

TB treatment
saved about

66 M
LIVES
globally
between
2000 &
2020



Early &
effective
detection of
Tuberculosis
is
important

Comprehensive testing solutions for
TUBERCULOSIS

Diagnosis

* <https://www.who.int/news-room/facts-in-pictures/detail/tuberculosis>

For Rapid Detection of Tuberculosis

AFB TB by PCR



Specific detection of Mycobacterium tuberculosis complex (MTBC) and Nontuberculous mycobacteria (NTM)



Rapid detection of Tuberculosis by Real-Time PCR



High sensitivity- 99%



Shortest turnaround time

For Early & Effective Detection of Drug-resistant Tuberculosis

MTB Drug resistance INH-RIF by RTPCR



Qualitative resistance detection within a single assay for the two most important first-line M. tuberculosis (TB) drugs- Rifampicin & Isoniazid



Differentiates Rifampicin/ Isoniazid-susceptible and resistance between wild and mutant strains as per the current WHO guidelines

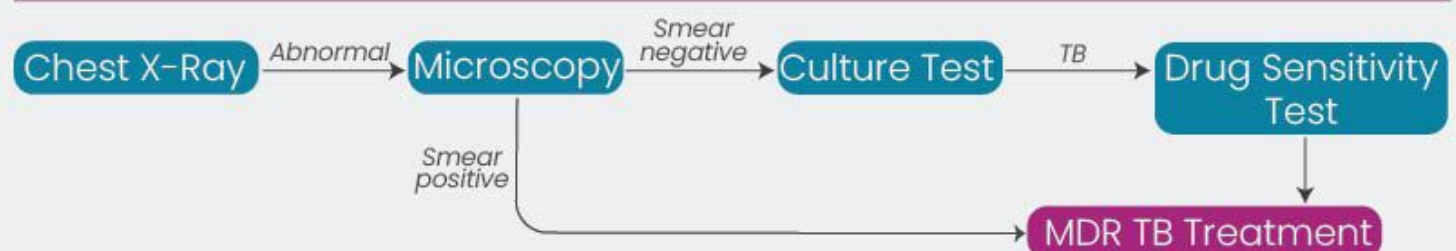


Highly reliable, accurate and sensitive



Sensitivity is 96%, Specificity is 100%

Algorithm: Tuberculosis Screening & Diagnosis



New Introduction

Mycobacterium tuberculosis- Whole Genome Sequencing- Drug Resistance Panel



Rapid & Comprehensive



DST results for 18 antibiotics



Recognized and recommended by WHO



Tested & validated on >10,000 TB genomes & >300 clinical isolates



High specificity (85-98%) & sensitivity (99.8%)



Accurate & clinically relevant report

WGS: More than DST

- Mixed infection/ Co-infection
- Novel Mutations
- Relapse/ Reinfection
- Lineage/Variant identification

Report Illustration

SAMPLE SUMMARY

Sample ID → 1 | Test ID → OmegaTB | Patient ID → MRN-XXXX | Client → XXX | Registered → 19-02-2022 | Reported → 17-03-2022

CLINICAL SUMMARY

Mycobacterium tuberculosis detected : **Detected** | Lineage : **Beijing** | Genomic DST profile : **MDR-TB** | Coverage : **214.41** | Proportion of genome covered : **1.00**

DRUG RESISTANCE PROFILE

First Line		Group A		Group B		Group C	
Drug	Interpretation	Drug	Interpretation	Drug	Interpretation	Drug	Interpretation
Isoniazid (INH)	Resistant*	Ofloxacin (OFX)	Sensitive**	Clofazimine (CLO)	Sensitive**	Streptomycin (SM)	Resistant*
Rifampicin (RMP)	Resistant*	Moxifloxacin (MOX)	Sensitive**			Pyrazinamide (PZA)	Resistant*
Ethambutol (EMB)	Resistant*	Gatifloxacin (GAT)	Sensitive**			Amikacin (AMK)	Sensitive**
		Linezolid (LZD)	Sensitive**			Delamanid (DMD)	Sensitive**
		Bedaquiline (BDQ)	Sensitive**				

