



Molecular Diagnostics Tuberculosis

Know it Right ,Know it Fast

Tuberculosis (TB) Diagnosis Challenges

- Early, specific and sensitive diagnosis of TB
- Diagnostic difficulties especially in children, old people, those with sputum negative disease and Extra Pulmonary TB (EPTB).
- Emergence of multi-drug resistant (MDR) tuberculosis.
- Poor patient adherence leading to failure to reliably diagnose drug resistance pattern leading to improper prescription and further emergence and spread of MDR/ XDR TB.

TB Status- 2017 India



TB Incidence
27.4 Lakh



TB Mortality
4.21 Lakh



MDR
1.31 Lakh

Source: Global Tuberculosis Report WHO 2018

Conventional methods

AFB detection by smear examination (ZN Staining)

⌚ 2-3 hours

- Quick, inexpensive and simple to perform
- Less sensitive, cannot distinguish *Mycobacterium tuberculosis* complex (MTC) from Non-tuberculous mycobacteria (NTM/ MOTT)
- **Same Day Reporting**

Rapid AFB culture- MGIT 320 (Gold Standard)

⌚ 4-6 Weeks

- For the detection of viable TB bacteria and drug susceptibility testing.
- Extensive turnaround time
- Leading to delayed treatment and further emergence and/ or spread of MDR TB.

Nucleic acid amplification tests (NAAT)

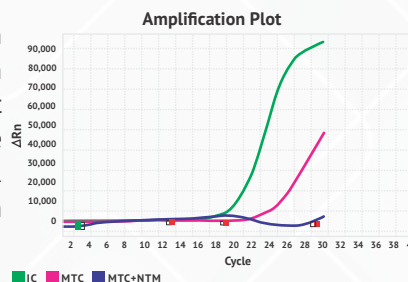
- NAA tests are used to amplify DNA and RNA segments to rapidly identify the micro-organisms in a specimen.
- Within 24 hours laboratory confirmation of TB disease and earlier treatment initiation leading to improved patient outcomes.

AFB –detection of DNA (TB-PCR)

⌚ 24 hours

Sensitive and specific detection and differentiation between MTC and NTM

Amplification of an internal control (IC) in the same tube as test reaction excludes the possibility of PCR inhibition and confirm successful amplification



Advisory Annexure

- It is critical to know drug sensitivity/ resistance information before prescription.
- Dr. B. Lal lab offers WHO endorsed Line Probe Assay (LPA)/ Hain's test for MDR screening-first/second line drugs.



Real-Time PCR Platform at Molecular Diagnostics division, Dr. B. Lal Clinical Laboratory

LPA/ Hain's test/ MDR screening- First line Drugs- WHO endorsed test IPAQT associated

⌚ 24- 48 hours

Detects presence/ absence of MTC and it's resistance to Rifampicin and Isoniazid.

LPA- Hain Lifesciences (MDR- First line drugs)	V/S	GeneXpert MTB/ RIF
Detects MTC and resistance to Rifampicin and Isoniazid		Detects MTC and resistance to rifampicin only
MGIT-DST showed 100 percent alignment with LPA results* Superior performance as compared to GeneXpert		MGIT-DST showed 65 percent alignment with GeneXpert results*
Multiple samples can be processed at same time		Only 1-4 samples can be processed simultaneously

*J Clin Microbiol. 2014 Jun; 52(6): 1846–1852

Reference: GenoType MTBDRplus Hain Lifesciences

LPA/ Hain's test/ MDR screening- Second line Drugs- WHO endorsed test IPAQT associated

⌚ 24- 48 hours

Detects Presence/ absence of MTC and it's resistance to Fluoroquinolones, Amikacin, Capreomycin, Viomycin and Kanamycin

Reference: GenoType MTBDRsl Hain Lifesciences

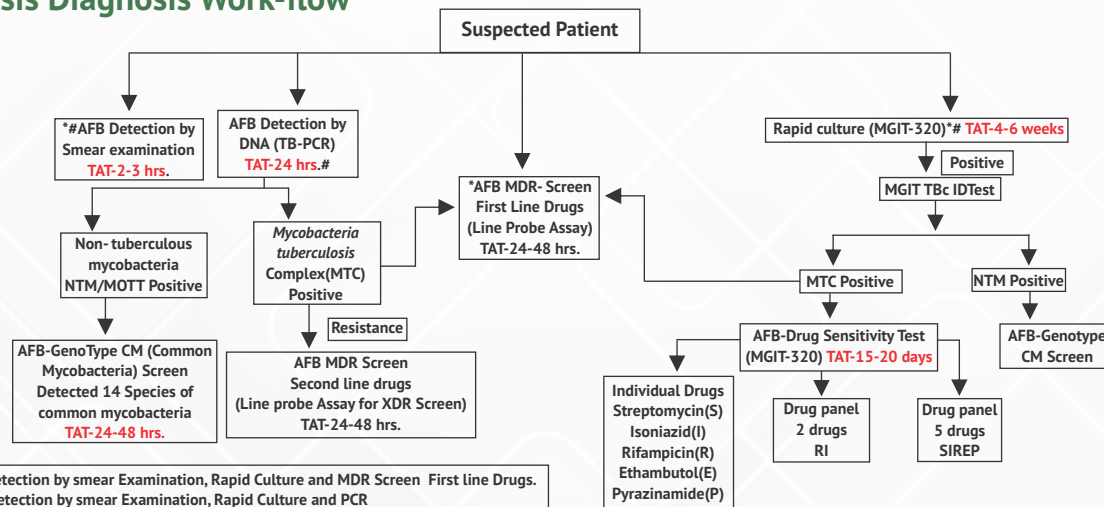
GenoType Common Mycobacterium (CM)

⌚ 24- 48 hours

Identification of the MTC as well as 14 species of clinically relevant CM/ NTM/ MOTT species

Reference: GenoType Mycobacterium CM Hain Lifesciences

Tuberculosis Diagnosis Work-flow



Key Highlights

- Dr. B. Lal Clinical Laboratory is IPAQT associated and offers TB tests at subsidized rates with high quality standards and short TAT of 24 hours.
- TB tests are performed in Biosafety level II laboratory with Biosafety cabinets and negative pressure installation in the rooms to avoid infection or cross-contamination. We follow Biosafety level III work ethics while handling infectious material.
- Our TB reports for AFB-MDR screening- First line drugs and Second line drugs are accepted by Government and patients can take treatment from Govt. facilities.
- We report and register positive cases on Government portals like Nikshay and the registration number is provided to doctors and patients as required for availing Govt. treatment facilities.
- Perform AFB- detection of DNA (TB-PCR) and AFB-MDR screening for drug sensitivity on extra-pulmonary samples in addition to cultivated and pulmonary samples.

- Comprehensive analysis of reports is done by our expert consultants with more than 12 years experience in their field of specialization. Our consultants are available for discussion, implications and further course of action suitable for TB diagnostics.

Sample Collection Guideline :

All clinical samples must be stored and transported at 4°C to reduce growth of contaminating micro- organisms. Specimens must be delivered to central laboratory within 12 hours of collection. Specimens should be collected in containers that are sterile, clean, plastic and leak proof and must be screwed properly before transport.

Contact Details

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Comprehensive panel for Tuberculosis detection and determination of drug resistance with focus on Molecular diagnostic methods

Don't Guess. Know.

