

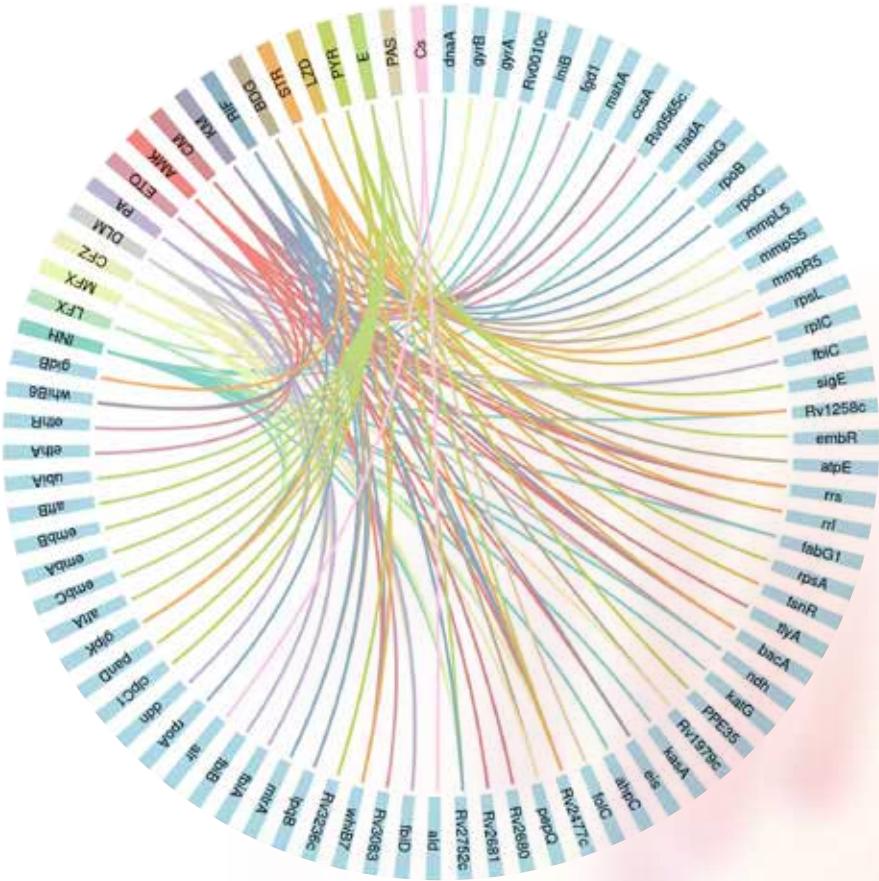


## *For a Confident Diagnosis –*

# Mycobacterium Tuberculosis and Drug Resistance

## Comprehensive solutions ranging from...

-  Next Generation Sequencing Solutions
-  Point of Care Testing Solutions
-  Real Time PCR Solutions



# A Targeted Approach for MTB & MDR-TB Detection with NGS

Multi-drug resistant tuberculosis (MDR-TB) is a global health threat. They are more difficult to treat, requiring specialized medications and longer treatment regimens. The longer the delay in diagnosis, the higher the risk of transmission to others, requiring timely and accurate detection to ensure effective treatment. Targeted Next-Generation Sequencing (NGS) helps by identifying genetic mutations linked to drug resistance, enabling faster and more precise detection of resistant strains.

G2M offers a rapid detection and identification platform for *Mycobacterium Tuberculosis Complex* and drug-resistant TB, using a targeted sequencing approach directly from clinical specimens, eliminating the need for culture. This assay is designed to map 100 kb region of the *M. tuberculosis* genome for >60 drug resistance genes and associated mutation sites, as well as SNP loci. This assay is based on Hybridization capture based Target enrichment.

## G2M TB-NGS Library Preparation & Target Enrichment Solution

**MTBC species identification**

**Spoligotyping**

**Lineage Identification**

**Drug Resistance Profile**

- Resistance Prediction for >15 Anti-TB Drugs
- Identify the lineage, sub-lineage, spoligotype of MTBC strains in the sample
- Identification of Over 100 Mycobacterial Species (including MTBC, *Mycobacterium canetti*, *Mycobacterium tuberculosis*\_H37Rv and many more.)