MUTATION TABLE

Position	Ref Allele	Alternate Allele	Type	Prequency	Coverage	Substitution	Gene Symbol	Gene Name	Drug	PMID	High Confidence SNP
761155	C	T	SNP	40.99	161	Ser450Leu (tcg/tTg)	Rv0667	rpoB	RMP	21300839	yes
781687	A	G	SNP	37.01	281	Lys43Arg (aag/aGg)	Rv0682	rpsL	SM	22646308	yes
2155168	C	G	SNP	45.37	227	Ser315Thr (agc/aCc)	Rv1908c	katG	INH	8878604	yes

GENOME SEQUENCING SUMMARY

Library type | Library Date | Library QC | Genome Sequencer | Run Date | Machine/ Flow cell ID
 150x2 paired end | 12.03.2022 | Pass | Illumina NextSeq | 14.03.2022 | NB501457-HL27LAFX3

Application | Application Run By | QC Check
 OmegaTB v2.0.1 | HAPL | Pass

Test Ordering Information

Test Code	Test Name	Technique	Specimen Type	TAT
A0005c	AFB - TB by PCR, Body fluids	Real Time PCR	3ml body fluids in sterile container	Daily by 6 pm; Report by next day
A0005d	AFB - TB by PCR, CSF	Real Time PCR	2-3ml CSF in sterile container	
A0005e	AFB - TB by PCR, Tissue	Real Time PCR	20-25mg tissue in sterile container	
A0005f	AFB - TB by PCR, Urine	Real Time PCR	10ml urine in plastic/ 30ml tube/ clean plastic aliquot container with no metal cap or glued insert	
A0005o	AFB - TB by PCR, Menstrual Blood	Real Time PCR	3ml menstrual blood in sterile container	
A0005p	AFB - TB by PCR, EDTA Whole Blood	Real Time PCR	3ml whole blood in K2 EDTA (lavender top) tube	
A0005m	AFB - TB by PCR, Intestinal Fluid	Real Time PCR	3ml intestinal fluid in sterile container	
A0005l	MTB - Xpert plus Extra Pulmonary	PCR + AFB Smear + MGIT Culture	3ml body fluids/ biopsy tissue in sterile container	Daily by 9 pm; Report within 2 days
A0005k	AFB Speciation, Other Body Fluids	DNA Sequencing	3ml sputum/ body fluids/ biopsy tissue in sterile container	
M0010	MTB Drug resistance INH-RIF	Real Time PCR	3-10 ml endometrial tissue/ EDTA/ body fluids in K2 EDTA tube/ sterile container	
A0005aa	AFB - GeneXpert MTB/RIF, Body Fluids	GeneXpert- MTB/RIF	3ml body fluids in sterile container	Daily by 9 pm; Report within 24 hours
A0005ab	AFB- Genexpert MTB/RIF, Sputum	GeneXpert- MTB/RIF	5ml Sputum in sterile container	
A0005ah	AFB - Genexpert MTB/RIF, Tissue	GeneXpert- MTB/RIF	20mg tissue in sterile container	
TBWGS	Mycobacterium tuberculosis- Whole Genome Sequencing- Drug Resistance	Whole Genome Sequencing	Sputum, Urine, or CSF/ Tissue/Biopsy/ Positive TB Culture in sterile container/ MGIT culture tube	Daily by 6 pm; Report within 15-21 days
A0005j	AFB - TB Culture Positive Reflex MDR	Real Time PCR + Sanger Sequencing	2ml Sputum/ body fluids/ biopsy tissue in sterile container	Daily by 9 pm; Report within 7 days

Guidelines

Global as well as Indian authorities have evaluated and indicated the promise of NGS-based approaches. The guideline for the programmatic management of drug resistant tuberculosis (2021) also mentions that next generation sequencing (NGS) may be used for:

- Detection of genomic sequence variants to predict TB drug-resistance phenotypes
- Identification of strain lineage and resistance mechanisms for TB surveillance
- Recognition of genetically related strains for resolution of transmission chains

References:

1. World Health Organization. WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-resistant tuberculosis treatment. 2020.
2. National Tuberculosis Elimination Programme. Programmatic management of drug resistant tuberculosis. 2021.

Name of Salesperson: Contact: