Minutes of 19th National Laboratory Committee meeting
19th January 2011

Venue: Gandhi Medical college, Hyderabad ***Time: 2.00 PM***

The 19th National Laboratory committee meeting was held at Conference Hall, ART Centre of Gandhi Medical College, Hyderabad on 19th January 2011. Agenda and list of participants are annexed at annexure-IV and annexure-V respectively.

DDG-TB welcomed the participants and appreciated the support to the programme from all the National Reference Laboratories.

The NRLs presented an update on the status of accreditation of laboratories. During the presentations, the following recommendations were made by the committee.

Update by NTI:
Mr. Anand, Microbiologist, NTI presented about the accreditation status of the labs supported by NTI. The following recommendations were made during the discussions.

- The pre-assessments of the laboratories of Jammu and Kashmir have been long pending due to local problems. This was discussed and considering that there has been an improvement in local situation in the state, it was recommended that a team led by NTI and including FIND, PATH and CTD should visit the state at the earliest for a detailed laboratory assessment.
- It was noted with concern that IRL Nagpur had failed proficiency testing for Rifampicin DST using solid media in spite of re-training the IRL team of microbiologist and LTs. NTI informed that an on-site training has been conducted by the microbiologist since and all the issues have been identified. Another round of proficiency testing has been initiated and the results would guide the future course of action.
    - *As a policy, the committee recommended if a laboratory fails the annual proficiency testing (in solid DST) after accreditation, the lab team has to be retrained and a fresh round of PT to be initiated. If the lab fails proficiency again, then the results of laboratory (using solid DST) should not be used for patient management while continuing to use LPA DST results and solid culture. If the laboratory fails a third round of PT, then the accreditation status of the laboratory should be derecognized.*
- DDG urged that the various laboratories in the private/NGO sector which have passed proficiency testing be accredited at the earliest as this was discussed at the Health Ministers and Secretaries meeting held in Jan 11 as action points.
- To the concern that many private/NGO laboratories are not willing to sign the MoU after accreditation citing pricing constraints in the existing scheme, it was decided that all future accreditations should be initiated only if the laboratory is committed to provide services to RNTCP as per guidelines. All the laboratories that have passed PT currently should be accredited for 6 months, with a pre-condition that the same would be reviewed subject to provision of services under RNTCP.
- The BMHRC laboratory at Madhya Pradesh has been taken over by Department of Atomic Energy (DAE), a government department thus making it ineligible to sign a culture DST scheme under RNTCP. It was recommended by the committee that Central TB Division should discuss with the concerned in the DAE at central level for facilitating this process so that the services of the laboratory can be used under RNTCP.

- The ICMR lab at Jabalpur has expressed the need for additional human resources for extra workload arising due to planned provision of services to RNTCP. In this regard, it was decided that CTD (after receiving updated feedback from STO, Madhya Pradesh) should communicate to Dr. Katoch, DG-ICMR to issue necessary directions to the Director RMRCT, Jabalpur.
- Since, Madhya Pradesh is a large state with more than 50 districts and a population of about 71 million, the need for a second IRL is completely justified. The activities at IRL Indore are progressing as per plan since shifting of IRL from Bhopal. Since the laboratory at Bhopal is in the preliminary stages of its development with no budgeted provision of equipments under RNTCP, it was recommended that alternative mechanisms of funding like NRHM additionalities may be explored. As an alternative, it was suggested that the lab at BMHRC may be re-designated as the second IRL of the state and considered part of the National laboratory scale-up plan for deploying rapid diagnostics including LPA and to receive additional HR support. The feasibility and long term sustainability of this partnership should be explored by STO MP with BMHRC and intimated to Central TB Division for further directions.
- *As a policy, the committee recommended that all NRLs should meet once every quarter along with CTD, WHO and other partners like FIND and PATH to review the progress and issues related to individual laboratories and that only policy issues need to be brought to National Laboratory Committee. These meetings will be coordinated by the WHO Lab Focal Point and supported by PATH.*
- It was decided to conduct Training on Bio-Safety at ICELT, NTI in collaboration with FIND, CTD and NTI.

Update by JALMA:
Dr. Chauhan, microbiologist from JALMA presented about the labs coming under the purview of JALMA. The committee stressed upon the report of accreditation visit made by JALMA to KGMU Lucknow and also emphasized to complete the accreditation visit to IRL Dehradun. It was also decided that the certificates for these labs would be sent by CTD at the earliest.

Update by TRC:
Dr. Vanaja Kumar, Microbiologist from TRC Chennai presented about the activities carried out by the institute for the labs coming under their purview. It was informed that a software called "e-PROCULTB", which provides an electronic system for recording of PT results and reporting, is being used by TRC. The committee recommended that this software may be shared with the other NRLs after a demonstration in the next quarterly meeting.

To ensure uniformity across the country, the committee recommended that Proficiency Panels for DST would be sent to all the accredited labs annually in the month of February by the respective NRLs.

Update by LRS:
Dr. Niti Singh, Microbiologist from LRS presented about the activities carried out by the Institute.

