Ministry of Health & Family Welfare
Government of India

Pre-Assessment Tool to Facilitate NTEP Certification of Tuberculosis Laboratory in Private Sector

Send the electronic copies of the completed form to

Dy. Director General (TB)
Central TB Division
JEEVAN VIHAR BULDING
SANSAD MARG,
New Delhi -110001

E mail: ddgtb@rntcp.org

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Contents

List of Abbreviations

AMC	Annual Maintenance Contract
BSL	Biosafety level
CTD	Central TB Division
DST	Drug susceptibility testing
DNA	Deoxyribonucleic acid
DGHS	Directorate General of Health Services
FL	First Line
FQ	Fluoroquinolones
GoI	Government of India
GLI	Global Laboratory Initiative
LPA	Line Probe Assay
MDR-TB	Multidrug-resistant TB
MTB	*Mycobacterium tuberculosis*
MTBC	*Mycobacterium tuberculosis* complex
NTEP	National TB Elimination Programme
RIF	Rifampicin
SL	Second Line
SLID	Second-Line Injectable Drugs
TB	Tuberculosis
WHO	World Health Organization

PRE-ASSESSMENT TOOL TO FACILITATE NTEP CERTIFICATION OF TB LABORATORY IN PRIVATE SECTOR

A. Introduction

To help eliminate TB, the Government of India (GoI) introduced interventions to expand and improve diagnosis, treatment, and care for patients with TB. It intends to extend the umbrella of high-quality TB diagnostics to TB patients diagnosed in the private sector laboratories.
Scope of this document is to cover the minimum required information for laboratory assessment and is designed to assess the readiness of a C&DST TB laboratory in private sector to be certified by National TB Elimination Program (NTEP) for TB diagnostic services.

The document comprises of the following:

1. General information
2. Data collection form for assessing the following focus areas:
   - Structural, functional and policy profile of the laboratory,
   - Quality assurance processes,
   - Performance of TB diagnostic technologies,
   - Availability of human resource,
   - Procurement of laboratory equipment, supplies and maintenance services
   - Bio-safety measures, data management and TB notification
3. Sample letter for conveying willingness

B. An overview of certification process:

The certification process are a multi-pronged approach with proactive role from laboratory to ensure the certification is awarded. The certification is provided for First and Second Line-Line Probe Assay (FL and SL LPA) and First and Second Line MGIT DST to ensure that all quality parameters enlisted by National TB Elimination Programme are adhered and patients are provided with best available quality service.

Each of the steps involved in the certification process is described below with responsibilities of respective stakeholders. (Annexure 1)

Table 1: Description of stepwise process of NTEP certification and role of stakeholders

Step	Process	Role of Stakeholder	Description
1	Laboratory submits application for Certification	Interested laboratory may approach the respective State TB Office and submit the application (via e-mail communication from Competent Authority of the establishment). The application is available for download in the Central TB Division (CTD) website	Laboratory to review the application document and incorporate the details of the information requested in the application form. The duly filled application form with necessary details is submitted online to the respective State TB Officer.

Step	Process	Role of Stakeholder	Description
2	STO and CTD Review	The STO reviews the application (support extended by IRL/STDC) for its completeness. Following the review of the application, the office communicates to CTD for further process. The nodal officer at CTD reviews the application and communicates to the respective National Reference Laboratory (NRL).	The office responds to the private laboratory about the receipt of application and communicates about any requirement of additional information if needed. The nodal officer may reach to private laboratory directly for any additional information.
3	Pre-Assessment by NRL	The NRL, reviews the application and schedules the pre-assessment visit in coordination with State, Private laboratory, and CTD to validate the information shared in the application form.	The NRL constitutes a team that is composed of representatives from the CTD laboratory team, the Intermediate Reference laboratory, a representative from the State TB cell, WHO consultant, and independent laboratory experts (as required) in addition to the Microbiologist(s) from NRL. The team visits the private laboratory where all information provided in the application is validated. During the process, any gaps/nonconformities (NC) identified that are essential for meeting the quality requirements of certification are noted and discussed with the private laboratory with mutually agreed timelines for resolving the NCs. A report is shared with the Private laboratory and CTD, with a copy to STO and IRL. The NRL team review the responses shared by the laboratory. If need be, representative from the NRL or any nominated officer from IRL may visit the facility to validate the responses.
4	Proficiency Testing by NRL	The NRL Team explains the laboratory regarding the process of Proficiency testing (External Quality Assurance)	Proficiency testing consists of - Retesting (performed once when the lab applies for certification) and Panel testing (performed annually). If required, NRL provides training for LPA/LCDST free of cost. The NRL analyses the results and

