sensitive DNA-based diagnostic test, cannot distinguish between viable and non-viable mycobacterial DNA. NAAT is not recommended for treatment follow-up because it can give false positive results and detect even a low number of dead bacilli in specimens from patients who have successfully completed treatment.
2	Coverage of existing mechanism of sample transportation	Number of TDCs linked for sample pick-up and transportation by existing mechanism	Total number of TDCs X100	• In order to comply with the DR-TB diagnostic algorithm, TB specimens need to be transported to and tested at different tier laboratories. Therefore, a robust and efficient mechanism is required that ensure sample transportation from SC to PHC, PHC to CHC and from CHC to District /TB C&DST/IRLs. • Ideally an agency (courier/speed post) with a pan district presence should be identified by the DTO of every district for prompt transport of the specimen under strict biohazard precautions. • All necessary materials for specimen collection and transportation need to be made available at the specimen collection centre and the NAAT facility by the DTO.
3	Percentage utilization of existing NAAT testing resources	Number of CBNAAT tests performed by all available CBNAAT machines in one month	Monthly testing capacity of available CBNAAT machines X100	• NTEP intends to provide DST-guided treatment to all TB patients. In 2019, approximately 56% of notified patients received UDST; thus, there is scope of improving NAAT coverage further. • To ensure complete diagnostic coverage, the laboratory network has recently been massively expanded. While further laboratory network expansion may be required, it is critical to maximize the
		Number of Truenat tests performed by all available Truenat machines in one month	Monthly testing capacity of available Truenat machines X100	

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				utilization of existing NAAT resources. This can be achieved by ensuring i) an adequate number of HR; ii) a robust sample transportation system; iii) equipment maintenance (including optimal testing environment); and iv) adequate supply of kit/consumables.
4	Percentage of microbiologically confirmed-TB cases	Number of presumptive TB patients confirmed as TB using smear microscopy and/or NAAT	Total notified TB patients X100	• Microbiological findings at diagnosis and at the end of treatment are relevant for evaluating TB treatment programmes, and therefore microbiologically confirmed diagnosis is always preferred globally. However, a significant proportion of notified TB patients (especially in private sector) are diagnosed clinically through chest X-ray. • Chest X-ray is a sensitive screening tool but has lower specificity than microbiological tests (like NAAT/ smear). Moreover, intrareader and inter-reader variability exist with chest X-ray.
5	Percentage of presumptive TB patients tested with NAAT as the initial diagnostic	Number of presumptive TB patients offered upfront NAAT testing	Total presumptive TB patients X100	• Smear microscopy has long been used as an initial test for TB confirmation. However, smear microscopy has a moderate sensitivity and may result in a false negative in case of paucibacillary load (like childhood-TB, TB among PLHIV, EPTB cases). • NAAT (both CBNAAT and Truenat) is highly sensitive test and are currently offered as upfront to certain key population (extra- pulmonary, PLHIV, children, smear -ve /NA with x-ray suggestive of TB, other vulnerable groups as defined in TOG-2016 and DR-TB contacts). • Upfront TB testing using NAAT improves case finding as well as

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				UDST coverage. Therefore, NTEP is aiming to gradually replace smear microscopy with NAAT.
Increase effort to case-finding				
6	Annualized presumptive TB cases examination rate	Number of presumptive TB cases tested (Smear microscopy + CBNAAT +Truenat)	Total population of the area X (1,00,000 X 12 / duration in months)	• Presumptive TB examination rate is the number of presumptive TB cases who have undergone sputum examination/NAAT per lakh population per year. • Increase of presumptive TB examination per lakh population relates to a more robust and strengthened case finding activities. • Emphasis on health education by various means and strategies is required for improving the symptom awareness among the general community to improve the health care seeking behavior and thereby prevent the further spread of TB.
7	Annualized TB case notification rate	Number of TB patients notified	Total population of the area X (1,00,000 X 12 / duration in months)	• Case notification rate is the number of TB cases registered in a specified time period (per year) in unit population (per lakh) in a defined area (e.g., TU/district/state). • This indicator provides information on the burden of disease, number of cases to be treated, and resources required. However, the number of cases reported can be compared with incidence estimates to detect deficiencies in case detection and notification. • Trends over time in case notification usually indicate changes in programme coverage and capacity to detect TB cases; at high levels of case detection, the indicator reflects changes in the prevalence of TB in the community. • The case notification rate provides data for programme planning and M&E purposes,

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				and it should be used to guide these activities. E.g., an upward trend in case notification rates can reflect an improvement in programme performance.
8	Number Needed to Test (NNT)	Number of presumptive TB cases tested (Smear microscopy + CBNAAT +Truenat)	Number of TB patient notified/ diagnosed (out of total tested)	• NNT is the number of individuals that were tested to identify one person with TB. This indicator helps in evaluating both reach of the case finding efforts as well as TB incidence in any given geography. • A decline in TB notification over years combined with an increase in NNT, indicates a decline in TB incidence in the region. • If the TB notification has reduced with NNT remaining same or lower, it indicates that case finding efforts are not optimal.
9	Proportion of TB cases notified against the target estimated (Public and Private)	Number of TB patients notified/ diagnosed (Public and Private)	Target number of TB patients (Public and Private) estimated to be notified X 100	• Every year, the CTD, MoHFW provides TB notification target for each state and district, both public and private. The target estimation is based on prevalence survey data, notification data, under-reporting factors and expert's opinion. *(See also Table 1-KPIs)*
10	Proportion of PLHIVs screened as presumptive TB in HIV care / treatment settings	Number of PLHIVs identified to have TB symptoms	Total PLHIVs cases screened/enrolled in HIV care setting X100	• Intensive screening of TB among PLHIVs are important since they are more likely (about 30 times higher) than others to become sick with TB. • PLHIVs are screened for four TB symptoms at HIV care settings on a regular basis (at the time of enrolment and at each follow-up visit). All newly enrolled PLHIVs who do not have TB symptoms are given TB prevention treatment. • Due to the paucibacillary nature of disease in HIV-MTB coinfections, TB detection by smear microscopy is difficult. Therefore, all presumptive TB
11	Proportion of presumptive TB among PLHIVs who were tested using NAAT	Number of PLHIVs with TB symptoms who were tested by NAAT	Total presumptive TB cases among PLHIVs X100	

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				among PLHIVs should be offered upfront NAAT at nearest located site. • Timely testing, treatment initiation, and improved coordination between TB and HIV Programmes at the district/state level reduce TB morbidity and mortality among PLHIVs.
12	Proportion of contacts of Index TB patient evaluated for TB disease (and TB infection)	Number of contacts of Index TB patient evaluated for TB disease (and TB Infection)	Total number of contacts of Index TB patients	• Close contacts of people living with TB is another important vulnerable group and they have high risk of TB infection as well as TB disease. • As part of the Public Health Action provided to all notified TB patients, STS/TB-HV screens all household contacts for TB during the patient's home visit (at the time of treatment initiation). Any presumptive TB patients identified during contact tracing visit are offered NAAT. Intensified contact screening may be further strengthened by including proximal contacts as well as workplace settings. • More than 50% children who become ill due to TB are aged less than 5 years. In NTEP, children (less than 5 years) in close contact with DS-TB patient are offered TB preventive treatment after ruling out active TB by paediatrician/medical officer. • TPT for contacts of other age groups, selected groups (including health care workers), or contacts of DR-TB patients is rolled-out in phased manner.
13	Proportion of paediatric TB cases among total TB cases notified	Number of paediatric TB cases notified	Total TB cases notified X 100	• Paediatric TB is difficult to diagnose and there is no reliable data on the incidence and prevalence of the paediatric TB in India.

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				• Children up to 14 years constitute about 30% (Census 2011) of the population in India and are expected to contribute about 13% of the caseload. In 2019, the NTEP reported 1.5 lakh TB cases of children aged 0–14 years, indicating a gap of 55% in TB notifications in this age group. Therefore, programme manager should monitor the TB notification among paediatric age group. • In order to increase the case detection as well as reduce morbidity and mortality due to paediatric TB, NTEP has developed a framework that are expected to be implemented jointly by NTEP, RBSK and Rashtriya Kishor Swasthya Karyakram (RKSK) at district and state level.
14	Proportion of notified Extra-pulmonary TB case amongst total TB cases notified	Number of EPTB cases notified	Total TB cases notified X 100	• The burden of EPTB is high, ranging from 15– 20% of all TB cases in HIV-negative patients, while in HIV-positive people it accounts for 40–50% of new TB cases (Sharma S.K., 2004). In 2019, 0.6 million (25%) EPTB cases were notified out of total notified 2.4 million. • Diagnosis of EPTB is difficult due to the pauci-bacillary nature of disease, the variable clinical presentation, and need for invasive procedures to secure appropriate sample. Presumptive EPTB cases are considered as key population and upfront NAAT is offered. All fluid EP samples can be processed in CBNAAT in the periphery. • EPTB samples, such as tissue biopsy and lymph nodes, must be homogenised in a TB containment facility, which is available at TB C&DST labs.

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				Large volume EP specimens (such as pleural fluid) must also be sent to the TB C&DST laboratory because they require concentration using a safety centrifuge available at a higher lab.
Ensuring comorbidity testing among notified TB case and relapse free TB cure				
15	Proportion of notified TB patients with known HIV status	Number of notified TB cases tested for HIV	Total TB cases notified X 100	• HIV and diabetes are key co-morbid conditions that if not treated promptly, it may affect treatment outcomes. This is why, NTEP ensures that all notified TB patients are screened for HIV and diabetes at the time of treatment initiation. • Coverage of HIV and diabetes screening has increased over the past year. In 2021, about 95% and 89% of all notified TB patients were aware of their HIV and Blood sugar status. *(See also Table 1-KPIs)*
16	Proportion of notified TB patients with known status of diabetes	Number of notified TB cases tested for diabetes	Total TB cases notified X 100	
Reaching universal access to rapid DSTs				
17	Coverage of rapid DST (NAAT) for all notified TB case (Universal DST)	Number of notified TB patient who were offered NAAT (upfront or after clinical or microbiological confirmation)	Total notified TB patients X100	• These indicators will help in quantifying the coverage and implementation gaps of rapid DSTs (NAAT and FL/SL LPA). • As per Integrated DR-TB diagnosis and treatment algorithm NAAT is offered to all notified TB patients. The algorithm is designed to segregate patients based on NAAT results as RR detected or RR not detected and offer DST guided treatment. • When rifampicin resistance is not detected, the patient is offered FL LPA for detecting resistance to H. If H resistance is not detected, the patient is continued on a DS TB regimen. If H resistance is detected, the patient is eligible for H mono/Poly DR-TB regimen. SL LPA is also performed for
18	Coverage of rapid DST for Isoniazid among TB patients with RR-TB not detected	Number of TB patients with RR-TB not detected who were offered a rapid DST (like FL LPA) for Isoniazid	Total bacteriologically confirmed TB patients with RR-TB not detected X100	
19	Coverage of rapid DST for FQs among Isoniazid-monoresistant Tuberculosis (Hr-TB)	Number of Hr-TB patients who were offered a DST (like SL LPA) for at least FQ	Total Hr-TB patients with RR-TB not detected	

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
20	Coverage of FL and SL LPA testing (DST for FQs, second-line injectable drugs (SLIDS), Eto) among TB patients with MDR/RR-TB detected	Number of TB patients with MDR/RR-TB detected who were offered both FL and SL LPA	Total bacteriologically confirmed TB patients with RR-TB detected X100	detecting resistance to FQ, followed by LC DST for Mfx (if resistant by SL LPA), Z, Lzd and Cfz. Treatment is initiated, taking LPA results into account and modified further based on the LC DST results. • When rifampicin resistance is detected, the patient is offered FL and SL LPA. While FL LPA provides information on *inh*A mutations associated with Eto resistance, SL LPA provides information on resistance to Lfx, Mfx and Am. Additional LC DST would also be required [for Z, Mfx (if resistance detected by LPA), Lzd, Cfz, Bdq and Dlm] to further optimized the treatment regimen. If FQ resistance is not detected and H resistance is detected due to mutations either in *katG* or *inhA* (but not both) the patient is eligible for shorter oral Bdq -containing MDR/RR-TB regimen. If FQ resistance is detected or H resistance is due to mutations in both *katG* and *InhA*, the patient is eligible for longer oral M/XDR-TB regimen. • The implementation gap in offering DSTs can be minimized by ensuring ○ Robust specimen transportation mechanism ○ NAAT & TB C&DST labs have proficiency and testing capacity (including HR, equipment and kits/ consumables) are enough to meet the anticipated testing load. ○ Timely specimen transportation preferably before the start of treatment. As the TB treatment progress, the bacillary load in specimen

