

IVD

*High-Performance  
Molecular Diagnostics for  
Tuberculosis & Non-tuberculosis*

## WizDx™ CrystalMix MTB/NTM

WizDx™ CrystalMix MTB/NTM kit is a real-time PCR test for qualitative detection of *Mycobacterium tuberculosis* (MTB) and Non-tuberculosis mycobacteria (NTM).



Easy & Fast  
All-in-one premix type



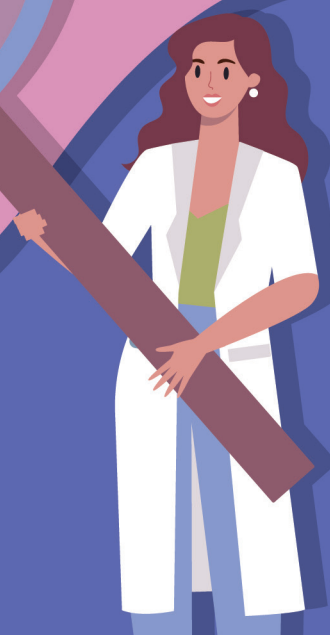
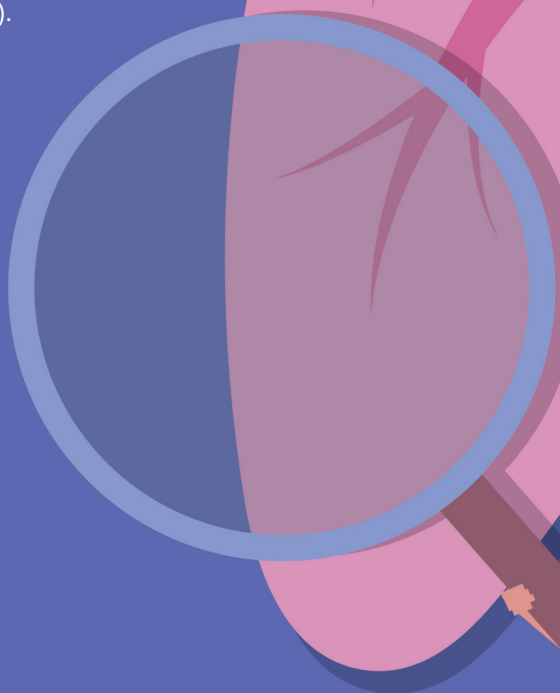
Accurate  
Prevent carryover contamination



Lyophilized PCR mix  
Room temperature storage



All-in-one premix type  
Reduce human error





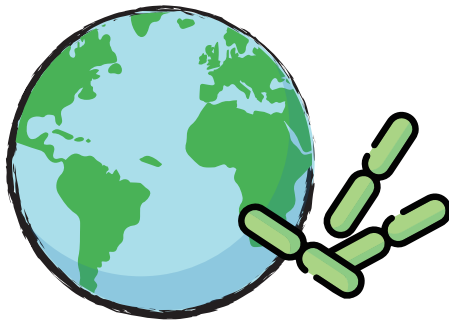
## What is Tuberculosis ?

Tuberculosis (TB) is an infectious disease usually caused by *Mycobacterium tuberculosis* (MTB) bacteria. Tuberculosis generally affects the lungs, but it can also affect other parts of the body. Most infections show no symptoms, which is known as latent tuberculosis. Around 10% of latent infections progress to active disease which, if left untreated, kill about half of those affected. Typical symptoms of active TB are chronic cough with blood-containing mucus, fever, night sweats, and weight loss. Infection of other organs can cause a wide range of symptoms.

Non-tuberculous mycobacteria (NTM), also known as environmental mycobacteria, atypical mycobacteria, and mycobacteria other than tuberculosis (MOTT), are mycobacteria that do not cause tuberculosis or leprosy/Hansen's disease. NTM can cause pulmonary diseases that resemble tuberculosis. Mycobacteriosis is any of these illnesses, usually meant to exclude tuberculosis. They occur in many animals, including humans, and are commonly found in soil and water.