## Drug Resistance Profiling

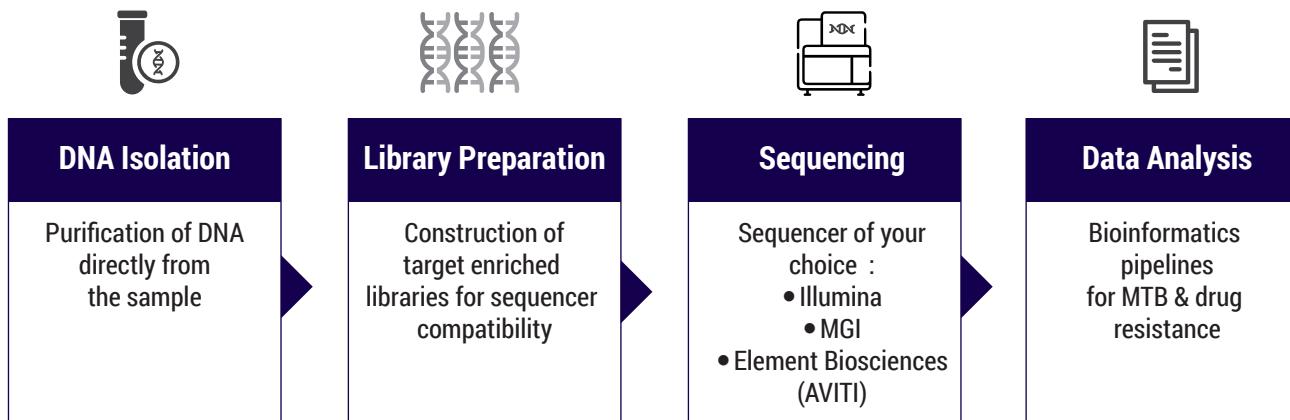
With G2M TB-NGS solution, get a drug resistance profile for all the major first line and second line drugs including newer compounds like Bedaquiline and Linezolid, making it one of the most extensive genotypic tool directly applicable to clinical specimens.

First Line Drugs	Second Line Drugs		
	Group A/B	Group C	Others
Rifampicin (nusG, rpoB, rpoC, rpoA)	Fluoroquinolones (gyrA, gyrB) Levofloxacin, Moxifloxacin	Amikacin (rrs)	Capreomycin (tlyA+, rrs)
Isoniazid (KatG, inhA, ahpC, fabG1)	Bedaquiline, Clofazimine (rv0678+)	Streptomycin (gidB, rrs, rpsL+)	Kanamycin (eis, rrs)
Pyrazinamide (pncA, clpC1, panD)	Linezolid (rrl, rplC)	Ethionamide (ethA+, inhA, fabG1)	
Ethambutol (embR, embC, embA, aftA ubiA)			

*Note : Limited genes listed in the table*

# Workflow for NGS-based analysis of TB samples

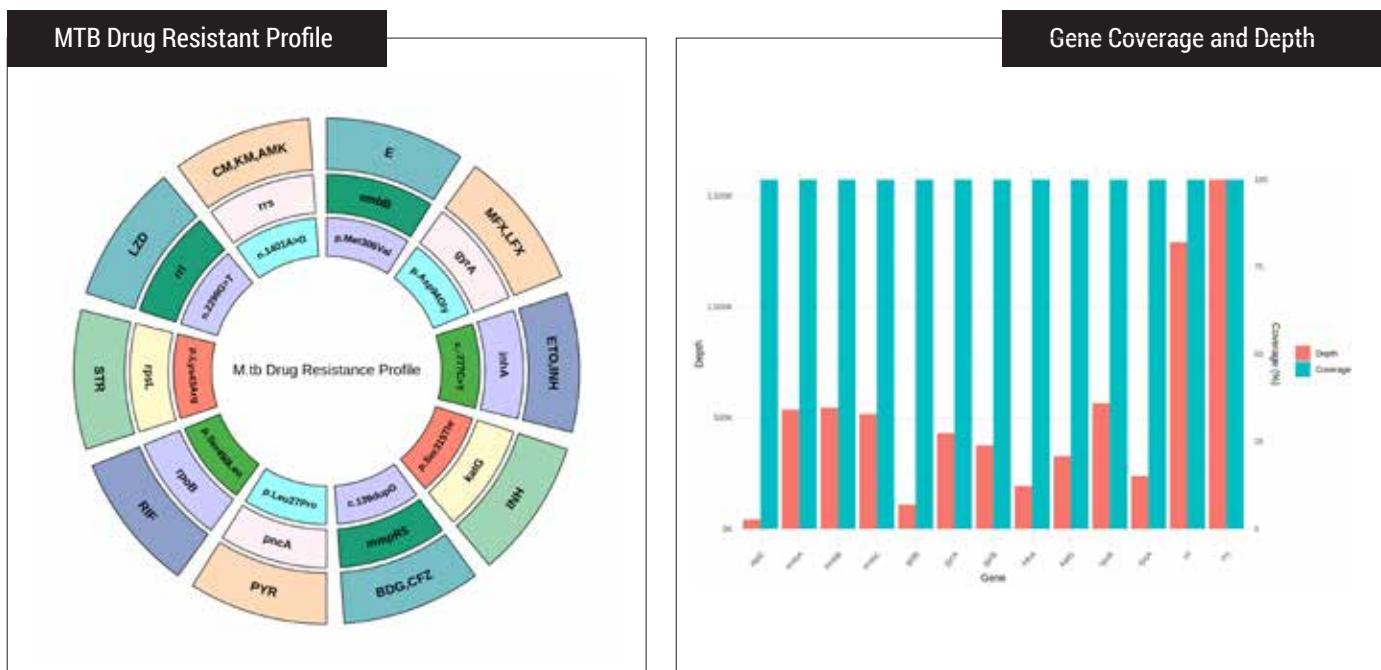
The G2M TB NGS assay eliminates the need for mycobacterial cultures and can be applied directly to clinical samples with even minimal micro-organism loads. The entire process from DNA extraction, followed by genomic library preparation, hybridisation (only 4 hours) and sequencing preparation takes 2 to 3 days.



