

Detection of MTB/NTM & Drug-resistant TB

powered by patented MMCA/MeltArray technology



- MTBC
- MDR: Rifampin - & Isoniazid-resistant
- Drug Resistance Detection: RIF, INH, EMB, STR, PZA, FQ, SLID
- NTM Identification: 19 Mycobacteria

Tuberculosis is one of the top infectious killers in the world

8 countries accounted for **67.9%** of the global total TB cases:

India, Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and the Democratic Republic of the Congo.

TB



An estimate of
10.6 million
people fell ill with TB in 2022

MDR/RR-TB



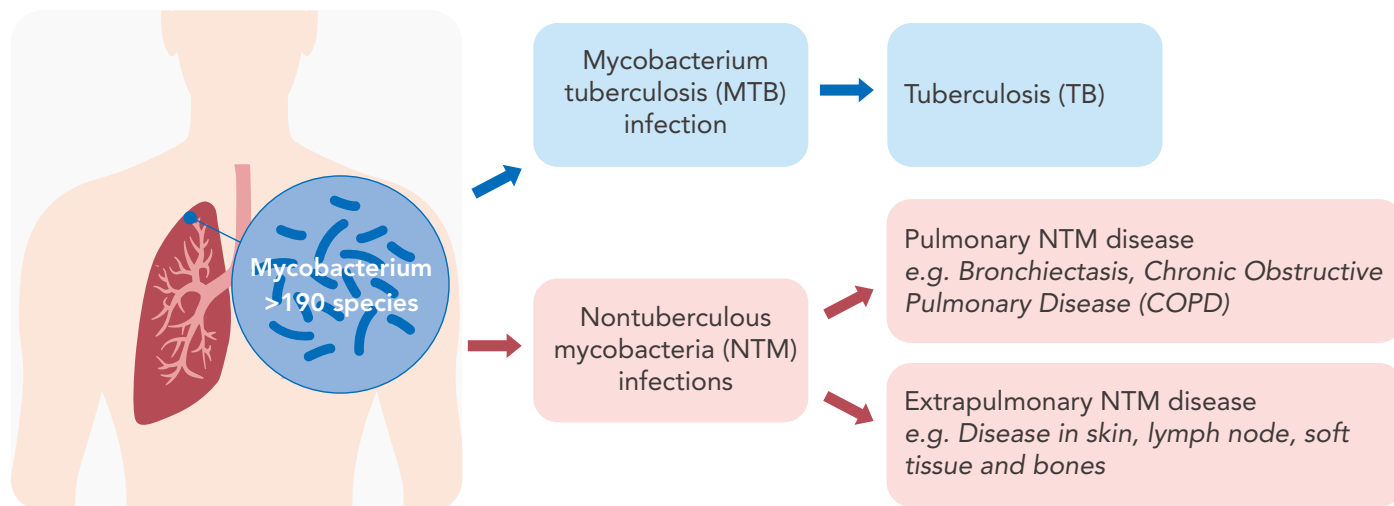
An estimate of
410,000
people developed multidrug-resistant
or rifampicin-resistant TB in 2022

- Estimated 1.3 million TB deaths including 167 000 deaths among people with HIV.
- Drug-resistant TB remains a public health crisis with gaps in detection & treatment.

