

Advanced Molecular Diagnostics for Drug-Resistant Tuberculosis

WizDx™ CrystalMix MTB/MDR

- Multidrug-resistant tuberculosis (MDR-TB)
- Easy-to-use
- High Sensitivity & Specificity
- Room temperature Storage/Shipping
- Lyophilized PCR Kit



Easy & Fast



Room temp.
Storage/Shipping



Accurate



No need PCR
preparation step



Lyophilized
All-in-One



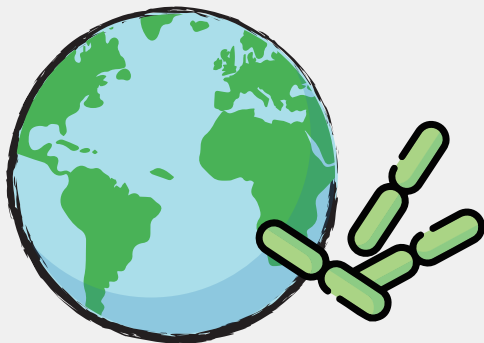
Reduce human error
Prevent contamination



WizDx™ CrystalMix MTB/MDR

WizDx™ CrystalMix MTB/MDR kit is developed to achieve qualitative detection of *Mycobacterium tuberculosis* (MTB) resistance to Rifampicin (RIF) and Isoniazid (INH) in MTB samples.

TUBERCULOSIS IS THE WORLD'S LEADING INFECTIOUS DISEASE KILLER



1.25 Millon

TB deaths including

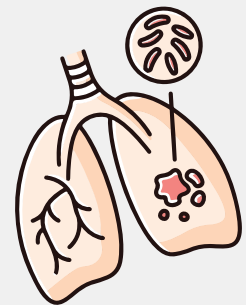
161,000

Deaths among people with HIV

TB is also the leading cause of deaths among people with HIV and a major contributor to deaths associated with antimicrobial resistance.