To the concern noted by NRLs regarding the delay in release of funds, DDG-TB mentioned that this is due to the delay in submission of Statement of Expenditure (SoE) and Utilization Certificates (UC). He also informed that in case of such situations, the respective organizations may use their own funds which may be refilled once they receive funds from Central TB Division so that the planned activities are not disrupted.

Accreditation reforms and endorsements:
Dr.Ranjini Ramachandran, WHO SEARO, presented about the accreditation reforms.
In the presentation, the status of accreditation of C&DST lab in the concerned NRLs was highlighted.

Name of NRL	Accredited	Pending	In process	Not yet initiated
NTI	5	0	2	5
TRC	4	0	1	5
LRS	1	1	0	2
JALMA	0	2	0	2

There were 11 laboratories that have passed proficiency testing and are awaiting accreditation.

1. IRL Dehradun, Uttarakhand
2. IRL Lucknow, Uttar Pradesh
3. IRL Karnal, Haryana
4. JJ Hospital, Mumbai, Maharashtra
5. T Choitram – Indore, Madhya Pradesh (MoU)
6. BMHRC – Bhopal, Madhya Pradesh
7. PGI Chandigarh
8. QUEST- Gurgaon, Haryana (MoU)
9. SRL-Gurgaon, Haryana (MoU)
10. SRL-Mumbai, Maharashtra (MoU)
11. DFIT Nellore, Andhra Pradesh (MoU)

The experience with the existing accreditation process was briefed. The existing accreditation process of solid/liquid culture and DST is slow resulting in enormous delays in service delivery. Delays especially for RT (Re-testing) and PT (Proficiency testing) process, Delays in accreditation visits (due to various reasons) and delays due to suboptimal coordination between IRLs/NRLs/CTD mean that the lead time for accreditation is between 8-24 months. In view of the targets set in National Laboratory Scale-up plan wherein about 43 laboratories in Line Probe Assay and 33 laboratories in liquid culture and DST have to be accredited in addition to the Solid culture and DST accreditations ongoing by 2013, it was necessary to bring reforms in the accreditation process. It was noted in the pinch-point analysis done by Clinton Foundation that the rapid scale-up in laboratory capacity is essential to meet MDR-TB scale-up plans and avoid expiry of costly second line drugs. The following accreditation reforms were proposed to avoid the accreditation delays which in turn would derail all planned scale up targets for laboratories and PMDT.

1. Currently, unless a laboratory is accredited for solid DST, it cannot be accredited for other rapid diagnostics like LPA. This creates difficulties in adhering to the committed timelines of developing LPA labs with assistance through EXPAND TB project. Hence, it was decided that accreditation process for LPA be independent of the accreditation process of conventional DST and may be initiated simultaneously.
    - *However, it was emphasized that the lab should have capacity to perform culture using conventional methods (either solid or liquid culture) before LPA accreditation process to enable examination of follow-up specimens from MDR-TB patients on treatment (which will be assessed by the NRL during an OSE based on the existing laboratory performance indicators).*
2. The proficiency testing mechanism for LPA (detailed later), as endorsed by the lab committee will be used for LPA accreditations. Initially, Proficiency testing

will be done by JALMA and coordinated by CTD/FIND. The committee recommended that PT for other NRLs (NTI, TRC and LRS) needs to be completed on priority in the next 4-6 weeks. Further to this accreditation – PT may also be done by other NRLs (with support from Lab task force & ICELT).

3. It was decided to simplify the application forms for accreditation containing minimum essential information.
4. Acknowledging the enormity of task of developing many laboratories in the next 2 years, the committee recommended that the NRLs take the assistance of other technical partners like FIND and PATH in undertaking detailed laboratory assessments. Preferably, pre-assessment visits should be planned to be conducted by a team consisting of NRL, FIND, WHO and CTD. In case it is not possible, the other available team members may conduct the assessment visit and the findings shared with all the technical partners. Once the observations and recommendations are endorsed by the concerned NRL and CTD, the report may be sent to the concerned laboratory/state for further action.
5. Once the infrastructure facility in the lab has been developed and assessed by the NRL, RT and PT will be completed by NRL and confirmation of satisfactory performance in proficiency testing will be communicated to CTD. It was recommended that CTD will then send the accreditation certificate electronically to the concerned lab with a copy to NRL.
6. Involvement of labs (accredited) in other government sectors (Defence, DAE, ICMR) etc will require further streamlining to add value to the RNTCP lab services. The committee recommended that CTD should engage with the concerned departments/ministries in this regard. DDG-TB clarified that there is no provision of funding these laboratories for infrastructure up gradation, equipment procurement or deployment of additional human resources unless the laboratory is in the national lab scale-up plan.
7. It was suggested to accredit new laboratories only for INH and RIF initially; DST for SM and EMB can be taken in a phased manner. It was also proposed to make routine DST for HROK (Isoniazid, Rifampicin, Ofloxacin and Kanamycin) instead of HRES. It was decided that this may be started at IRL Ahmadabad & Hyderabad, with Ofloxacin and Kanamycin DST initially set up on both solid and liquid media after training the concerned microbiologists at the earliest. This approach reflects programme need for timely diagnosis of fluoroquinolone resistance. The committee also recommended that routine training for culture and DST for all IRL microbiologists and technicians should include training for Ofloxacin and Kanamycin DST as well and the laboratory standard operating procedure (SOPs) should be modified to reflect the same.

