

IVD

REF TR-02-100

# EuDx™ MDR-TB Detection Kit

Advanced Molecular Diagnostics for Drug-Resistant Tuberculosis



Easy & Fast



High Sensitivity & Specificity



Ready-to-use PCR premix type



Prevent carryover contamination  
Reduce human error



# Key Features



- **Fast Results**  
Provides acc 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 detection of **single-gene mutations**
- **Built-in Internal Control**  
Prevents false negatives and ensures reliable results
- **Enhanced PCR Technologies**
  - **Uracil-DNA Glycosylase (UDG)**: Prevents carryover contamination
  - **Hot-start PCR**: Reduces non-specific reactions and enhances specificity
  - **Ready-to-use PCR Mix**: Simplifies and speeds up test preparation
- **Seamless Operation with CLEO™ Q16**
  - **QR Code Setup**: Enables faster, simpler test preparation
  - **AI-driven Analysis**: Automatically interprets results for quick and intuitive confirmation

## Clinical Performance

Target	Sensitivity(%)	Specificity(%)
MTB	92.98	99.48
MDR-RIF	97.14	98.04
MDR-INH	94.12	97.62

### Sensitivity

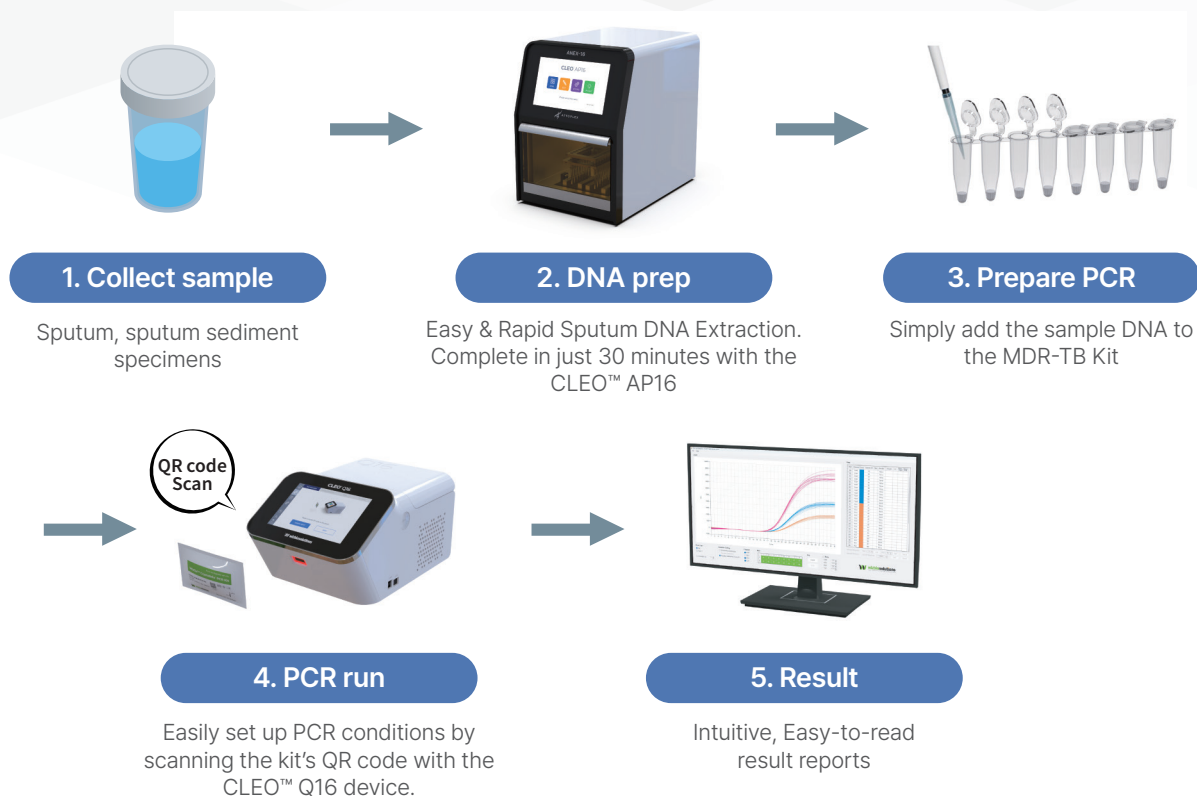
- Positive detection rates exceed **95%** at 100 copies across all 12 targets.
- **rpoB S531L, katG S315T, and inhA -15 C→T mutations** are reliably detected at as few as 50 copies.

