

Xpert[®] MTB/RIF Ultra

Raising the Standard for Tuberculosis Diagnosis



→ Active Case Finding
for TB Elimination

CE IVD In Vitro Diagnostic Medical Device
Not available in all countries.

 **Cepheid[®]**
A better way.



With Xpert® MTB/RIF Ultra as frontline diagnosis we are moving a step closer towards TB elimination. It's a game changer for overcoming the challenge of fast diagnosis of TB in smear-negative patients.”

Daniela Maria Cirillo, M.D., Ph.D.
WHO collaborating Centre and TB Supranational Reference Laboratory



The Need

Globally in 2019, an estimated 10.0 million people fell ill with TB. There were 1.4 million TB deaths (14% among HIV-positive people).¹

Today, the challenge to the global TB community is to 'End TB'. The reliance on microscopy, with a sensitivity of only 46%–78%,² is a severe limitation. Between 36%–59% of pulmonary TB cases are smear-negative/culture-positive and the relative transmission rate (10-24%) of these patients has a strong impact on patient management in hospitals, as well as TB control programs in developed and developing countries.^{3,4}

In order to support the goal of TB elimination, we must implement efficient active case finding. A precise and early detection of TB is needed to improve case management and significantly enhance prevention of TB transmission.



The Solution

Enhancing the Standard

Xpert® MTB/RIF revolutionized the management of *Mycobacterium tuberculosis* (MTB) infections by providing faster and more accurate MTB diagnosis that detects MTB and rifampicin (RIF) resistance simultaneously. Following World Health Organization endorsement in 2010, Xpert MTB/RIF has helped improve TB programs in over 130 countries and counting.

Building on this success, faster and more accurate detection of MTB from the first point of encounter in the community is critical. Partnered with GeneXpert® Systems, Xpert MTB/RIF Ultra will bring:

- Improved performance and faster time to result
 - Higher sensitivity especially in smear-negative TB cases
 - Results in <80 minutes⁵
- Increased accuracy of Rifampicin results
- Improved detection of mixed infections
- Same easy-to-use process



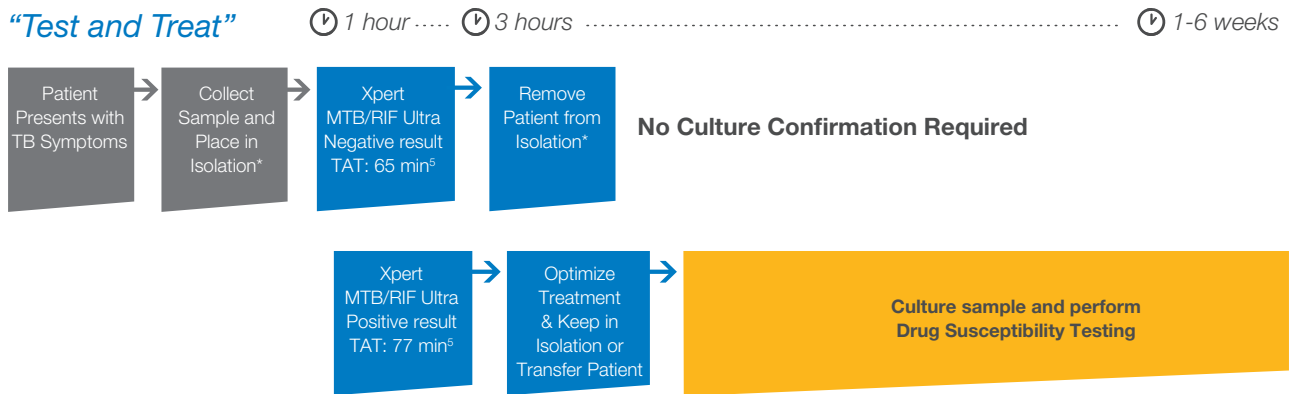
One of the key components of WHO's new End TB Strategy is to modernize all aspects of tuberculosis care and prevention through use of fast molecular diagnostics.⁶



The Impact

Preventing the transmission of MTB by fast identification of contagious patients, placing them in airborne infection isolation and initiating the right antibiotic therapy as soon as possible are crucial to 'END TB'. Recently published recommendations by global experts demonstrate the efficiency of using Xpert® MTB/RIF Ultra as a frontline test over smear microscopy or line probe assays followed by culture-based methods for drug susceptibility testing.^{7,8,9} Thus, a single modification of the diagnostic algorithm to detect smear-positive and smear-negative TB patients improves active case management, is more cost-efficient³ and could potentially reduce the relative rate of transmission. Using Xpert MTB/RIF Ultra has the potential to reduce the number of missed smear-negative TB patients and may lead to a decrease in total costs of patient care due to the detection of MTB in patient specimens and RIF-resistance in a single test.

Impact Patient Management Pathway



Clinical Impact

- Early identification of TB in suspected patients
- Faster detection of drug-sensitive and -resistant TB cases greatly improves initiation of appropriate treatment
- Cost-efficient case management³
- Enhanced performance in HIV-positive patients and children for a fast active case finding¹⁰
- Improved patient outcome

Laboratory Impact

- Faster time to result
- Lower number of culture confirmations due to the high negative predictive value of Xpert MTB/RIF Ultra
- Enhanced sensitivity over smear microscopy of MTB-complex in pulmonary samples
- On-site and on-demand test availability
- Reduced complexity and labor requirements

* Based on the local guidelines



Workflow:

3 Easy Steps

Total hands-on time: <1 minute

1

Add Sample Reagent to sample tube and incubate for 15 minutes at room temperature



2

Pipette 2 mL of inactivated sample into cartridge



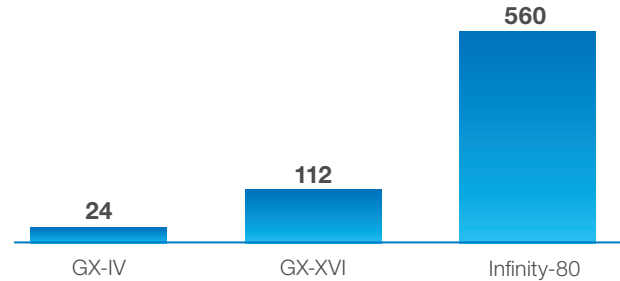
3

Insert cartridge and start test



System Throughput*

8-hr shift



* Assume 15% MTB positivity rate and average TTR of 66.8 min per test. Actual throughput may vary based on the local prevalence.



GeneXpert® Infinity-80

GeneXpert® I

GeneXpert® II

GeneXpert® IV

GeneXpert® XVI

CATALOG INFORMATION

Xpert® MTB/RIF Ultra	10 tests	GXMTB/RIF-ULTRA-10
	50 tests	GXMTB/RIF-ULTRA-50

References:

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