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				reduces day by day. Thus, if there is a significant delay in sample collection after treatment initiation, the DST result may not be conclusive due to high rate of smear negative. Additionally, delay in transportation or testing (from sample collection to test date) can also affect LC DST and in-direct LPA result because of a high rate of culture contamination. (see also Table 1 KPIs).
Continued monitoring of DR-TB				
21	MDR/RR-TB proportion among bacteriologically confirmed TB	Number of patients detected with at least Rifampicin resistance	Total micro-biologically confirmed TB patients offered a rapid DST for at least Rifampicin	• Previous studies and survey showed variation in types of DR-TB across different states; therefore, local epidemiology is important. • Drug surveillance can be done using the approaches of systematic periodic survey as well as continuous surveillance based on routine DST (for most TB patients using NAAT, LPA and LC DST). • Drug resistance trends are monitored in the programme through routine testing, which helps in gaining a better understanding of the disease burden, improving access to timely and appropriate treatment, and forecasting the need for drug supplies, kits and consumables. It also provides programmatic benefits such as the rapid detection of outbreaks, guidance to research programs for developing and implementing strategic interventions in diagnosis, treatment, and infection control.
22	FQ resistant proportion among MDR/RR-TB	Number of patients detected with FQ resistance among MDR/ RR-TB	Total MDR/RR-TB patients offered DST for FQ	
23	XDR-TB proportion among MDR/RR-TB	Number of MDR/RR-TB patients with resistance to FQ and at least one of the 2 group A drugs (Bdq / Lzd)	Total MDR/RR-TB patients offered DST for FQ, and Bdq and/or Lzd	
24	Isoniazid mono resistant TB (Hr-TB) proportion among TB patients with RR-TB not detected	Number of patients detected with Isoniazid resistant among TB patients with RR-TB not detected	Total micro-biologically confirmed TB patients with RR-TB not detected and offered a rapid DST for Isoniazid	

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
25	FQ resistant rate among Hr-TB	Number of patients detected with FQ resistance among Hr-TB	Total Hr-TB patients with RR-TB not detected and offered DST for FQ	• The first ever National Drug Resistance Surveillance (NDRS) conducted in India during 2014-16 showed ○ DR-TB was 6.19% (CI 5.54–6.90%) among all TB patients with 2.84% (CI 2.27–3.50%) in new and 11.60% (CI 10.21–13.15%) in previously treated cases. ○ Among MDR-TB patients, additional resistance to any FQ was 21.82% (17.33–26.87%), and 3.58% (1.8–6.32%) to any SLIDS. ○ Among MDR-TB patients, additional resistance to at least one drug from each of the two classes, i.e., FQ and SLIDS (erstwhile XDR-TB) was 1.3% (0.36–3.30%). ○ Any first- or second line drug resistance among all TB patients was 28.0% (CI 26.77–29.29%) with 22.54% (CI 21.10–24.10%) in new and 36.82% (CI 34.64–39.04%) in previously treated TB patients. ○ Any isoniazid resistance was 11.06% (CI 9.97–12.22%) and 25.09% (CI 23.1–-27.11%) in new and previously treated TB patients, respectively. ○ Any pyrazinamide resistance was 6.95% (CI 6.07–7.91%) and 8.77% (7.53–10.13%) in new and previously treated TB patients, respectively.
Strengthen the quality of laboratory services				
26	Percentage of DST sites that have qualified PT for all DST methods performed	Number of DST sites that have qualified PT for all DST method performed	Total sites providing DST services to the patients X100	• NRLs facilitate annual PT for NAAT, LPA, and LC DST through the NTEP laboratory network. • NRLs provide an EQA panel to each participating laboratory that must meet a minimum concordance (see Chapter 3) in

S.No.	Indicator	Numerator	Denominator X Multiplier*	Remarks
				order to qualify PT and provide testing services to patients.
27	Percentage of supervisory OSE visits conducted to TB C&DST labs and IRLs by respective NRLs	Number of TB C&DST labs and IRLs visited by NRLs in one calendar year	Total number of TB C&DST labs and IRLs linked with respective NRLs	• OSE of TB laboratories (including IRLs, TB C&DST laboratories and districts) is a critical component of QA program. • NRL conducts OSE visits to all IRLs and TB C&DST laboratories within their geographic area at least once a year. • Similarly, IRL conducts OSE visits to all districts (DTCs and few TDCs) within their geographic area at least once a year. IRLs should also conduct OSE visits of C&DST labs within their jurisdiction at least twice a year.
28	Percentage of supervisory OSE visits conducted to TB C&DST labs and district by respective IRLs	Number of TB C&DST labs and districts visited by IRLs in one calendar year	Total number of TB C&DST labs and districts linked with respective IRLs	
29	Percentage of operational microscopy facilities in a district that participated in monthly RBRC activity	Number of operational microscopy facilities in a district that participated in monthly RBRC activity	Total number of operational microscopy facilities in a district	• RBRC of routine slides a process of rereading a statistically valid sample of slides from a laboratory to assess whether that it has an acceptable level of performance. • RBRC activity is carried-out under supervision of DTO on monthly basis for their linked microscopy facilities.
30	Percentage STLSs available in the district	Number of STLSs available in the district	Number of STLSs recommended/ approved in the district	• STLS is the key NTEP staff who supervise allotted TDCs in the districts. The DTO/MO-TC/MO coordinate with the STLS to ensure that TB-related laboratory services are properly performed and recorded by the laboratory technician. • One STLS will continue to be in 5 lakh population (one per 2.5 lakh population for tribal/hilly/ difficult areas).

* Wherever applicable

In addition to the above indicators, higher level laboratories in NTEP monitors a set of indicators specific to each test procedure on a monthly basis. These include the following indicators, which are also annexed (Annexure 6.1 - 6.4).

i) CBNAAT indicators
ii) Truenat indicators
iii) Annexure M
iv) Laboratory performance indicators

Annexure 6.1: CBNAAT Monthly Indicator

CBNAAT MONTHLY INDICATOR			
Reporting month/ year:			
Name of the CBNAAT Facility: (PHC/CHC/Sub- District Hospital/ DH/Med College/ DTC/ IRL/NRL/others)			
Complete Mailing Address with pin code:			
Type of CBNAAT Facility (Public/Private)			
Name of the District			
Name of the Block/TU			
Contact Details (Name, contact no. & Email ID):			
Type of Module: (2/4/8/16):			
Number of Machines:			
Serial No. of the Machine/s:			
Date of Installation:			
Date of last calibration:			
S.No.	**Workload**		
1	**Total number of tests performed using CBNAAT**		
2	Total number of MTB not detected (MTB-)		
3	Total number of MTB detected (MTB+)		
4	Total number of MTB detected and RIF resistance NOT DETECTED (MTB+/Rif-)		
5	Total number of MTB detected and RIF resistance DETECTED (MTB+/Rif+)		
	Referral from Public Sector		
6	**Total number of Presumptive TB (New & Relapse)**		
7	**Total number of Presumptive DR-TB (Notified TB patients and Non responders)**		
8	**Total number of Pulmonary samples**		
9	**Total number of EPTB samples**		
	Referral from Private Sector		
10	**Total number of Pulmonary samples**		
11	**Total number of EPTB samples**		
	Stratification of patients		
12	**Presumptive TB**	**PLHIV out of presumptive TB**	MTB not detected (MTB-)
13			MTB detected (MTB+)
14			RIF resistance not detected (Rif-)
15			RIF resistance detected (Rif+)
16		**Pediatric out of presumptive TB**	MTB not detected (MTB-)
17			MTB detected (MTB+)
18			RIF resistance not detected (Rif-)
19			RIF resistance detected (Rif+)
20		**Smear Negative, Xray suggestive of TB**	MTB not detected (MTB-)
21			MTB detected (MTB+)
22			RIF resistance not detected (Rif-)
23			RIF resistance detected (Rif+)
24		**Other Vulnerable group (as per ACF guidelines)**	MTB not detected (MTB-)
25			MTB detected (MTB+)
26			RIF resistance not detected (Rif-)
27			RIF resistance detected (Rif+)
28			MTB not detected (MTB-)