### Specificity

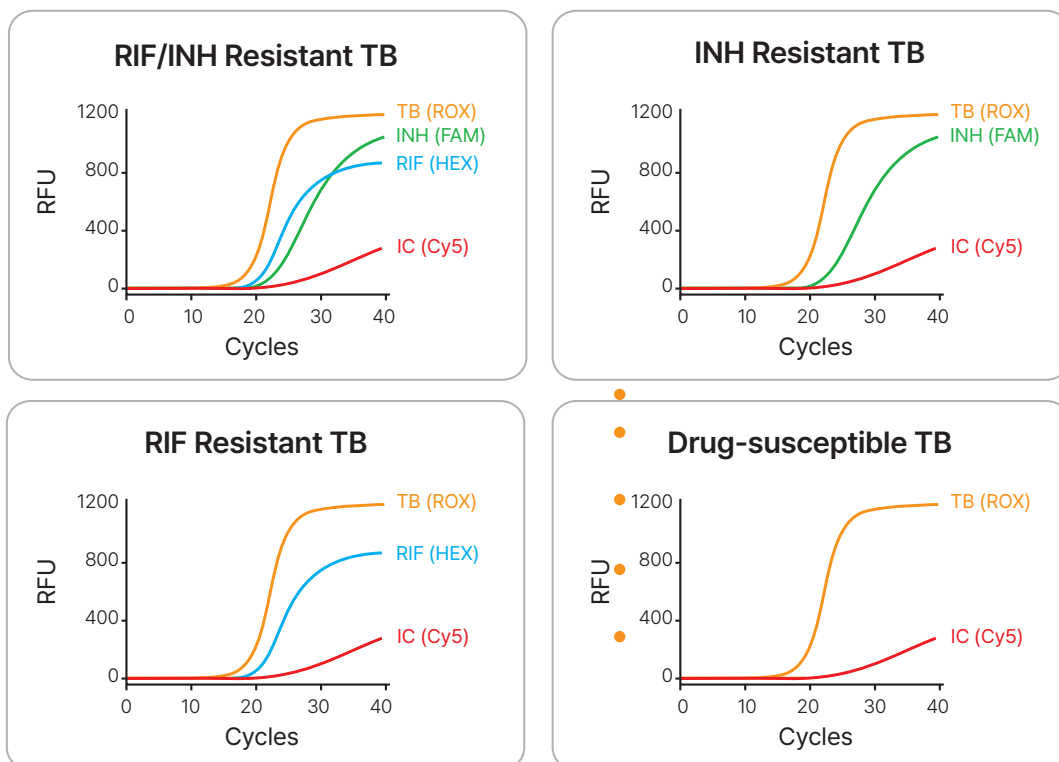
- No cross-reactivity observed with genomic DNAs from **13 species of non-tuberculous mycobacteria** and **14 other pathogens**.
- Potential inhibitors such as human genomic DNA, PCR inhibitors, and antibiotics do not interfere with the reaction.

## Simple & Fast PCR test workflow

With EuDx™ 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	100 Tests/kit
Reagent Type	Ready-to-use premixv
Limit of Detection (LoD)	100 copies/rxn for MTB, 50 copies/rxn for <i>rpoB</i> , 100 copies/rxn for <i>inhA</i>
Precision	MTB Sensitivity: 92.88%, Specificity 99.48% MDR-RIF Sensitivity: 97.14%, Specificity 98.04% MDR-INH Sensitivity: 94.12%, Specificity 97.62%
Sample Types	Sputum, sputum sediment specimens.
Shipping/Storage	Storage at -20 for 18 months
Compatible Instruments	CLEO™ Q16 (Wizbiosolutions), CFX96 (Bio-Rad), ABI7500

## Ordering Information

Product	Cat No.	Package	Note
EuDx™ MDR-TB Detection Kit	TR-02-100	100 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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