## Data Analysis and Reporting

# CliSeq Interpreter

Post sequencing, FASTQ (read) files can be uploaded to our cloud based platform – CLISEQ INTERPRETER using the coupon credentials provided along with the kit. The fully automated reporting pipeline analyses the data in under an hour, which helps in graphic-visualization reporting.



## Scan for TB NGS Sample Report



# Point-of-Care Solutions for TB Detection

Multidrug-resistant TB (MDR-TB) are difficult to treat, requiring specialized medications and longer treatment regimens. Fast & reliable detection of resistance allows healthcare providers to initiate the appropriate drug regimen without delay and also help avoid the use of ineffective treatments, which could contribute to the development of resistance and further complications.

With the emergence of cutting-edge & highly sensitive point-of-care testing technologies, these platforms represent powerful diagnostic tools capable of significantly advancing TB detection, particularly in remote, resource-constrained, or high-risk settings. With G2M, get access to the latest and advanced Point of Care platforms for TB detection along with other compatible 50+ assays for various therapies segments.

Module 01

SAMPLE IN



RESULT OUT



4  
N  
O1  
PCR

**FULLY AUTOMATED  
NUCLEIC ACID  
DETECTION SYSTEM**



1 Sample  
upto 20 Targets



40<sup>+</sup> Detection  
Assays available



1 sample 20 target detection

Five channel fluorescence based detection system

Automated Analysis & Reporting

Ready to use cartridge based assays

Uncompromised detection accuracy

Standalone operation with precise and robotic liquid handling

QR Code scanning feature

## Ergonomic designs for ease of use

compact, light weight machine with built-in intuitive display

OnePCR  
PCR

OnePCR is an all in one automated detection system that offers a streamlined sample to result workflow, eliminating the need for sample transfers between different instruments, thereby reducing the overall run-time and minimizes the risk for human error. It is based on cartridge technology, seamlessly integrating Nucleic Acid Extraction and Real-time PCR functionalities into one streamlined instrument, maximizing efficiency and convenience for the user.

Observe real-time amplification data, Ct values, & determine the positive or negative status of the sample.