*Data from WHO Tuberculosis Report 2023

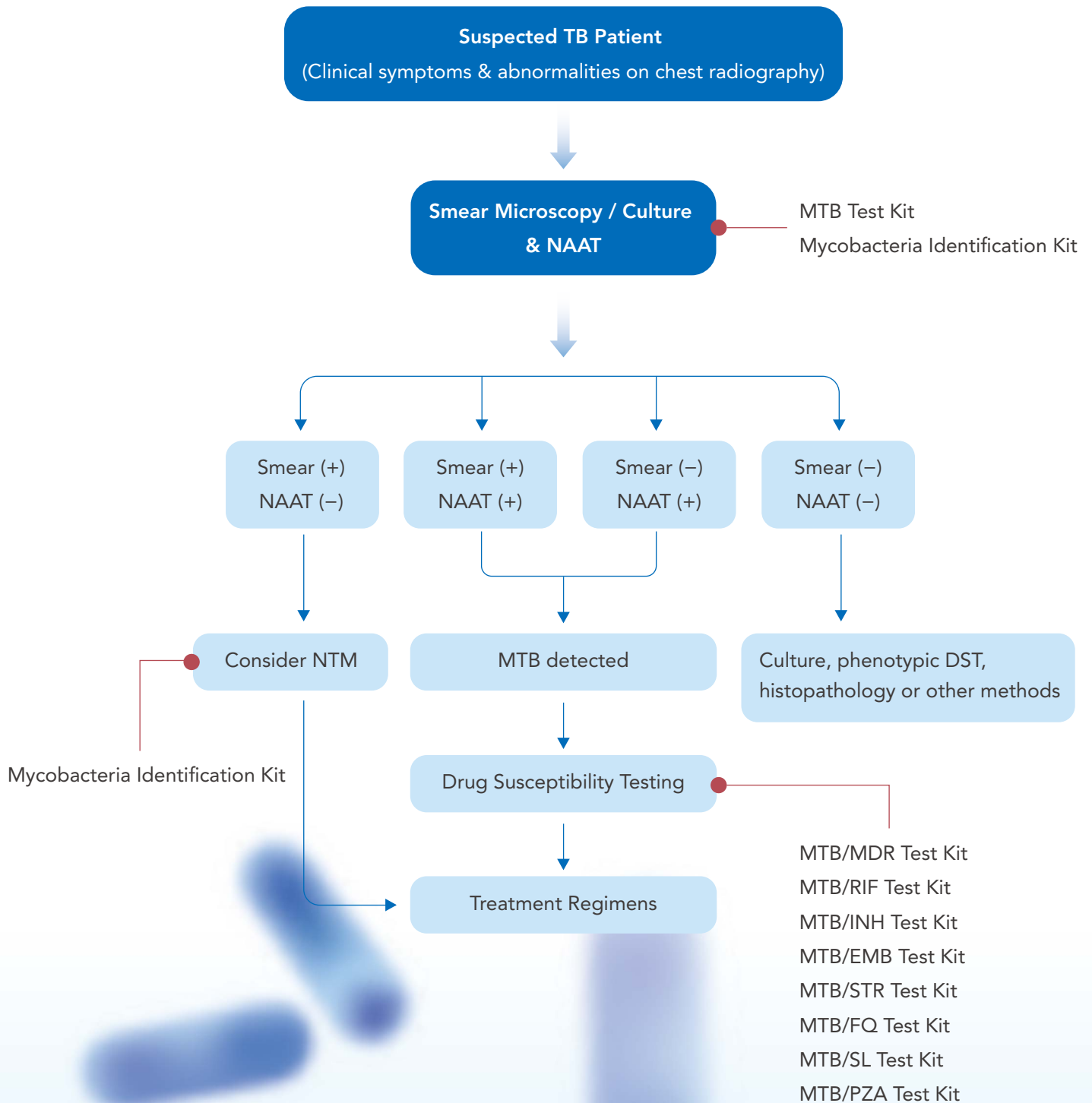
Accurate and timely identification of TB and drug-resistant TB plays a pivotal role in minimizing unnecessary antibiotic interventions, therefore shortening treatment duration and improving patient outcomes.

Infection by nontuberculous mycobacteria (NTM) may cause inflammation and lung damage



NTM infections are gaining more attention as noteworthy factors in the occurrence of illness and death among patients. This is primarily attributed to the prevalence of misdiagnosis and inadequate treatment.