The recommendation from WHO (2010) on use of serologic testing and IGRA for TB diagnosis was presented to the committee:

- Commercial serological tests provide inconsistent and imprecise estimates of sensitivity and specificity. There is no evidence that existing commercial serological assays improve patient-important outcomes.
- Overall data quality was graded as very low and the Expert Group strongly recommended that these tests not be used for the diagnosis of pulmonary and extra-pulmonary TB.
- Active TB: The quality of evidence for use of IGRAS in diagnosis of active TB was low and it is recommended that these tests should not be used as a replacement for conventional microbiological diagnosis of pulmonary and extra-pulmonary TB in low- and middle-income countries (strong recommendation).
- LTBI: The quality of evidence for use of IGRAS for LTBI screening in various groups (HIV, contacts, children, HCWs) was very low and recommended that these tests should not be used as a replacement for TST for the assessment of LTBI (strong recommendation).

The committee endorsed the negative policy recommendations from WHO (2010) and suggested CTD to disseminate this among the medical professional associations of the country. It was noted that this has already been endorsed by Indian Association of Pediatrics.

It was noted with concern that in spite of these recommendations, such tests are widely available in the Indian market. Hence, there is a need to take this matter with Drug Controller General of India (DCGI). It was informed by Dr Puneet Dewan that RNTCP can propose the minimum performance standards that a diagnostic test should fulfill before its permitted use and share with DCGI for implementation. DDG-TB informed that a Inter-ministerial committee has been formed to discuss and decide on the minimum performance standards for all laboratory diagnostics tests by Government of India and NCDC is part of the committee.

- The lab committee recommended that CTD should prepare a brief on the minimum standards of performance for a TB diagnostic and represent to the committee duly constituted for the purpose.

EQA for LED based fluorescent microscopy

The fluorescent microscopy is being carried out at IRL and tertiary hospitals and it was decided to use the results for patient management. It was recommended that the patient's sputum examination results from FM under EQA are to be treated equally under the programme as results from conventional ZN under EQA. **Dr. Ranjini suggested that there is a need to** update the EQA module for smear microscopy at the earliest to incorporate and adapt the newer EQA protocol on Fluorescent microscopy. This was agreed by the committee and NTI proposed to host a workshop for updating this module.

Multisite demonstration of the use of cartridge-based automated NAAT (Xpert-MTB/Rif) under programmatic conditions

A proposal for evaluating cartridge-based NAAT as the initial diagnostic test for TB suspects in 18 TUs in various settings (high HIV, high MDR and low risk rural areas) were presented by Dr. Puneet Dewan, MO-TB, WHO-SEARO. The committee raised the concerns about the high costs of equipment, reagents and its operational feasibility under programmatic conditions, but agreed on the need to develop in-country evidence for scale-up through such demonstration projects before decision of its wider use. The activity was endorsed, and it was suggested that the inputs of the members of lab committee may be incorporated into the detailed protocol.

DRS (Drug Resistance Survey):

DRS study has been planned for 2011-12 in the States of Rajasthan, Tamil Nadu, Madhya Pradesh and West Bengal. It was decided to try LQAS (Lot Quality Assurance Sampling) method for conducting the survey and validate the methodology as this would mean a substantial reduction in sample size and rapid availability of results for decision making. Further, it was also decided to represent the private sector in the study sample so as to obtain information on magnitude of DR-TB in private sector as well. It was recommended that information on HIV status of the participants should be collected as part of the DRS in all future surveys.

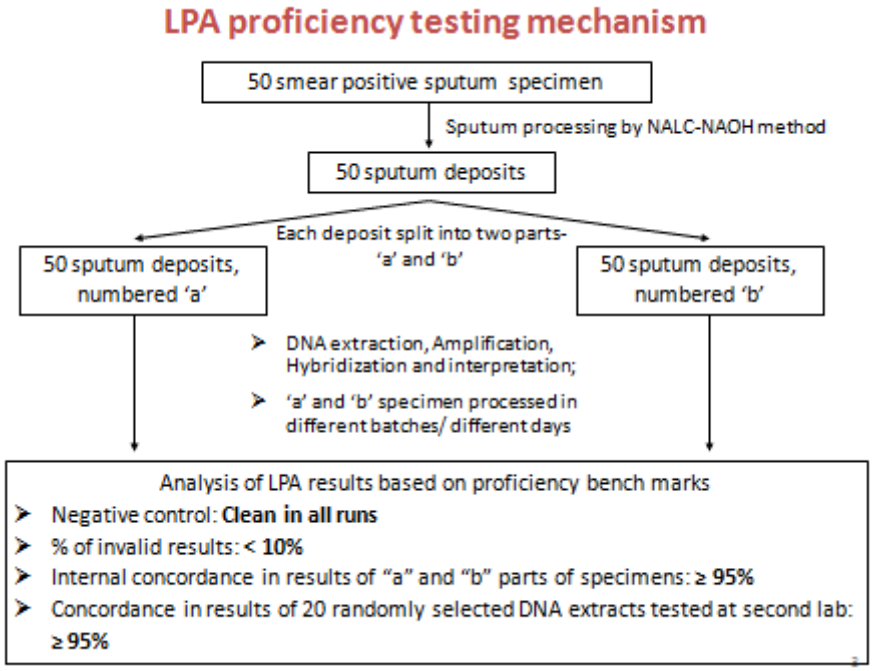
LPA proficiency testing:

The presentation on LPA proficiency testing was made by Dr. DS Chauhan, Microbiologist from JALMA and it was endorsed by the lab committee.

The installation of LPA equipment and staff training using standardized operating procedures will be done which is common across all the laboratories.

LPA proficiency testing (LPA PT) mechanism:

1. Each laboratory will be undertaking LPA testing on 50 smear positive TB patients.
   - √ These could be any smear-positive diagnostic specimen from re-treatment (preferable) or new patients, taken freshly the same day after routine microscopy.
   - √ Since the turnaround time for a LPA test is 8-12 hours and LPA proficiency testing can be finished in a maximum of two weeks, including specimen collection, processing, testing, and transportation of specimens to external lab for panel testing; **hence sufficient arrangements should be made with DMCs to collect sufficient fresh specimens after routine microscopy**.
   - √ Sputum should only be collected fresh, without any CPC. Before transportation the specimen should be preferably **stored in a refrigerator** from the time of collection.
2. During this LPA PT, one smear-positive sputum specimen per patient would be anonymized (stripped of name and any personal identifiers), assigned a number, and processed by NALC-NAOH method. After processing, each specimen deposit should be split into two parts, recorded as "1st" and "2nd". Each specimen part should be individually subject to DNA extraction, amplification, and hybridization (Total 100 LPA tests on 50 patient specimens). The 1st and 2nd parts should be tested on different days/batches.
3. Processed sputum deposit, DNA extracts and PCR products of all samples are to be stored at -20C.
4. Once sample size of 50 patients is achieved, High-resolution scanned images of the 'line-probe result form' and line probe assay result strips (scotch-taped onto separate LPA-run form) should be sent to JALMA and FIND by e-mail.
5. 20 of the 100 DNA extracts will be randomly selected (by FIND/CTD/JALMA) for testing for external concordance.
6. Selected DNA extracts should be sent by express courier using routine shipping procedures to either JALMA or another external lab identified by JALMA.
7. Blinded LPA testing on the 20 DNA extracts sent to JALMA/identified external lab would be conducted by lab staff. Once the results of the blinded testing are available, these results would be compared with the original results from the lab undergoing LPA PT for concordance.
8. Once the pilot and proficiency phase has been satisfactorily completed, the site would be assessed for proficiency, based on the indicators below.
   a. Proportion of invalid LPA results; PT benchmark : less than 10%
   b. Contamination of negative controls- PT benchmark : Clean in all runs
   c. Internal concordance: Concordance of results between 1st and 2nd tested parts for each specimen; PT benchmark : Should be **≥ 95%**
   d. External concordance: Concordance of results of randomly selected specimens with the reference site; PT benchmark : Should be **≥ 95%**



9. If satisfactory results are obtained, the site would commence the LPA testing on DR-TB suspect specimen. Subsequent to attaining LPA testing proficiency, the lab would be monitored on an annual basis on basis of:
    1. Proportion of invalid LPA results; less than 10%,
    2. Frequency of Contamination of negative controls
    3. JALMA would be sending panel of 20 blinded DNA extracts (with standardized DST results on LPA, Liquid Culture and LJ DST) to each lab on annual basis/ need based (in case any technical issue with LPA testing is identified). This Panel would comprise of :
        - H37Rv
        - MDR with common rpoB and katG mutation
        - MDR with common rpoB and inhA mutation
        - MDR with uncommon rpoB and katG mutation
        - MDR with uncommon rpoB and inhA mutation (not a must to have this strain)
        - Mono INH resistant with katG mutation
        - Mono Rif resistant with common rpoB
        - Mono Rif resistant with uncommon rpoB
        - NTM (M. gordonae)

    The sending on specimen to the lab would be coordinated by JALMA and FIND

The committee was informed that LAMP validation is being conducted at MGIMS Wardha in association with FIND

Update by PATH:
The activities of PATH were briefed by Dr.Satish, Director PATH. On the issue of the labs to be selected for LPA up gradation in the States of Maharashtra and Rajasthan, the committee recommended the States to take the final decision. The PATH has planned the laboratory experience sharing workshop in the month of April 2011. **PATH will also support the quarterly NRL meetings in consultation with CTD and WHO.**

The lab committee decided to develop a comprehensive national preventive maintenance guidelines for Laboratory equipments on the lines of a recent WHO guidance in consultation with NRLs, WHO, CTD and PATH.