Module 02



## RAPI-X16

Fast & Automated Nucleic Acid Extraction System

Can process 1-8/ 16 samples per run

Extraction time ~ 15 minutes

## RAPI-

Point-of-Care RT-PCR System

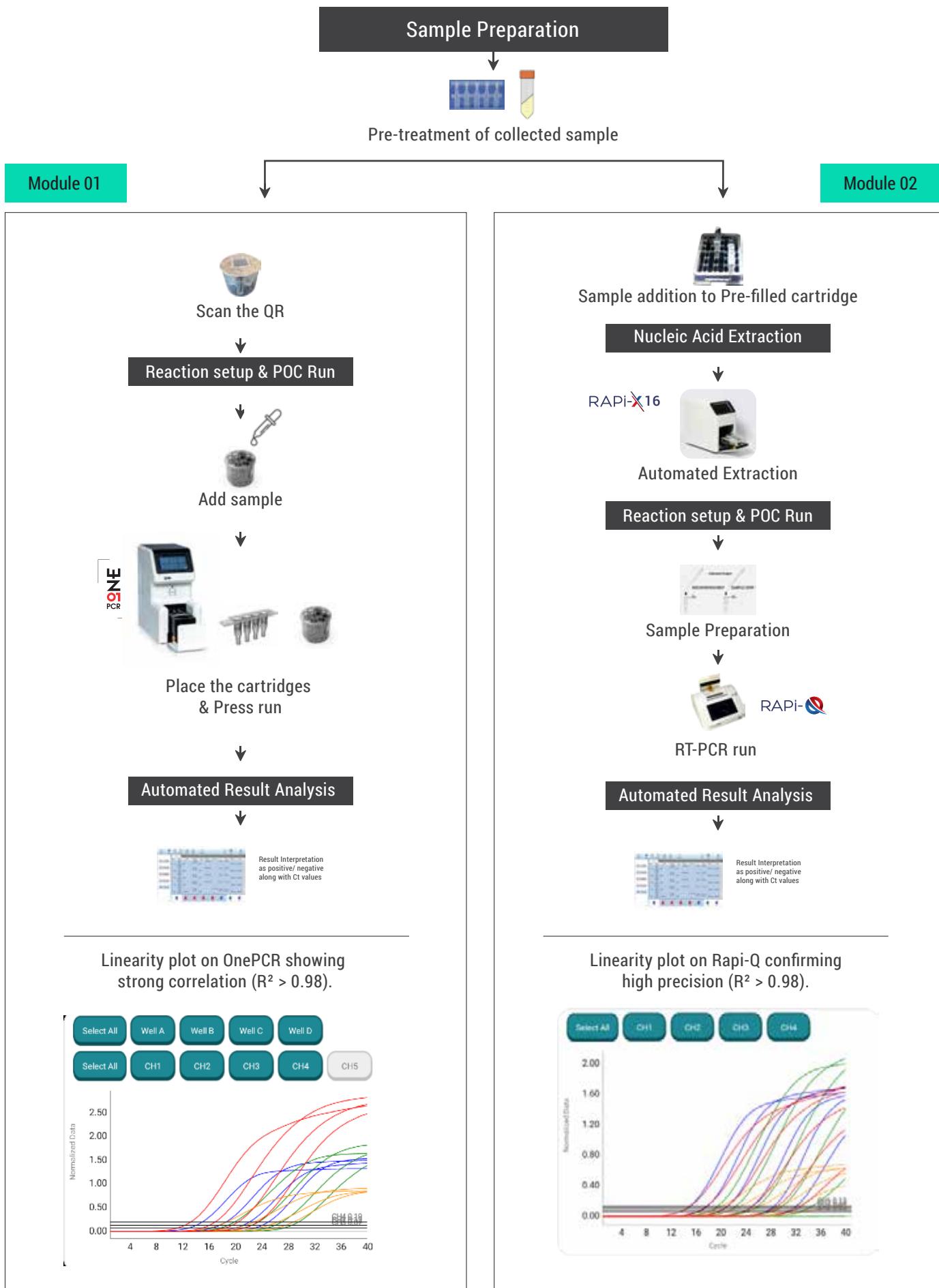
1-8 samples

4 Channel fluorescence based detection

Light weight & Compact (1.4 Kg)

Can be operated with Portable Lithium Battery Pack

# Point-of-care workflow for TB detection



# Real -Time PCR Assays for TB detection

The Mycobacterium tuberculosis complex (MTC or MTBC) includes detection of species causing tuberculosis, which spreads through respiratory and digestive tracts or skin injuries. High-risk individuals include those with prolonged infections or close contact with infected persons, with untreated cases spreading the disease further.

Genes2Me's qRT-PCR kits enable rapid and accurate detection of *M. tuberculosis*, reducing delays in diagnosis and preventing severe health impacts.

## TB-Q Comprehensive Real Time PCR Kit



- Allows simultaneous detection of MTB and MDRTB (Multi drug resistant tuberculosis)
- 16 mutations covered for two first line drugs ie. isoniazid (INH) & rifampicin (RIF) resistant/ sensitive tuberculosis.
- Targets covered: rpoB, katG, inhA, mpt64 genes.

## MTB-NTM Multiplex Real Time PCR Kit



- Accurate Detection and Differentiation of tuberculosis with NTM.
- Multiple NTM genotypes including: *M. abscessus*; *M. avium*; *M. fortuitum*; *M. kansasii*; *M. intracellulare*; *M. massiliense*; *M. chimaera*
- Targets Covered: NTM specific - KU gene. MTB specific - mpt64 gene.

## MTC-Q Real Time PCR Kit



- Detection of *Mycobacterium tuberculosis* infection in clinical samples.
- Targets Covered : IS6110, MPt64 genes.

### 1. Limit of Detection (LoD)

Target	LoD (copies/mL) on OnePCR	LoD (copies/mL) on Rapi-Q
MTC	112 copies/mL	112 copies/mL
MTB-NTM	120 copies/mL	120 copies/mL
TB-Comprehensive(MDR-TB)	150 copies/mL	150 copies/mL

### 2. Analytical Specificity

Parameter	Cross-reactivity Observed	Interference Observed
MTC/NTM/MDR-TB	No cross-reactivity	No interference
Tested Organisms	Adenovirus, Influenza A/B, HIV Candida, Parainfluenza, <i>M. kansasii</i> , <i>M. fortuitum</i>	
Interference Check	Human genomic DNA, nicotine hemoglobin, TB medications	

### 3. Clinical Sensitivity and Specificity

Parameter	TB Detection	NTM Detection	MDR-TB Detection
Sensitivity	98%	98%	97%
Specificity	99%	99%	98%

Fully Automated State-of-the-art Manufacturing Facility  
of 1,50,000 Sq.Ft. in Manesar, INDIA



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