Cepheid
A better way.

Xpert® MTB/RIF

Accurate Detection of MTB and Rifampin Resistance Mutations



The Need

- Each day, more than **3,400** people lose their lives to TB and nearly 30,000 people fall ill with this preventable and curable disease[1]
- In the United States, there were 10,347 cases reported, an **8%** increase from 2023[2]
- **Precise and early detection of TB** is needed to improve case management and significantly enhance the prevention of TB transmission[3]

The Solution

The **Xpert MTB/RIF** test provides fast and accurate detection of Mycobacterium Tuberculosis (MTB) and Rifampicin (RIF) resistance simultaneously from patient samples

- Simple three-step process and results in less than 2 hours
- Designed to provide accurate MTB and Rifampicin detection
- On-demand testing supports clinician decision-making

The Impact

- Supports timely clinical decision-making by providing rapid detection of MTB and RIF resistance[4]
- May be used as an aid to decisions regarding continued AII (airborne infection isolation), potentially reducing AII duration versus serial smear in certain settings[4]
- Economic modeling studies in US settings have found implementation is cost-effective for diagnosing pulmonary TB in the United States[5]

1 Global Tuberculosis Report 2023. https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2023. Accessed Jan 2024.

2 The Global Statistics. Tuberculosis Facts in the U.S. 2025| TB Stats. Accessed March 2026. https://www.theglobalstatistics.com/united-states-tuberculosis-facts/

3 Centers for Disease Control and Prevention—Guidelines for preventing the transmission of TB-- https://www.cdc.gov/mmwr/preview/mmwrhtml/00001897.htm. Accessed Jan 2024.

4 Christopher K. Lippincott et al, Xpert MTB/RIF Assay Shortens Airborne Isolation for Hospitalized Patients With Presumptive Tuberculosis in the United States Clin Infect Dis. 2014 Jul 15; 59(2): 186–19

5 H. W. Choi, et al, Cost-effectiveness of Xpert® MTB/RIF for diagnosing pulmonary tuberculosis in the United States Int J Tuberc Lung Dis. 2013 October ; 17(10): 1328–1335

Xpert® MTB/RIF

Product Reference Sheet — US-IVD

Test Reagent Kit	Xpert MTB/RIF
Catalog Number	GXMTB/RIF-US-10
Technology	Qualitative nested PCR
Targets	rpoB gene
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	Sputum sediment and unprocessed sputum
Sample Extraction	Automated/Integrated
Precision Pipetting	Not Required
TAT	Less than 2 hours
Controls: Probe Function/Detection	Probe Check Control (PCC)
Controls: Process	Sample Processing Control (SPC)
Sensitivity*	93.8%
Specificity*	98.7%
Sample Storage	**Sputum sediment:** 2–8 °C for up to 7 days **Unprocessed sputum:** 3 days at a maximum of 35 °C and additional 7 days at 2–8 °C
Kit Storage	2–28 °C
Commercial Controls	Refer to Package Inserts or Contact Cepheid Technical Support

* The performance of Xpert MTB/RIF for detection of MTB relative to MTB culture.

US-IVD. *In Vitro* Diagnostic Medical Device.

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