10.8 Millon

People fell ill with TB in 2023 an estimated



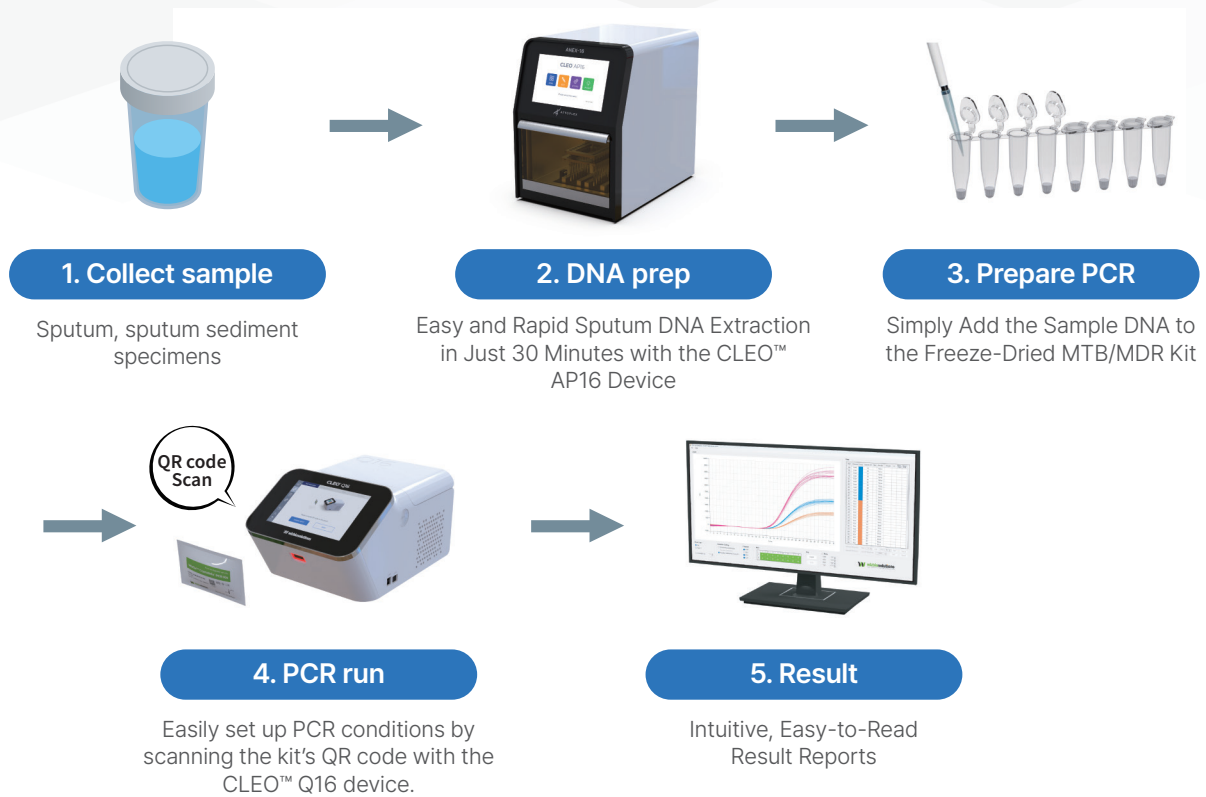
Key Features

- **Fast Results**
Delivers accurate diagnosis within **65 minutes**
- **High Sensitivity**
Detects as low as **150 copies per reaction**
- **Simultaneous and Accurate Detection**
Detects *Mycobacterium tuberculosis* and drug-resistant strains (RIF and INH) in a single test
- **Accurate Mutation Identification**
Enables precise single-gene mutation detection
- **Built-in Internal Control**
Prevents false negatives and ensures reliable results
- **Enhanced PCR Technologies**
 - **Uracil-DNA Glycosylase (UDG):** Prevents carryover contamination
 - **Hot-start PCR:** Minimizes non-specific reactions and enhances specificity
 - **Freeze-dried PCR Mix:** Ready-to-use, room-temperature stable formulation requiring no cold chain
- **Seamless Operation with CLEO™ Q16**
 - **QR Code Setup:** Enables faster and simpler test preparation
 - **AI-driven Analysis:** Automatically interprets results for quick and intuitive confirmation

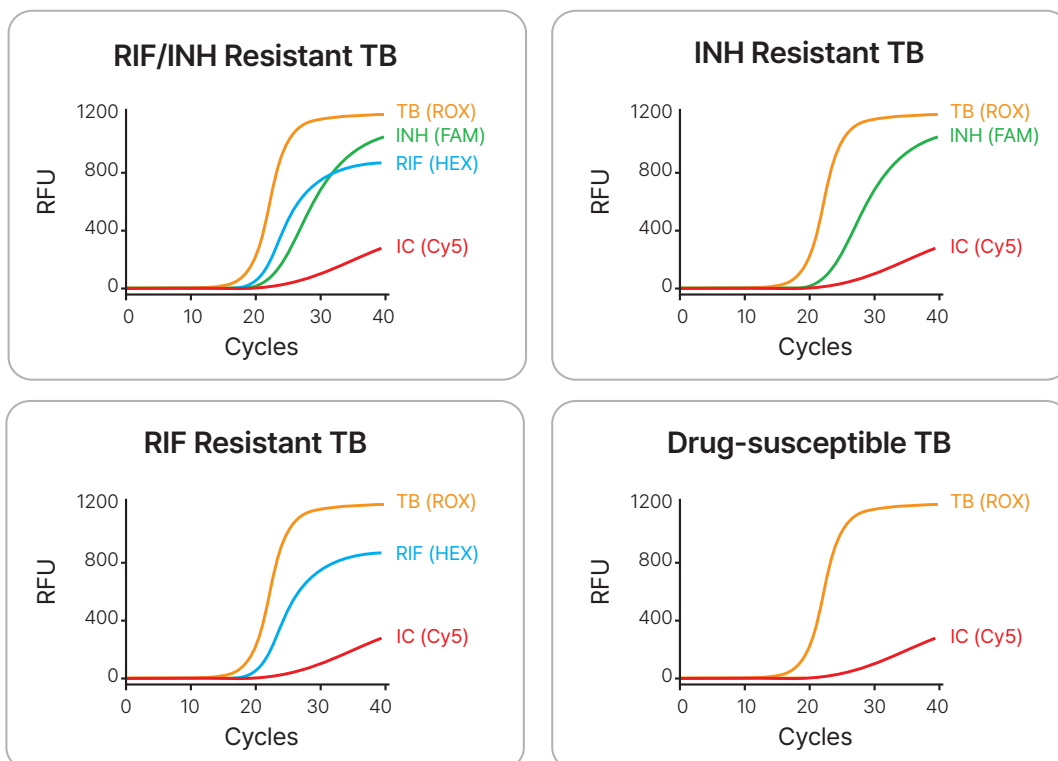


Simple & Fast PCR test workflow

With WizDx™ and CLEO™, move from sample collection to results in under 2 hours - delivering a faster, smarter, and smoother healthcare experience.



Accurate Identification of Antibiotic Resistance



Specifications

Principle of Procedure	Multiplex Real-time PCR
Target	FAM (INH), HEX (RIF), ROX (MTB), Cy5 (Internal control)
Tests for Package	48 Tests/kit
Reagent Type	Lyophilized (Freeze-dried) in PCR tube
Limit of Detection (LoD)	100 copies/rxn for MTB, 100 copies/rxn for <i>rpoB</i> , 100 copies/rxn for <i>inhA</i>
Precision	Respectively detect the reference specimen of high and low concentrations in different time ranges-10 times, and the precision values of intra-assay and inter-assay Ct values were all <5%.
Specificity	No cross-reactivity of the assay was observed with other mycobacterium, non-TB DNA, or susceptible strains.
Sample Types	Sputum, sputum sediment specimens.
Shipping/Storage	Shipping and storage at room temperature for 12 months
Compatible Instruments	CLEO™ Q16 (Wizbiosolutions), CFX96 (Bio-Rad)

Ordering Information

Product	Cat No.	Package	Note
WizDx™ CrystalMix MTB/MDR	DX1221	48 tests	
CLEO™ Q16 Real-time PCR	CL0016	1 system	16 sample/run
CLEO™ AP16 Nucleic acid extractor	CL2016	1 system	Up to 16 sample/run
CLEO™ AP48 Nucleic acid extractor	CL2048	1 system	Up to 48 sample/run
WizMag™ Sputum DNA	W7130 / W7131	64 preps / 192 prep	16 prep/run
	W7132 / W7133	32 prep / 96 prep	1-8 prep/run



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