Step	Process	Role of Stakeholder	Description
		NRL team reviews the results of Proficiency testing	recommends for certification if the desired concordance is achieved. (Please refer to the Annexure 1 for details)
5	Central TB Division	The recommendations of NRL are considered and approved for certification	CTD assigns a certificate number for the laboratory and communicates to the NRL. NRL submits the duly filled in certificate with signature of NRL Director and submits to CTD. CTD then issues the certificate to the laboratory.
6	Laboratory	The certification is awarded for two years	Subsequent to certification, laboratory participates in annual proficiency testing and applies a recertification at least a month before the expiry of certificate.

Pre-Assessment Tool
for
Mycobacteriology Laboratory Certification

I. General Information

i. Basic Information of the laboratory to be assessed

Facility Name: _____

Facility Address: _____

_____

Name of the nodal person: _____

Designation: _____

Contact No.: _____

Email: _____

Ni-kshay Private Health Facility ID: _____

II. Current TB Diagnostic Tests in the Laboratory

	Tests	Yes/No	Certification requirement from NTEP Yes/No
1	Smear Microscopy • ZN • FM		NA
2	GeneXpert Last calibration done on-		NA
3	Truenat Last calibration done on-		NA
4	Liquid Culture		NA
5	Liquid culture DST (MGIT 960)-First Line		
6	Liquid culture DST (MGIT 960)-Second Line		
7	FL LPA		
8	SL LPA		
9	Other tests		

A) Sample collection and transportation facilities (Tick (√) whatever is applicable)

- Hub and Spoke Model- (own network) ☐
- Referral from clinician ☐
- Referral from other laboratories ☐

B) Branches/centers in the country

1. No. of Branches- Please include whether the branches/ sub centers are enrolled in Ni-kshay and is preferred so that patients are linked to their original state/ district
2. List of Branches

Sl no	Name of the Branch /Facility	List of TB related diagnostic services provided	Enrollment in Ni-kshay (Yes/No)	Willingness to be part of NTEP certification

III. Laboratory Organization and Human Resources:

Staff and laboratory personnel involved in TB Diagnostics (Please enter details separately for all staff working on each of the technologies, Enclose organogram)

Name of Staff	Designation	Qualification	Diagnostic Technology	Training in		Received NTEP training		Years of experience in relevant technology	Remarks
				Yes/ No	Date of last training	Yes/ No	Date of last NTEP training received		

IV. Physical Infrastructure of the Laboratory Section (Enclose layout of laboratory floor plan)

Sub-section	Within the Lab, TB activities conducted in		No. of rooms
	Separate space	Shared space	
Registration			
Smear preparation, staining and reading			
Washing room			
Sterilization room			
Media preparation			
GeneXpert room			
Truenat Room			
Master mix room			
Amplification room			
Hybridization room			
BSL 3 laboratory/TB Containment Laboratory			
BSL 2 laboratory			
Culture (LJ) reading room			
Equipment room (if any, including walk-in incubator and cold rooms)			
Store room			
Staff room			
Walk-in cold room			
Walk-in incubator room/ space for keeping incubators			

V. Equipment and Maintenance

a. List of major test equipment available for use (attach a separate sheet, if required)

Name of equipment	No. of units available	Date of installation	Date of last Maintenance	Annual/ Quarterly Maintenance due on	AMC in place	Downtime – (No. of days in last year)	Alternate arrangement in case of downtime (Yes/No)
TB Containment Lab							
Gene Xpert- 6 colour (No. of modules)							
GeneXpert 10 colour (No. of modules)							
Truenat (Duo/Quatro)							
Microscope							
Refrigerated Centrifuge							
MGIT 320/ 960							
Autoclave							
Water Bath							
Micro incinerator							
Microlitre centrifuge							
Inspissator							
Thermocycler							
GT Blot							
Twincubator							

