Test details

Test Code	RS062
TAT	15 working days
Sample Specimen	Sterile container- To be transported within 24 hours in cold condition
Additional Requirements	Duly filled TRF with available TB test reports

Validation results

SPIT SEQ, the direct sputum based whole genome sequencing test for Mtb is validated with 100 samples.

Sensitivity	100% compared to LPA as reference standard
Specificity	98.04% compared to LPA as reference standard

References

1. https://www.who.int/tb/publications/global_report/en/
2. Approaches to improve sputum smear microscopy for tuberculosis diagnosis, expert group meeting report geneva: 31 october 2009.
3. Boehme CC, Nabeta P, Hillemann D, Nicol MP, Shenai S, Krapp F, et al. Rapid molecular detection of tuberculosis and rifampicin resistance. N Engl J Med. 2010 Sep 9;363(11):1005–15.
4. The diagnostic accuracy of the MTBDRplus and MTBDRsl assays for drug-resistant TB detection when performed on sputum and culture isolates. Scientific Reports | 6:17850 | DOI: 10.1038/srep17850

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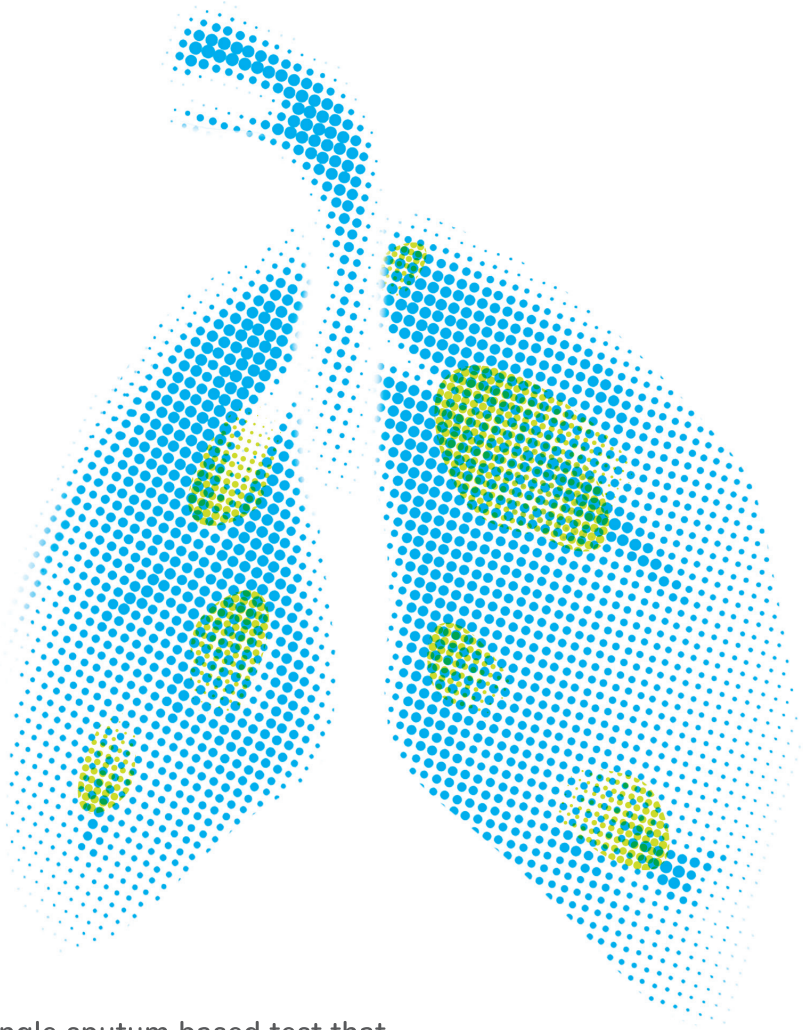
SPIT SEQ - Whole Genome Sequencing of Mtb (Mycobacterium Tuberculosis) for Pulmonary Tuberculosis



A single sputum based test that provides diagnosis and drug resistance prediction report in **just 15 days.**

Prevalence of Tuberculosis in India[1]

Worldwide, tuberculosis (TB) is one of the top 10 causes of death, and the leading cause from a single infectious agent (above HIV/AIDS). According to a WHO report, India saw 2.7 million TB cases (incidence + relapse) in 2017. India accounted for 27% of global TB deaths.

Globally, 3.5% of new TB cases and 18% of previously treated cases had multi-drug resistant/rifampicin resistant TB (MDR/RR-TB). India is one of the top 3 countries with the largest number of MDR/RR-TB cases that constitute 47% of global MDR/RR-TB cases.

MedGenome Genomic Mtb Test

SPIT SEQ, MedGenome's Mtb Test sequences the whole genome of Mycobacterium Tuberculosis (Mtb) from the sputum of patients.

Key Features:

- Single test for diagnosis and drug resistance detection - As the test includes sequencing the Mtb genome, it can diagnose the presence of Mtb as well as identify the mutations that are likely to cause drug mutations.
- Comprehensive Drug Panel - The existing molecular techniques have a limitation of covering only a few drugs. The whole genome sequencing of Mtb covers all drug resistance markers - common as well as novel.
- Sample Requirement - The SPIT SEQ test uses direct sputum as the clinical sample for sequencing which renders the process simple and fast. The use of sputum eliminates the requirement of growing a culture and hence reduces the time delay in diagnosis.
- Multiple applications - Over and above diagnosis and drug resistance testing, the whole genome sequencing test for Mtb, due to its voluminous data availability, can be used for strain typing, epidemiology studies and disease surveillance.

Advantages of Mtb genome sequencing Vs. Traditional methods

Parameter	Smear Microscopy	Culture Technique	Nucleic Acid Amplification Test (Xpert MTB/ CBNAAT)	Line Probe Assay	MedGenome Whole Genome Sequencing of MTB
Test application	Diagnosis	Diagnosis + Drug Resistance	Diagnosis + Drug Resistance	Diagnosis + Drug Resistance	Diagnosis + Drug Resistance
Strain Typing	No	Yes, but confirmation required	No	No	Yes
Specimen requirement	Direct Sputum	Culture	Direct Sputum	Culture	Direct Sputum
Drugs for which resistance testing can be done	NA	All (to be tested individually for each drug in a separate culture)	Rifampicin[3]	Rifampicin (RIF) Isoniazid (INH) Ofloxacin (OFX) Amikacin (AMK)[4]	All (done in a single sequencing cycle)
Novel drug resistance mutations coverage	NA	NA (doesn't check for markers, but action of the drug on grown TB culture)	No	No	Yes
Turn around time	1-2 hours	4-8 weeks for diagnosis and drug resistance test	2 hours	5 days (once the culture is grown)[4]	15 working days
Sensitivity	55% (among pulmonary tuberculosis)[2]	Less for Conventional Lowenstein Jensen- Solid Media High for Automated MGIT- Liquid Culture	98% in smear positive cases 70% in smear negative cases[3]	95.6% for RIF and INH 74.5% for OFX and AMK[4]	100% (compared to Line Probe Assay as reference standard)
Specificity	98% (among pulmonary tuberculosis)[2]	NA	NA	90.1% for RIF and INH[4] 98.6% for OFX and AMK[4]	98.04% (compared to Line Probe Assay as reference standard)