29		**Contacts of TB & DR-TB patients**	MTB detected (MTB+)
30			RIF resistance not detected (Rif-)
31			RIF resistance detected (Rif+)
32		**EPTB**	MTB not detected (MTB-)
33			MTB detected (MTB+)
34			RIF resistance not detected (Rif-)
35			RIF resistance detected (Rif+)
36		**Upfront Molecular test offered**	MTB not detected (MTB-)
37			MTB detected (MTB+)
38			RIF resistance not detected (Rif-)
39			RIF resistance detected (Rif+)
40	**Presumptive DR-TB (Pulmonary)**	**Notified TB patients (New)- UDST**	MTB not detected (MTB-)
41			MTB detected (MTB+)
42			RIF resistance not detected (Rif-)
43			RIF resistance detected (Rif+)
44		**Notified TB patients (Previously treated) - UDST**	MTB not detected (MTB-)
45			MTB detected (MTB+)
46			RIF resistance not detected (Rif-)
47			RIF resistance detected (Rif+)
48		**Non-responders (DS TB & Hr TB)**	MTB not detected (MTB-)
49			MTB detected (MTB+)
50			RIF resistance not detected (Rif-)
51			RIF resistance detected (Rif+)
52	**Private sector**	**Pulmonary TB**	MTB not detected (MTB-)
53			MTB detected (MTB+)
54			RIF resistance not detected (Rif-)
55			RIF resistance detected (Rif+)
56		**EPTB**	MTB not detected (MTB-)
57			MTB detected (MTB+)
58			RIF resistance not detected (Rif-)
59			RIF resistance detected (Rif+)
60	Total Number of MTB Detected Rif Indeterminate (MTB+/Rif Indeterminate)		
61	Total Number of test(s) showing "Invalid" result		
62	Total Number of test(s) showing "No result"		
63	Total Number of Errors		
64	Total number of Samples sent for 1st & 2nd line DRT (LPA)		
65	Total number of cartridges in stock at end of the month		

Annexure 6.2: Truenat Monthly Indicator

TRUENAT MONTHLY INDICATOR			
Reporting month/ year:			
Name of the Truenat Facility: (PHC/CHC/Sub- District Hospital/ DH/Med College/ DTC/ IRL/NRL/others)			
Complete Mailing Address with pin code:			
Type of Truenat Facility (Public/Private)			
Name of the District:			
Name of the Block/TU:			
Contact Details (Name, contact no. & Email ID):			
Type of Module: (Uno/Duo/Quatro):			
Number of Machines:			
Serial No. of the Machine/s:			
Date of Installation:			
Date of last calibration:			
S.No.	**Workload**		
1	**Total number of MTB tests performed using Truenat**		
1a	Total number of MTB not detected (MTB-)		
1b	Total number of MTB detected (MTB+)		
1c	Total Number of test(s) showing "Invalid" result		
1d	Total Number of Errors		
2	**Total number of RIF tests performed using Truenat**		
2a	Total number of RIF resistance not detected (Rif-)		
2b	Total number of RIF resistance detected (Rif+)		
2c	Total Number of Rif Indeterminate (Rif Indeterminate)		
2d	Total Number of Errors		
	Referral from Public Sector		
3	**Total number of Presumptive TB (New & Relapse)**		
4	**Total number of Presumptive DR-TB (notified TB patients and non-responders)**		
5	**Total number of Pulmonary samples processed**		
6	**Total number of EPTB samples processed**		
	Referral from Private Sector		
7	**Total number of Pulmonary samples**		
8	**Total number of EPTB samples**		
	Stratification of patients		
9	**Presumptive TB**	**PLHIV out of presumptive TB**	MTB not detected (MTB-)
10			MTB detected (MTB+)
11			RIF resistance not detected (Rif-)
12			RIF resistance detected (Rif+)
13		**Pediatric out of presumptive TB**	MTB not detected (MTB-)
14			MTB detected (MTB+)
15			RIF resistance not detected (Rif-)
16			RIF resistance detected (Rif+)
17		**Smear Negative, Xray suggestive of TB**	MTB not detected (MTB-)
18			MTB detected (MTB+)
19			RIF resistance not detected (Rif-)

