Cepheid®
A better way.

Raising the Standard for Tuberculosis Diagnosis

Xpert® MTB/RIF Ultra

CE-IVD. *In Vitro* Diagnostic Medical Device.
Not available in all countries. Not available in the United States.
2797

“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 2020, an estimated 10.0 million people fell ill with TB. There were 1.4 million TB deaths (including 214,000 people with HIV).[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. 2017 WHO endorsed MTB Ultra as a replacement to MTB/RIF and smear microscopy.

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 minutes[5]
- 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 PCR molecular diagnostics.[6]

Coverage, plus
Accuracy, plus
Peace of mind

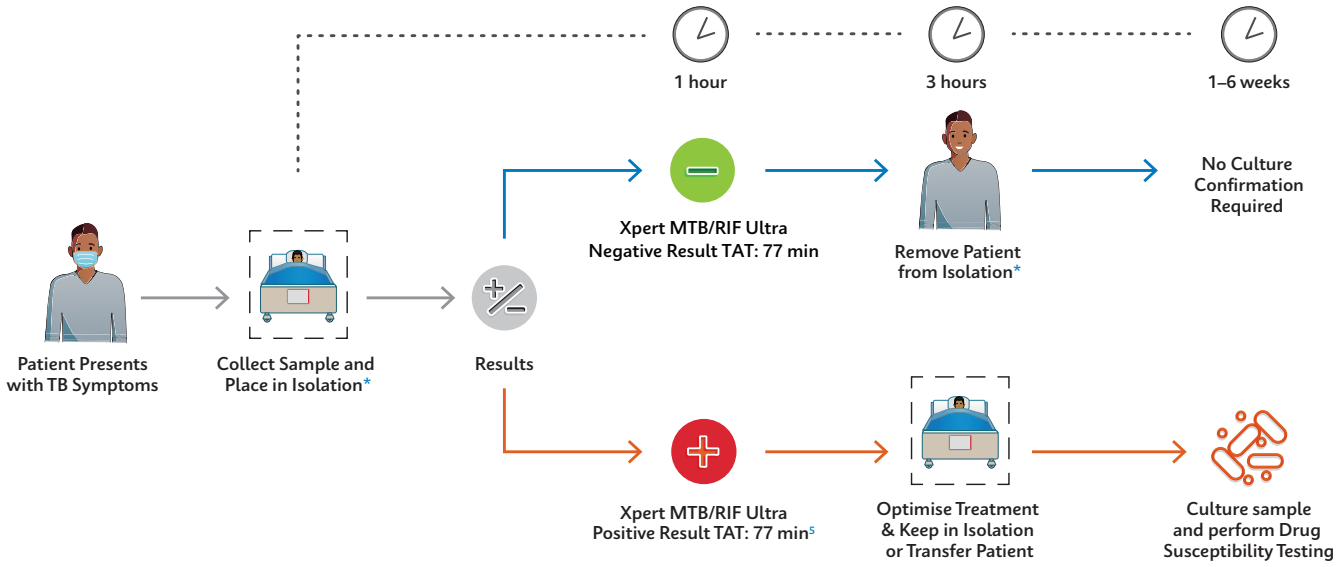
That's the **PCR***plus* advantage.
From Cepheid.

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-efficient,[3] 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 on Patient Management Pathway

"Test and Treat"



Clinical Impact

- Early identification of TB in suspected patients
- Enhanced performance in HIV-positive patients and children for a fast active case finding[10]
- Faster detection of drug-sensitive and resistant TB cases greatly improves initiation of appropriate treatment
- Cost-efficient case management[3]
- Improved patient outcome

Laboratory Impact

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

* 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*

* Based on test run time of 77 min

Catalog Information

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

References:

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