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Ministry of Health & Family Welfare
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Nirman Bhavan, New Delhi-110108

D. O. No. Z-28015/561/2019-TB
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Dear All,

As you are aware, rapid changes have been taking place in the diagnostic front and newer guidance emerges with increasing availability of scientific evidence. Global evidence as well as in-country evidence have been deliberated by various National Committees and operational recommendations derived. The key recommendations with respect to diagnosis of TB as well as Drug Resistant TB (DR TB), detailed below are to be followed with immediate effect:

1. Based on the recommendation of the National Technical Expert Group (Diagnosis):

- Reconfirmation of Rifampicin Resistance (RR) in new patients diagnosed by CBNAAT is not required for test results of RR with MTB detected (high & medium). However, a repeat test to be performed for reconfirmation in MTB detected (low and very low) among new RR cases.
- DST for Moxifloxacin at 1µg/ml (CB) should be performed for all DR TB (RR/H mono resistant) patients with any FQ class resistance detected by SL LPA.
- LC-DST for second line injectables may be performed on a case to case basis as requested by treating clinician.

2. Based on the recommendations of the NRL capacity building workshop:

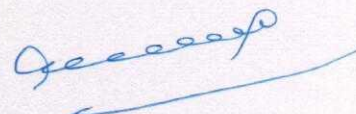
- NRLs will continue to maintain their proficiency in DST on LJ medium. PT for LJ DST shall be discontinued for IRL as well as C& DST laboratories.
- Backup on LJ slopes to be continued along with liquid culture. LJ medium may either be prepared in house or purchased.

3. LPA interpretation and Discordance resolution:

- First and second line LPA results are to be reported in accordance with the Guidelines for PMDT in India 2019 (Pre-final text). Differential interpretation of resistance such as: 'Resistance Detected', 'Resistance Inferred' (with levels of resistance wherever applicable) and 'Resistance Not Detected' to be indicated.
- Discordance of RR results between NAAT and FL LPA are to be resolved by reflex testing using CBNAAT at C& DST laboratories. Two of the 3 test results

are to be considered as final. If 3rd test is not possible due to non-availability of a specimen, DR TB Committee needs to take the decision based on the history and patient's clinical condition.

4. Efforts must be taken to implement Laboratory Information Management System (LIMS) in all C DST laboratories, IRLs & NRLs for real time data entry. Data entry must be monitored periodically and any delay addressed promptly.
5. Sanctioned staff positions at C& DST laboratories, IRLs and NRL to be filled at the earliest to ensure availability of uninterrupted diagnostic services.



(Dr. K. S. Sachdeva)

To,

1. STO (All States & UTs)
2. DTO (All districts)
3. All NRLs, All IRLs and C-DST labs

Copy for information to

1. PPS to JS (TB), Ministry of Health and Family Welfare, GoI.
2. Chairman & Co-Chair of National Technical Expert Group (Diagnosis) & National Technical Expert Group on treatment of TB
3. All officers and Consultants, Central TB Division, Nirman Bhavan, New Delhi