Name of equipment	No. of units available	Date of installation	Date of last Maintenance	Annual/ Quarterly Maintenance due on	AMC in place	Downtime – (No. of days in last year)	Alternate arrangement in case of downtime (Yes/No)
UV hood							
Spinwin							
Vortex							
pH meter							
Hot Air Oven							
Deep Freezer -80							
Deep freezer -20							
Refrigerator							
Autoclave							
Incubator							
Weighing balance							
Universal oven							
Walk-in Cold Room							
Walk-in Incubator							
Distillation Unit							

Use extra sheets/rows if needed

VI. Method of Culture and Drug Susceptibility Testing Currently Used

Sl. No.	Particulars	Methodology (wherever applicable)
1	Registration of specimens (LIMS/HIS/Manual)	
2	Primary culture method (NALC-NaOH etc.)	
3	Culture Media (brand/company if readymade / in-house preparation)	
4	Drugs/Drug media' (prepared in-house/ brand if commercial/ drugs used/ concentrations used/ method of calculation of drug concentration etc)	
5	DST Method (Direct/ Indirect/MIC/Proportion)	
6	Anti-TB drugs for which DST is being performed (First and Second Line)	
7	Standard cultures used ($H_{37}Rv$/other NTM standard strains, ATCC numbers, and their maintenance)	

VII. Laboratory workload analysis

a. Details of tests done during the last year (year ……)

Details of GeneXpert tests performed					
Total tests performed	MTB not detected	MTB detected and RIF resistance not detected	MTB detected and RIF resistant detected	Error/invalids/no results	Spare capacity (Tests/day)

Details of Truenat tests performed									
Total MTB tests perform-ed	MTB not detect-ed	MTB detec-ted	Invalids / errors	Total RIF tests perform-ed	RIF resistance not detected	RIF resistant detected	Errors	Indeter-minates	Spare capacity (Tests/ day)

Details of LPA (First Line) tests performed								
Total DNA subjected to LPA	Total Susceptible	Resistant			Invalid	MTBC Not Detected	MDR TB cases detected	Spare capacity (Tests/day)
		HR	R	H				

Details of LPA (Second Line) tests performed SL LPA (FQ&/ SLID)								
Total DNA subjected to SLPA	Total Susceptible	Resistant				Invalid	MTBC Not Detected	Spare capacity (Tests/day)
		FQ+SLID	FQ	SLID	Mono low-level KAN			

Details of Liquid cultures performed						
	Total cultures performed	MTB +ve	Culture -ve	Nontuberculous mycobacteria (NTM)	Contamination	Spare capacity (Tests/ day)
Diagnosis						
Follow up						
Total						

Details of Liquid culture (Second line DST) performed					
Number of SL DSTs conducted	Total Susceptible to FQ & SLID	FQ resistance detected	SLID resistance detected	DST Contaminated	Spare capacity (Tests/ day)

VIII. Quality Control System

A. Describe how Quality Control (QC) & External Quality Assessment (EQA) are implemented

Sl No	Components	Quality Control	EQA*	TAT
1	Smear microscopy			
2	Truenat			
3	GeneXpert			
4	Liquid culture (controls used/frequency)			
5	Liquid culture DST			
6	Line Probe Assay			

* NTEP provides free-of-cost panels for EQA of GeneXpert and Truenat (kindly visit https://www.naateqa.in/ for further registration). Laboratories interested may send the request to NRL National Tuberculosis Institute (NTI) Bangalore at Email: NRLBLRNTI@rntcp.org

B. Proficiency testing results of the laboratory (external proficiency testing) for last two years (for Smear, NAAT, LPA and LC DST as applicable)

Sl. No.	Test / culture	Details of Test(s)	Date of Testing	Nodal Laboratory (Accreditation body/ Country)	Performance (percentage of sensitivity/ specificity/ positive and negative predictive values/ efficiency)	Corrective action taken if any

IX. Bio-Safety Practices

i) House-keeping activities

Sl. No	Equipment	Frequency of Cleaning	Disinfectants used
1	All work-surfaces, telephones, sinks, door handles, drain taps		
2	Floors		
3	Biosafe centrifuges, biological safety cabinets, incubators, refrigerators etc.		

ii) Is the Laboratory layout designed to control the airflow? Explain briefly

iii) Enlist the bio-safety tests conducted for each Bio-safety cabinet and attach the certificates

iv) Is the staff trained in Biosafety and spill management and appropriate PPE available?