Diagnostic Algorithm

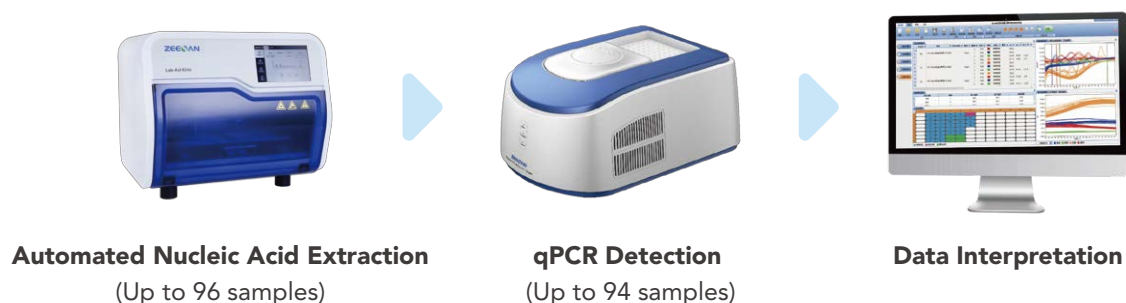


Reference: WHO consolidated guidelines on tuberculosis, 2021

Note: It may vary among countries due to their local clinical practice guidelines.

Two workflow solutions catering to different requirements

Option 1 High-throughput Detection Workflow



Option 2 Sanity 2.0® All-in-one Platform



(Up to 4 samples)

- Sample-in, result-out
- Minimal hands-on time
- Pre-loaded reagents
- Small footprint

➔ MTBC Detection

MTB Test Kit is a real-time PCR assay for the detection of *mycobacterium tuberculosis* complex (MTBC).

Specimens

- Sputum
- Bronchial washing fluid

Compatible Platforms

- Real-time PCR System
SLAN-96S/P, SLAN-48P,
Fascan 48S, ABI 7500
- Sanity 2.0® All-in-one Platform

Features

- **High Sensitivity**
Limit of detection is as low as 10 bacilli/mL.
- **Ease of use**
Automated result interpretation through Zeevan integrated software. Pre-loaded lyophilized reagents for easy handling and room-temperature transportation.
- **Reliable**
UNG system and internal control are included to prevent carry-over contamination.
- **Flexible**
MTB test kit in combination with DR-TB test kits to detect MTBC and drug-resistant TB simultaneously.

➔ DR-TB Detection

DR-TB test kits consists of a collection of real-time PCR assays designed to detect mutations associated with resistance to rifampin (RIF), isoniazid (INH), ethambutol (EMB), streptomycin (STR), pyrazinamide (PZA), fluoroquinolones (FQ) and second-line injectable drug (amikacin, kanamycin, capreomycin).

Broad coverage of DR-TB test kits

Product	Target	Mutation Sites	Coverage (%)
MTB/RIF Test Kit	Rifampin	rpoB 507~533 (81bp)	95-99
MTB/INH Test Kit	Isoniazid	ahpC promoter (-44~-30, -15~3), inhA 94, inhA promoter (-17~-8), katG 315	70-90
MTB/EMB Test Kit	Ethambutol	embB 306, 406, 497	75-95
MTB/STR Test Kit	Streptomycin	rpsL43, rpsL88, rrs 513~517	70-90
MTB/PZA Test Kit	Pyrazinamid	pncA (561 bp), pncA promoter region (positions -16~-1)	72-99
MTB/FQ Test Kit	Fluoroquinolones	gyrA 88~94	70-90
MTB/SL Test Kit	Second-line Injectable Drugs		
	- Amikacin (AMK)	rrs1401, 1402, 1484,	AMK > 80
	- Kanamycin (KAN)	eis promoter -37, -14, -10	KAN > 85
	- Capreomycin (CAP)		CAP: 70~80

Specimens

- Cultured cells
- Sputum

Compatible Platforms

- SLAN-96S/P, SLAN-48P, Bio-Rad CFX96, Rotor-Gene 6000, Roche LC480 II

➔ MTB/MDR Detection

MTB/MDR test kit enables simultaneous detection of MTBC and rifampin-resistance and isoniazid-resistance mutations in a single test.

MDR-TB test kit enables simultaneous detection of rifampin-resistance and isoniazid-resistance mutations in a single test.