### TUBERCULOSIS IS THE WORLD'S LEADING INFECTIOUS DISEASE KILLER



## 1.25 Million

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 Million

People fell ill with TB in 2023 an estimated

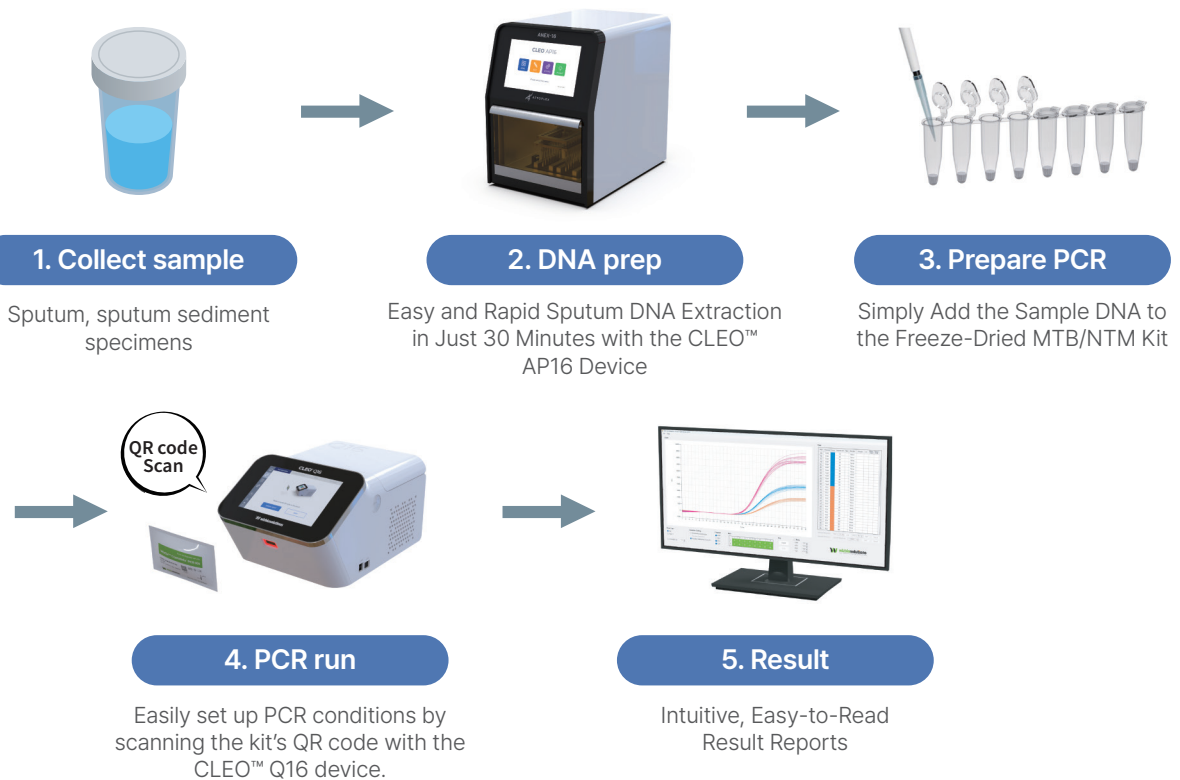
## Key Features

- **Fast Diagnosis within 59 Minutes**
- **Excellent Sensitivity**
  - 10 copies/rxn for *Mycobacterium tuberculosis* (MTB)
  - 25 copies/rxn for non-tuberculous mycobacteria (NTM)
- **Simultaneous Detection:** MTB and NTM tested in a single tube for rapid and accurate results
- **UDG Technology:** Uracil-DNA glycosylase prevents carryover contamination
- **Hot-start PCR:** Minimizes non-specific reactions and enhances specificity
- **Freeze-dried PCR Mix:** Ready-to-use formulation enables convenient storage and streamlined testing
  - Stable at room temperature
  - No cold chain required
- **Seamless Operation with CLEO™ Q16**
  - **QR Code Setup:** Enables faster and simpler test preparation
  - **AI-driven Analysis:** Automatically interprets results for quick, intuitive confirmation

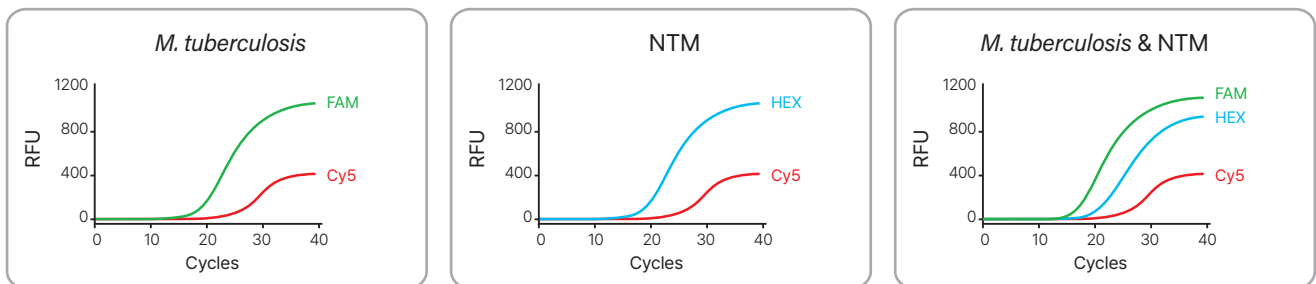


## Simple & Fast PCR test workflow

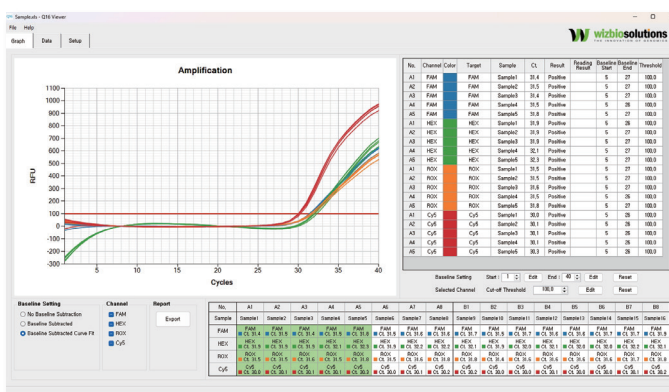
With WizDx™ and CLEO™, move from sample collection to results in under 2 hours - delivering a faster, smarter, and smoother healthcare experience.



## Multiple targets and accurate diagnostics



## CLEO™ Q16 Viewer/Software



### Comprehensive Result Reporting

- **Automated Analysis:** Generates result reports instantly
- **Raw Data Verification:** Enables confirmation of raw data analysis
- **Rapid Result Screening:** Quick identification of positive and negative results
- **LIS Compatibility:** Seamless integration with Laboratory Information Systems
- **Flexible Output Options:**
  - Print-ready result reports
  - Export and download in Excel format

## Specifications

Principle of Procedure	Real-time PCR
Target	FAM for <i>Mycobacterium tuberculosis</i> (MTB), HEX for Non-tuberculosis mycobacteria (NTM), and Cy5 for the internal control
Tests for Package	96 Tests/kit
Reagent Type	Lyophilized (Freeze-dried) in PCR tube
Limit of Detection (LoD)	10 copies/rxn for <i>Mycobacterium tuberculosis</i> (MTB) 25 copies/rxn for non-tuberculosis mycobacteria (NTM)
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 for Adenovirus, hCoV, Parainfluenza, RSV, SARS-CoV-2, Influenza virus, <i>Legionella pneumophila</i> , <i>Mycoplasma pneumoniae</i> , <i>Streptococcus pneumoniae</i> , <i>Enterococcus faecalis</i> , <i>Enterococcus faecium</i> , HPV, and HIV.
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/NTM	DX1234	96 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



A-1806, Woolim Lions Valley 2, Sagimakgol-ro 45beon-gil 14,  
Jungwon-gu, Seongnam-si, Gyeonggi-do 13209  
Republic of Korea

🌐 [www.wizbiosolution.com](http://www.wizbiosolution.com)  
✉ [support@wizbiosolution.com](mailto:support@wizbiosolution.com)  
☎ +82 70 7605 5066



© 2025 Wizbiosolutions Inc. All rights reserved.

WizDx, CLEO, WizMag and CrystalMix is a trademark of Wizbiosolutions Inc.  
ISO13485:2016, GMP certified