v) Is engineer/engineering support available in the facility

X. Bio-medical Waste Management and Disposal

i) Solid and Liquid waste decontamination method:

ii) Describe the process of waste disposal and Linkages/MOU with the agency:

XI. Procurement and Distribution of Supplies and Equipment

i) Is there a plan for the procurement and distribution of supplies (laboratory reagents, consumables, etc.) for the current year

ii) Who is responsible for the procurement of supplies and equipment? Describe the system of recording and reporting for the status of supplies and equipment within the laboratory system.

iii) How is the availability of spare parts of the equipment and minor repair ensured?

iv) Has there been any interruptions in laboratory work due to shortages of supplies/ equipment downtime?

v) What mechanisms are in place to prevent interruption of work due to shortages of supplies and equipment? If there is a policy to keep a buffer stock of supplies and equipment or are their linkages with some other labs/facilities in such conditions and is the linked lab certified by NTEP? Please describe.

vi) Are there any major constraints in the procurement of equipment and supplies in TB diagnostics

Letter of Willingness for Certification of diagnostic tests with NTEP

To,
The State TB officer
National Tuberculosis Elimination Programme (NTEP)- Name of the State

Sub: Willingness to participate in the certification process by NTEP

Dear Sir/Madam,

We wish to enroll in the certification process by NTEP. Please find attached the duly filled application form for your kind perusal. **We clearly understand that certification does not guarantee the participation of the laboratory in NTEP Diagnostic services and will be dependent on the requirements of the state.** The certification if provided would be only for the _____ branch. Through this certification, patients will be assured of quality diagnostic care, therefore, avoiding the testing again in the public sector, and prompt initiation of treatment
We hereby declare that we have access to the latest versions of the following documents:

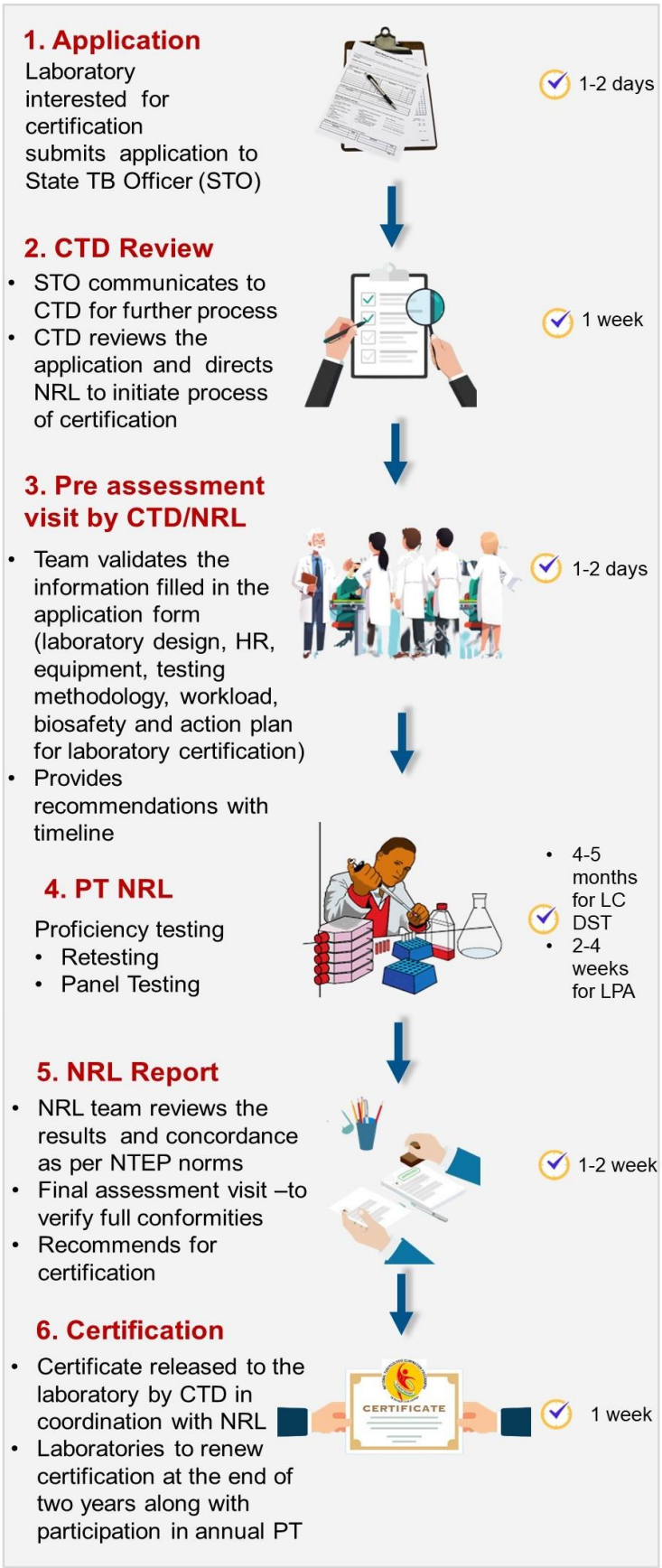
1. Training manual & SOPs of culture & DST, CTD, Dte.GHS, New Delhi, 2005.
2. Guidelines for programmatic management of Drug resistant Tuberculosis in India,
3. Guidelines on airborne infection control in healthcare and other settings
4. Guidelines for Surveillance of Drug Resistance in Tuberculosis, WHO/ CDS/ TB/ 2003.320, Second Edition
5. Guidelines for quality assurance of smear microscopy for diagnosing Tuberculosis CTD, Dte.GHS, New Delhi, 2005
6. Practical guide to implementation of Truenat tests for detection of TB and Rifampicin resistance (Stop TB partnership)
7. GLI TB laboratory safety handbook
8. GLI guide for the interpretation and reporting of Line Probe assay
9. GLI Mycobacteriology laboratory manual
10. WHO TB laboratory Biosafety manual
11. WHO Technical manual for drug susceptibility testing of medicines used in the treatment of tuberculosis
12. GLI Training Package on DST by Phenotypic and Molecular Methods
13. All other TB laboratory manuals, modules and guideline documents published by NTEP, National and International authorities