Update by FIND:
The activities carried out were briefed by Dr.Rahul Thakur. FIND has provided LPA equipments, human resources and training to six C&DST laboratories and by the end of March 31, 2011 FIND has planned to expand to another nine C&DST laboratories.

Modified laboratory records and reports:
The updated laboratory and Culture DST register and laboratory management report (HR, supplies) and the experience in the programme with using the new formats were shared by Dr.Puneet Dewan

- The committee endorsed the new formats; CTD to immediately circulate the same to all the labs for immediate printing and use.
- It was acknowledged that training would be required on new recording and reporting formats, and it was agreed to call laboratory staff to NTI for one-time training, or to use the planned PATH laboratory experience sharing workshops as training opportunities on recording and reporting. In addition, during field visits by any technical support (NRL, FIND, PATH, WHO), the R&R system and practices should be reviewed and any deficiencies corrected. (The forms are attached as Annexure – I, II & III)

Follow-up cultures for MDR-TB patients – 2 v/s 1 specimens:

Dr.Ajay Kumar, WHO Consultant, presented the data of a brief operational research which was conducted to assess the impact of a reduction in the number of follow up sputum specimens from 2 to 1 for MDR-TB patients. The objective of the OR was to assess the sensitivity and negative predictive value of single specimen strategy. The research suggested that Sensitivity and NPV of single specimen strategy are 82% and 96.5% respectively. This will lead to a substantial decrease in lab workload which can be leveraged for increased diagnostic work-up capacity with minimal clinical and programmatic impact.

- The committee agreed that 2 follow up specimens is likely to be unnecessary, and that it is primarily a clinical decision, not a laboratory decision, about whether the additional yield is worth it. Particularly in the context of limited nationwide laboratory capacity, it was acknowledged that freeing up laboratory capacity for MDR diagnosis will be more advantageous for the programme and for TB control than the additional information offered by the 2nd follow-up specimen on a very small number of patients. Also, it was acknowledged that collection of a single follow-up specimen would be operationally highly advantageous for decentralization of services, specimen transportation, and reducing patient and programme staff burden.
- The lab committee recommended that additional data on the clinical and programmatic impact of this strategy should be collected and presented to National DOTS-Plus committee for a final policy decision.

Culture and DST PPM Scheme for engagement of private laboratories:
The national DOTS plus scale-up plan was reported as showing that engagement of private/NGO laboratories for culture and DST services will be essential to meet patient treatment targets, and will be more important if further delays occur in IRL accreditation or lab expansion at crucial sites.
Dr.Ajay kumar, WHO Consultant presented about the weakness of the existing culture and DST schemes and proposed the changes that can be considered to include in the existing schemes. The key weaknesses were as follows

1. The prices were worked out keeping only Solid Culture and DST in mind – *but programme laboratories offering rapid DST as standard of care*. This is not

sufficient to compensate new rapid technologies including automated liquid C&DST and LPA.
2. No compensation for retesting of specimens in case of contamination.
3. No clear financial guidelines on specimen collection and transport for states.
4. Inflexibility of the scheme to accommodate specimen packaging and transport costs within current scheme reimbursement and consequent inability to take full advantage of existing excellent collection network and transport logistics available from large private labs.

The committee agreed that the existing scheme was inadequate in both compensation and flexibility, and decided that CTD should work on

1. Amending the existing C&DST scheme to address the above weaknesses
2. Amending the existing sputum collection and transport scheme to accommodate the transport of specimens for C&DST and communicate to all stakeholders after internal administrative and financial approval.

LPA and solid backup:

Currently, LPA alone remains the standard of care for basic DST, as per the decision of the previous laboratory committee meetings, the 3 original demonstration sites were to continue backup solid DST to add to the evidence base about correlation between LPA and phenotypic testing. Although the backup testing is beginning to limit the capacity of the IRL; the laboratory committee agreed that the LPA-LJ correlation data should be compiled and reviewed by a NRL before cessation of the activity by CTD.

Annexure – I

RNTCP Request for Culture and Drug Sensitivity Testing

(MO-PHI/DMC will initiate three copies, two copies to be sent to DTO. DTO sends one copy to Culture and DST laboratory. The laboratory will send electronic copies with Culture & DST results to the DTO and DOTS- Plus site)

Date _____ Name and address of referring health facility (PHI/DMC/DOTS-Plus site):_____

-

_____

_____

Name and address of DTC: _____-

_____

Patient Name: _____ Cat I/ Cat II / Cat III/ DOTS-PLUS TB No. :_____

Age: _____ Sex: M ❑ F ❑

Address (with landmarks)

_____

Sputum: Date of Collection: Sample 1 _____ Sample 2 _____

Diagnosis ☐ | 0 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 15 | 18 | 21 | 24 | 27 |

Follow up

Any other ☐ Second line DST ☐

Signature of MO of PHI/ DMC/DOTS-Plus site: _____

Smear results: Lab. Serial No.: DMC _____

Date of Examination	**Specimen**	**Visual appearance (M, B, S)***	**Results** (Neg or Pos)	**Positive (grading)**			
				3+	**2+**	**1+**	**Scanty ****

* M = Mucopurulent, B = Blood stained, S = Saliva ** Write actual count of AFB seen in 100 oil immersion fields

Date: _____Signature of MO-DMC/PHI _____Signature of DTO_____

LPA test results:

Test Valid / Invalid: **Valid** ☐ **Invalid, Please send a fresh patients specimen** ☐

Rifampicin: **Resistant** ☐ **Sensitive** ☐

Isoniazid: **Resistant** ☐ **Sensitive** ☐

Date _____ Reported by (Name & Signature) _____

LJ / Liquid Culture results:

				Culture Result (check one)						
Date Received	Specimen	Laboratory Specimen No.	Smear result	Neg	Pos	1 – 19 Colonies*	+*	++*	+++*	Contaminated/ Other result
	A									
	B			`						

Date _____ Reported by (Name & Signature) _____

* Not applicable for liquid culture

LJ / Liquid culture DST Results: (Note: Enter 'S' if susceptible and 'R' if resistant)

Date DST Initiated	Laboratory Specimen No.	S	H	R	E	Z	Km	Ofx	Eto	Others		

Reported by (Name and Signature) _____
Date_____

(Electronic copies of completed form with results should be sent promptly from Culture & DST Laboratory to DOTS-Plus Site and DTO

Annexure – II

Specifications for RNTCP Culture and DST Lab Register and formats

1.	Size:	11 inches X 16 Inches
2.	No. of Pages:	101 Sheets (pages Nos. 1-100 to be stamped)
3.	Paper:	
	a. Cover	Hardcore binding with cloth / rexin corners with end leaves
	b. Text	95 GSM Super sunshine/ ledger paper (light green color)
4.	Printing:	
	a. Cover:	1+0 color
	b. Text	1+0 color
5.	Fabrication:	Stitching with good quality hard-case binding on 11 inch side
		(Landscape)

Specimen Registration, LPA, Culture, and DST Results Register Month_____________ Year____________

S. No.	Lab Specimen No.	Lab PID	Name (in full) & address	Age	Sex (M/F)	Name of referring site (DMC/DOTS-plus site) & District	Reason for Testing* (Dx/FU)	MDR Suspect Criteria†	Diagnosis		Follow-up		Specimen	Date specimen collected from patient	Date received in culture lab	Specimen condition (CPC, MP, BLD, SAL, Contam) §	Culture lab smear result ¶
									RNTCP TB Reg No.	RNTCP TB Registration Type‡	DOTS-Plus Number-Year	Month of F/U					
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				
													A				
													B				

* Dx = Diagnostic specimen, FU= Follow-up specimen

† RNTCP MDR Suspect Criteria (Only record a single value)

1. **Cat I Smear positive at 5th month follow-up or later**
2. **Cat II Smear-positive at 4th month follow-up or later**
3. **Smear-positive after Intensive Phase of RNTCP regimen**
4. **Smear-positive, with more than one month of previous anti-TB treatment**
5. **Contact of known MDR TB case**

‡ Using standard RNTCP definitions for TB type of cu: **NSP, NSN, NEP, Relapse, TAD, Failure,** or **Other**

§CPC=specimen contains CPC. For all other specimens with no CPC, describe condition: **MP**=mucopurulent specimen, **BLD**=gross blood in specimen, **SAL=**Salivary specimen, **Contam** if gross bacterial overgrowth is suggested by visual examination.

¶Smear results for specimen deposit after concentration in culture laboratory, using standards definitions: **3+, 2+, 1+ , Sc, Neg.**

LPA Rapid DST Results					Culture Results				Standard DST Results									Date Sending Report to DOTS-Plus Site & DTO			
Date Tested	PCR valid* (Y/N)	TUB † (Y/N)	INH ‡ (R/S/NA)	RIF ‡ (R/S/NA)	Date Inoculated	Type (Solid / Liquid)	Results §	Date Result Reported	Date Inoculated	Type (Solid / Liquid)	SM (R/S)	▼ INH (R/S)	▼ RIF (R/S)	EMB (R/S)	FQ ¶ (R/S)	Inj ¶ (R/S)	Date Result Reported	LPA	Culture	DST	Remarks

*** PCR Valid=Y** if <u>both</u> Amplification Control (AC) band & Conjugate Control (CC) band present; if <u>either</u> are missing, record **N**, and record no additional LPA results for this specimen.
† TUB=Y if M. tuberculosis (TUB) band on LPA strip confirming identity as M. tuberculosis, **N** if no TUB band on LPA strip
‡ R=Resistant, **S**=Sensitive, **NA**=no result, judged by no locus control band on LPA strip for *rpo-B* (RIF), or for *inh-A* or *kat-G* (INH)
§ Negative=no growth, **Contam**=contaminated, **NTM**=Non-Tuberculosis Mycobacteria/fast grower, **3+**=confluent growth, **2+**= >100 colonies, **1+**=10-100 colonies; **Sc#**=Scanty<10 . Positive culture results should only be reported after identity for *M. tuberculosis* is confirmed with PNB, Niacin, Catalase, Rapid Immunoassay, or other methods.
¶ FQ=fluoroquinolone, Inj=injectable aminoglycoside/polypeptide (2nd line). Specify which drug used for testing (e.g. OFX=ofloxacin, LFX=levofloxacin, MFX=moxifloxacin; KA=Kanamycin, AK=Amikacin, CM=Capreomycin.) Specify which laboratory conducted second-line DST in remarks column.

Annexure III

Quarterly Report on Programme Management & Logistics of C& DST Laboratory

Name of the Laboratory:
Date of Reporting:

Human Resource:

S. No	Category of Staff	No. Sanctioned		No. in place		Training status		
		Govt	Contractual	Govt	Contr-actual	LJ C& DST	LC & DST	LPA
1	Microbiologist/ Bacteriologist							
2	Senior LT/Assistant Microbiologist							
3	Lab Technicians							
4	Lab attendants							
5	Cleaner							
6	DEO							

Equipments: Are all equipments covered under AMC: Yes/No
(Attach the list of Equipments not covered)

Equipment Name	Source of supply	Model no.	Date of procurement	Date of Last AMC Exp	Remarks

Instruments: Are all Instruments annually recalibrated:

Instrument Name	No.	Date of Last recalibration	Remarks
Centrifuge			
Thermometer			
Micropipettes			
Electronic weighing balance			

Laboratory Consumables:

Short expiry items

Item	Unit of Measure-ment (UOM)	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Stock Transferred Out *	Consumption during Quarter	Stock on last day of Quarter (a+b+c) – (d+e)	Quantity Requested (e/3*6)-f
		(a)	(b)	(c)	(d)	(e)	(f)	(g)
LPA Kits								
Taq Polymerase								
BBL 7ml tube (no of kits)								
Liquid culture supplement								
LC SIRE kit								
Rif for LJ DST								
INH for LJ DST								
SMP								
ETH								
Are there any items at risk of Expiry, if yes give details:								

Long expiry items

Item	Unit of Measure-ment (UOM)	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Stock Transferred Out *	Consumption during Quarter	Stock on last day of Quarter (a+b+c) – (d+e)	Quantity Requested (e/3*6)-f
		(a)	(b)	(c)	(d)	(e)	(f)	(g)
Falcon tubes(50ml)								
Maccartney bottles								
NaLC								
NaOH								
Phosphate buffer								
Ethanol								
Molecular grade water								

Sodium hypochlorite								
Filter tips (10-100ul)								
Filter tips (1-10ul)								
Filter tips(20-200)								
Filter tips (100-1000ul)								
N-acetyl-L-cysteine (NALC)								
Tri-Sodium citrate dihydrate								
Sodium chloride								
Para-nitrobenzoic acid								
Niacin strips								
Isoniazid								
Rifampicin								
Ethambutol								
Dihydro-streptomycin								
Formalin								
Stable chlorine disinfectant								
Ethanol								
LJ base								
Sodium Hypochloride								
Agarose								
Boric acid								
DNA ladder								
EDTA								
Ethidium bromide solution,								
Gel load buffer								
Sodium acetate trihydrate								
TRIS								
Potassium dihydrogen phosphate								

Di-Sodium hydrogen phosphate anhydrous								
Sodium hydroxide								
Rack for PP-tubes for centrifuge 50 ml								
PP-tubes for centrifuge, sterile, 15 ml								
TIPS, PP, 100-1000 µl, sterile, autoclavable with Filter - Generic								
DEPC Treat Water - Molecular grade water								
Disposable pasteur pipettes, graduated, non sterile, 155 mm, 3 ml								
Surgical gowns non sterile - Size S								
Surgical gowns non sterile - Size L								
Surgical gowns non sterile - Size L								
Shoe cover								
Hair Cover								
Plastic bags - 27L								
Stand for 30L plastic bags								
Single use paper towels								
Brain Heart Infusion agar								

Pipette Tips, Combitips plus Biopur® 10 Ml								
Single use syringes, sterile								
Syringe filter for single use								
Single use plastic Pasteur-pipettes sterile individually packed								
Masks								
Sterile, DNA-/RNAse-free TIPS, 0.1 - 10 µl - Gilson								
Sterile, DNA-/RNAse-free TIPS, 1.0 - 20 µl - Gilson								
Sterile, DNA-/RNAse-free TIPS, 10 - 100 µl - Gilson								
Sterile, DNA-/RNAse-free TIPS, 20 - 200 µl - Gilson								
Sterile, DNA-/RNAse-free TIPS 100 - 1000 µl - Gilson								
Long 1 ml tips with filter								
Cryo-vial, sterile with cap, 1.5 ml								
Cryo-vial, sterile with cap, for one hand operation								
Cryo-tags								
PCR tubes								
Forceps,								