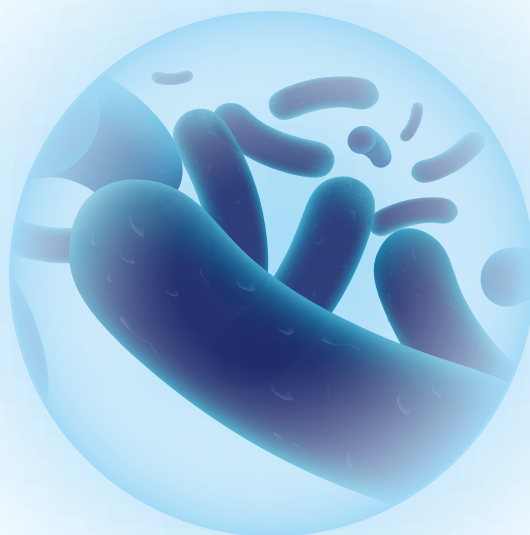


Specimens

- Cultured cells
- Sputum

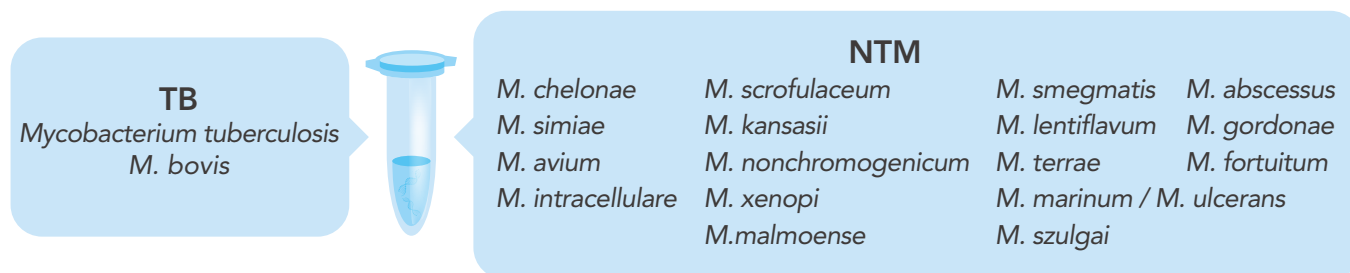
Compatible Platforms

- Real-time PCR System
SLAN-96S/P, SLAN-48P
- Sanity 2.0® All-in-one Platform



➔ NTM Detection

Mycobacteria Identification Kit allows for the identification of 19 clinically significant mycobacteria, including both TB and non-tuberculosis mycobacteria (NTM), at species level in just one reaction.



Features

- **Single-tube multiplex real-time PCR powered by patented MMCA/MeltArray technology**
Simultaneous detection of 52 species (including MTB and NTM) in a single-tube reaction.
A total of 52 species will be categorized into 19 distinct groups.
- **Ease of use**
Automated result interpretation through Zeesan integrated software.
Pre-loaded lyophilized reagents for easy handling and room-temperature transportation.
- **Fast and efficient**
Turnaround time is less than 3 hours for 52 targets.

Specimens

- Cultured cells
- Sputum

Compatible Platforms

- **Real-time PCR System**
SLAN-96S/P, SLAN-48P
- **Sanity 2.0® All-in-one Platform**

Product Information

Cat. No.	Product	Size	Compatible Platform
801176	MTB Test Kit (Sanity 2.0)	24 Tests/Kit	Sanity 2.0 System
801177	MDR-TB Test Kit (Sanity 2.0)	24 Tests/Kit	
801181	MTB/MDR Test Kit (Sanity 2.0)	24 Tests/Kit	
801180	Mycobacteria Identification Kit (Sanity 2.0)	24 Tests/Kit	
801219	MTB Test Kit	48 Tests/Kit	Real-time PCR Systems
801213	MDR-TB Test Kit (MMCA)	48 Tests/Kit	
801214	MTB/RIF Test Kit (MMCA)	48 Tests/Kit	
801215	MTB/INH Test Kit (MMCA)	48 Tests/Kit	
801216	MTB/EMB Test Kit (MMCA)	48 Tests/Kit	
801217	MTB/STR Test Kit (MMCA)	48 Tests/Kit	
801205	MTB/FQ Test Kit (MMCA)	48 Tests/Kit	
801206	MTB/SL Test Kit (MMCA)	48 Tests/Kit	
801218	MTB/PZA Test Kit (MMCA)	48 Tests/Kit	
801210	Mycobacteria Identification Kit (MMCA)	48 Tests/Kit	



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