The laboratory is committed to ensure complete and timely entry of patient details and test results on the Ni-kshay portal, comply with NTEP recommended TAT for the identified tests and NTEP certification criteria.

With Regards,
(Signatures of Head of Laboratory/or Authorized representative)

Name, Designation----------
Date

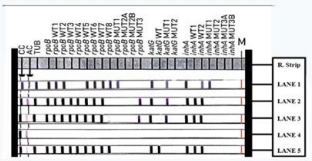
Annexure 1: Private Laboratory Certification Process in NTEP



PROFICIENCY TESTING (LPA)

50 smear positive samples in duplicates to be tested

100 DNA samples subjected to FL/ SL LPA along with quality control samples



Scanned copy of strips along with interpretation to be shared with NRL

NRL selects 20 DNA samples for retesting

For SLLPA: 50 smear positive sputum specimen from Rifampicin Resistant patients

LPA Proficiency benchmark

Invalid results : less than 10%
Contamination of negative control: clean in all runs
Internal concordance: >95% for FL and SL drugs
External concordance: >95% for FL and SL drugs

Selected DNA extracts (20 µl) sent to NRL

Note: Subsequent to attaining certification, laboratory is assessed through annual PT panel consisting of 20 blinded cultures sent to the laboratory

PROFICIENCY TESTING (LC-DST)

Phenotypic (MGIT)

Retesting

(Performed once when laboratory applies for certification)

Laboratory performs 100 DST for first line and 50 DST for second line anti-TB drugs

Results shared with NRL.
NRL selects 10 culture isolates with different resistance pattern in DST for retesting

Retesting performed at NRL and concordance shared with laboratory & CTD

Panel Testing

(Performed annually and also at the time of certification)

20 culture isolates representing different resistance patterns sent to laboratory by NRL

Laboratory performs DST for FL and SL (as applicable) and shares result with NRL

NRL shares concordance with laboratory and CTD
CTD issues the certificate based on the NRL recommendations

For more details, please refer to "NTEP Guidance Document for NABL Accreditation Assessment of Tuberculosis Laboratory in Private Sector"

Desired Concordance

H, R and Z ≥90%
S and E ≥80%
SL drugs and newer drugs ≥90%

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