Filter paper - sheets								
Parafilm sealing film								
plastic bottles 500 ml								
Special marker pens for Hain strips								
Tri-pod stand for waste bags of ca. 2 litres								
Plastic bags made from PP								
Laboratory coat size L								
Laboratory coat size M								
Laboratory coat size S								
Latex gloves size L								
Latex gloves size M								
Latex gloves size S								

Name and Designation of Laboratory In charge:_____
E-mail id:
Contact Number:

Workload and DST results – report SPECIMENS processed on culture or DST, NOT PATIENTS

Culture workload (from culture register)			DST workload and results (from DST register) [DST results summary combined all methods]						
Month	**Diagnostic Sputum SPECIMENS inoculated**	**Follow-Up SPECIMENS inoculated**	**Solid DST Processed**	**Liquid DST Processed**	**LPA DST done**	**Total H+R Sens**	**Total H+R Res**	**Total H only Res**	**Total R only Res**

Performance indicators

	Numerator (No.)	Denominator (No.)	Percent
(1) Specimens (all) received within 7 days of sputum collection (with CPC)			
(2)Specimens (all) received within 72 hours of sputum collection in 4-8 C (without CPC)			
(3)Number of specimen rejected at the lab due to various reasons (eg., Leakage, inadequate quantity, etc.,)			
(4) Specimens (all) with cultures reported as *Mtb.* complex			
(5) Smear-positive diagnostic specimens reported as culture-positive			
(6) Specimens (all) with culture-contaminated results (by culture system)			
(7) Specimens (all) with culture results reported as NTM			
(8) Patients (with diagnostic specimens) with DST completed within the benchmark turn-around time (by culture system or LPA)			
(9) Patients (all) with final culture results reported to providers within 1 days of declaration of result			
(10) Patients with final DST results reported to providers within 1 days of declaration of result			
(11) Number and percentage of invalid LPA results			
(12) Number of events of LPA contamination in the quarter			
(13) Most recent DST panel test performance (Report Date _____)	**Sensitivity (%)**	**Specificity (%)**	
	H:		
	R:		
(Reference lab_____)	E (opt):		
	S (opt):		
(14) Most recent On-Site Evaluation	Date: Ref. Laboratory: Evaluator:		

Annexure-IV

Agenda for the meeting:

Objectives:

⇒ Update on the WHO new and existing policy guidelines

⇒ Review and discuss the requirement of back up solid culture at Demo sites

⇒ To discuss on the results of the rapid assessment on adequacy of one v/s two Specimens for follow-up culture in treatment of MDR-TB patients

⇒ To review the updated EQA for LED FM by WHO and adaptation of the same by RNCTP for use in FM sites and EQAP for LPA

⇒ Presentation and endorsement of Accreditation reforms

⇒ SLDST – norms for DST and role of NRLs and need for additional labs

⇒ Laboratory Status reports from NRLs

⇒ Revision of recording and reporting formats at IRLs

⇒ Newer Diagnostic tools – Current position of RNTCP

⇒ Sputum collection and Transportation – update to suit newer tools

⇒ Any other issues

S.No	Agenda	
1	Policy changes and Endorsements for (a) new and existing technologies (b) Solid Culture back up at Demonstration sites (c) Use of single specimen for FU, single (d) EQAP for SM (both ZN,FM) (e) LPA Accreditation and PT (f) Minimum standards for TB diagnostics (g) AMC guidelines	WHO, CTD
2	Accreditation reforms (a) streamlining accreditation system based on methodology, (HR only) (b) reforms in accreditation process (c) outsourcing PT (d) renewal norms (e) SLDST (f) EQA for LPA	WHO, CTD
3	Lab Status update (accreditation, Expand TB project)	NRLs
4	Revised recording and reporting formats and lab registers	WHO, FIND
5	Plans for demonstration project (Cepheid and LAMP)	WHO and FIND
6	Sputum transportation issues and Mechanisms (Norms and MoUs)	CTD

Annexure- V

List of Participants:

1. Dr.L.S.Chauhan,DDG TB
2. Dr.Behera, LRS Director
3. Dr.P.Kumar, NTI Director
4. Dr.Aleyemma Thomas, TRC Director
5. Dr.K.S.Sachdeva, CMO,CTD
6. Dr.Puneet Dewan, MO-TB, WHO SEARO
7. Dr.Ranjini, Lab focal point, WHO SEARO
8. Dr.Niti Singh, Microbiologist, LRS
9. Dr.Vanaja Kumar, Microbiologist, TRC
10. Dr.Chauha, Microbiologist, JALMA
11. Mr.Ananad, Microbiologist,NTI
12. Mr.Pachuri, Microbiologist, JALMA
13. Dr.Satish, Project Director,PATH
14. Dr.Adhikaree, Microbiologist,PATH
15. Dr,Mayank Gheghdia, Microbiologist,PATH
16. Dr.Rahul Thakur, Medical Officer,FIND
17. Dr.M.V.Ajay Kumar, WHO Consultant, CTD
18. Dr.B.N.Sharath, WHO Consultant, CTD