20			RIF resistance detected (Rif+)
21		**Other Vulnerable group (as per ACF guidelines)**	MTB not detected (MTB-)
22			MTB detected (MTB+)
23			RIF resistance not detected (Rif-)
24			RIF resistance detected (Rif+)
25		**Contacts of TB & DR-TB patients**	MTB not detected (MTB-)
26			MTB detected (MTB+)
27			RIF resistance not detected (Rif-)
28			RIF resistance detected (Rif+)
29		**EPTB**	MTB not detected (MTB-)
30			MTB detected (MTB+)
31			RIF resistance not detected (Rif-)
32			RIF resistance detected (Rif+)
33		**Upfront Molecular test offered**	MTB not detected (MTB-)
34			MTB detected (MTB+)
35			RIF resistance not detected (Rif-)
36			RIF resistance detected (Rif+)
37	**Presumptive DR-TB (Pulmonary)**	**Notified TB patients (New)- UDST**	MTB not detected (MTB-)
38			MTB detected (MTB+)
39			RIF resistance not detected (Rif-)
40			RIF resistance detected (Rif+)
41		**Notified TB patients (Previously treated) - UDST**	MTB not detected (MTB-)
42			MTB detected (MTB+)
43			RIF resistance not detected (Rif-)
44			RIF resistance detected (Rif+)
45		**Non-responders (DS TB & Hr TB)**	MTB not detected (MTB-)
46			MTB detected (MTB+)
47			RIF resistance not detected (Rif-)
48			RIF resistance detected (Rif+)
49	**Private sector**	**Pulmonary TB**	MTB not detected (MTB-)
50			MTB detected (MTB+)
51			RIF resistance not detected (Rif-)
52			RIF resistance detected (Rif+)
53		**EPTB**	MTB not detected (MTB-)
54			MTB detected (MTB+)
55			RIF resistance not detected (Rif-)
56			RIF resistance detected (Rif+)
57	Number of errors during DNA extraction		
58	Number of repeat tests for TB diagnosis out of s.no.1c &1d		
59	Number of MTB Detected out of s.no.58		
60	Number of repeat tests for Rifampicin resistance out of s.no. 2c &2d		
61	Number of Rifampicin resistance detected out of s.no.60		
62	Total number of Samples sent for LPA out of s.no.2a & 2b		
63	Total number of Extraction cartridge in stock at the end of the month		
64	Total number of MTB chips in stock at end of the month		
65	Total number of RIF chips in stock at end of the month		

Annexure 6.3: Annexure M

TUBERCULOSIS LABORATORY MONTHLY ABSTRACT			
S. No			
State			
District			
TB Unit			
DMC			
Number of Adult OPD			
Number of Presumptive TB examined for diagnosis			
Number of Presumptive TB found to be positive			
Number of Presumptive TB undergoing repeat diagnostic examination			
Number of Presumptive TB found to be positive on repeat diagnostic examination			
Number of follow-up patients examined			
Number of follow-up patients found to be positive			
Total number of positive slides examined			
Total number of negative slides examined			
Total number of negative and positive slides examined			
Number of presumptive TB with known HIV status			
Number of presumptive TB found to be HIV positive			
Remarks			

Annexure 6.4: Laboratory Performance Indicators

FL LPA				
Month				
State				
Name of the Culture & DST Laboratory				
Total number of samples received for FL LPA				
Total number of tests conducted				
Total number of results available				
MTBC Not Detected				
Resistance not detected				
Mono R resistance	Inferred			
	Detected			
Mono H Resistance Inferred	Kat G			
	InhA			
Mono H Resistant Detected	Kat G			
	InhA			
	Both Kat G & InhA			
Resistance detected to H & R				
Number of tests with INVALID results				
Number of Batches contaminated				
Final results not available (*If any- to update in the same testing month during subsequent submission)*				
FL LPA offered for RS from NAAT	H resistance not detected			
	H resistance detected			
FL LPA offered for RR from NAAT	H resistance not detected			
	H resistance inferred & detected			
	Only KatG mutation detected			
	Only InhA mutation detected			
	Both InhA + KatG mutations detected			
Discordance in RIF (b/w NAAT and LPA)	Total observed			
	Number tested			
	RS in NAAT resolved as RR			
	RR in NAAT resolved as RS			
Type of patient offered FL LPA	Baseline			
	Follow up			
	Status Unknown			
Total number of Direct LPA tests conducted				
Total number of In-Direct LPA tests conducted				
Remarks				

SL LPA					
Month					
State					
Name of the Culture & DST Laboratory					
Total number of samples received for SL LPA					
Total number of tests conducted					
Total number of results available					
MTBC not detected					
FQ & SLID Resistance Not Detected					
Any FQ Resistance Inferred					
Any FQ Resistance detected					
Any SLID Resistance detected					
FQ+SLID Resistance detected					
Lfx resistance	Inferred				
	Detected				
Mfx resistance	Inferred- low level				
	Detected- low level				
	Detected- high level				
Km resistance	Inferred				
	Detected- low level				
	Detected-				
Cm resistance	Inferred				
	Detected				
Am resistance	Inferred				
	Detected				
Number of tests with INVALID results					
Number of Batches contaminated					
Final results not available *(If any- to update in the same testing month during subsequent submission)*					
Among Mono INH resistance	Number subjected to SL-LPA				
	SL LPA at Baseline				
	SL LPA at Follow up				
	Status Unknown				
	Any FQ resistance	Inferred			
		Detected			
	Any SLID resistance	Inferred			
		Low level Km resistacne detected			
		Detected			
Among RR/MDR	Number subjected to SL-LPA				
	SL LPA at Baseline				
	SL LPA at Follow up				
	Status Unknown				
	Any FQ resistance	Inferred			
		Detected			
		Inferred			

SL LPA					
	Any SLID resistance	Low level Km resistance detected			
		Detected			
Total number of Direct LPA tests conducted					
Total number of In- Direct LPA tests conducted					
Remarks					

LC DST					
Month					
State					
Name of the Culture & DST Laboratory					
PHENOTYPIC DST	SOLID CULTURE	Number Inoculated			
		Number of Cultures Positive for MTBC			
		Number of cultures contaminated			
	LIQUID CULTURE	Diagnostic specimen	Number Inoculated		
			Number of Culture Positive for MTBC		
			Number of Culture Negatives		
			Number of cultures contaminated		
		Follow Up specimens	Number Inoculated		
			Number of Culture Positive for MTBC		
			Number of Culture Negatives		
			Number of cultures contaminated		
		Total Number of Cultures Inoculated			
		Number of Cultures Positive for MTBC			
		Number of Cultures Negatives			
		Number of Cultures Negative for MTBC (Probable NTM)			
		Number of Results awaited *(if any-to update in the same testing month during subsequent submission))*			
	ICT	Number of tests conducted			
		Number of Positives			
		Number of SL DSTs conducted			
		Number of SL DST results finalized			

LC DST					
	DST for diagnostic samples	Total Number Susceptible			
		Moxifloxacin (1.0ug)	Sensitive		
			Resistant		
		Pyrazinamide	Sensitive		
			Resistant		
		Linezolid	Sensitive		
			Resistant		
		Clofazimine	Sensitive		
			Resistant		
		Bedaquiline	Sensitive		
			Resistant		
		Delamanid	Sensitive		
			Resistant		
		Other Drugs (Specify drugs ----------)	Sensitive		
			Resistant		
		Number of Pre-XDR detected (RR/MDR +FQ)			
		Number of XDR detected (RR/MDR +FQ+LZD/BDQ)			
		Number of DST Contaminated			
	DST for Follow up samples	Number of SL DSTs conducted			
		Number of results finalized			
		Total Number Susceptible			
		Moxifloxacin (1.0ug)	Sensitive		
			Resistant		
		Pyrazinamide	Sensitive		
			Resistant		
		Linezolid	Sensitive		
			Resistant		
		Clofazimine	Sensitive		
			Resistant		
		Bedaquiline	Sensitive		
			Resistant		
		Delamanid	Sensitive		
			Resistant		
		Other Drugs (Specify drugs)	Sensitive		
			Resistant		
		Number of Pre-XDR detected (RR/MDR +FQ)			
		Number of XDR detected (RR/MDR +FQ+LZD/BDQ)			
		Number of SL DST Contaminated			
		Results awaited/ Ongoing (*If any- to update in the same testing month during subsequent submission*)			
		Remarks			

Reference documents

(Key resources and suggested reading)

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9. Stepwise laboratory quality improvement process towards accreditation (SLIPTA) checklist version 2:2015 for clinical and public health laboratories. Brazzaville: World Health Organization. Regional Office for Africa; 2015 (https://apps.who.int/iris/handle/10665/204423).
10. TB laboratory accreditation. A training & mentoring programme. Geneva: Foundation for Innovative New Diagnostics; 2016 (https://www.finddx.org/wp-content/uploads/2016/11/TB-SLMTA-flyer-28NOV16.pdf).
11. Score-TB package: TB laboratory accreditation. Geneva: Stop TB Partnership; 2022 (https://www.stoptb.org/gli-guidance-and-tools/tb-laboratory-accreditation).
12. Guidelines for Programmatic Management of Drug Resistance Tuberculosis In India-2021 (https://tbcindia.gov.in/showfile.php?lid=3590)
13. Training modules for Programme Managers and Medical Officers https://tbcindia.gov.in/WriteReadData/NTEPTrainingModules1to4.pdf, https://tbcindia.gov.in/WriteReadData/NTEPTrainingModules5to9.pdf