

Xpert<sup>®</sup>  
MTB/RIF

*Release or treat in under two hours.*



## Xpert<sup>®</sup> MTB/RIF

Accurate detection of MTBC and rifampin resistance mutations.

 **Cepheid<sup>®</sup>**  
A better way.



*Because the MTB/RIF test can detect TB better than the smear, results from one or two MTB/RIF tests can be used in the decision to remove patients from isolation.\*"*

FDA News Release<sup>1</sup>

Feb 12, 2015



## THE NEED

Great challenges face the global community, including the United States, with the worldwide re-emergence of TB and increased number of multi-drug resistant TB (MDR-TB) cases. The need for fast and accurate TB diagnosis with indication for the drug resistance is greater than ever.

Current MTB diagnostics methods require weeks to deliver a definitive result. Delayed results reporting can lead to patients placed in respiratory isolation unnecessarily or put on ineffective therapies. AFB smear could provide faster turn-around time, but may be missing the true positive cases and patients may continue to spread MTB to others in the community, increasing the disease burden.



## THE SOLUTION

**Xpert<sup>®</sup> MTB/RIF, on-demand molecular testing — an ideal solution:**

- On-demand results that empowers physicians to manage patients effectively
- As few as one negative result can be used in the decision to remove patient from respiratory isolation
- Simultaneous detection of both MTB and rifampin resistance mutations, which are markers for MDR-TB strain
- Acceptable samples include raw or concentrated sediments prepared from induced or expectorated sputum



*WHO's endorsement of the Xpert MTB/RIF test, which is a fully automated NAAT (nucleic acid amplification test) follows 18 months of rigorous assessment of its field effectiveness in the early diagnosis of TB, as well as multidrug-resistant TB (MDR-TB) and TB complicated by HIV infection, which are more difficult to diagnose.*

**WHO endorses new rapid tuberculosis test**  
**WHO Press Release, Dec 2010<sup>2</sup>**



# THE IMPACT



## Microbiology Lab



The World Standard in TB diagnostics

## Clinician



Rapid diagnosis supports earlier initiation of appropriate therapy

## Hospital



Better utilization of respiratory isolation rooms to save costs<sup>3</sup> and support operational and financial efficiency<sup>4,5</sup>

## Quality

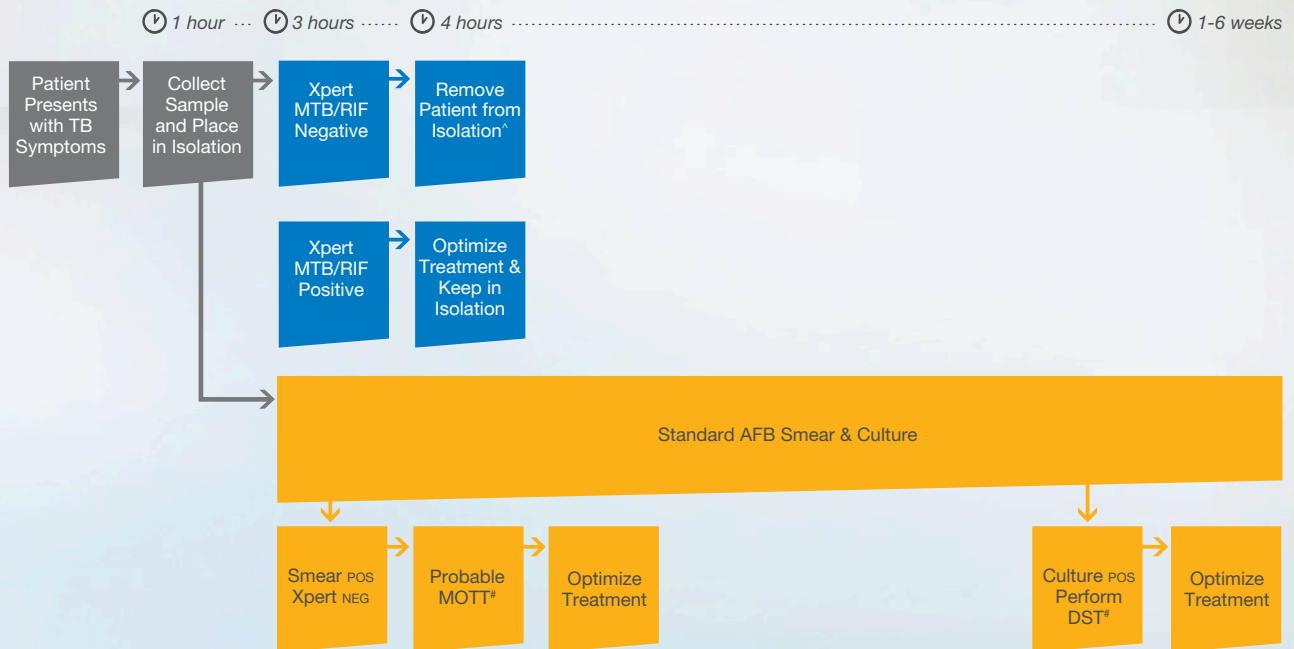


Control the risk of TB infection before it controls you



## IMPACT ON PATIENT ISOLATION PATHWAY\*

“Test and Release” or “Test and Treat”



\* Refer to the Xpert MTB/RIF package insert for details

^ Example with one Xpert® MTB/RIF negative result

# MOTT: Mycobacteria Other Than Tuberculosis; DST: Drug Susceptibility Test



## WORKFLOW:

# 3 EASY STEPS

Total hands-on time: <1 Minute

1

Pour Sample Reagent into sample tube and incubate for 15 minutes at room temperature



2

Pipette liquefied/decontaminated sample into cartridge



3

Insert cartridge and start test



> **Xpert® MTB/RIF is a qualitative real-time PCR test for automated detection of *Mycobacterium tuberculosis* complex DNA and rifampin resistance associated mutations of the *rpoB* gene.**

### CATALOG INFORMATION

Xpert MTB/RIF (10 tests) ..... GXMTB/RIF-US-10

### References:

1. FDA. New data shows test can help physicians remove patients with suspected TB from isolation earlier. Press Release. 2015 Feb 12. Accessed Feb 2015. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm434226.htm>
2. WHO. WHO endorses new rapid tuberculosis test. Press Release. 2010 Dec 8. Accessed Feb 2015. [http://www.who.int/mediacentre/news/releases/2010/tb\\_test\\_20101208/en/](http://www.who.int/mediacentre/news/releases/2010/tb_test_20101208/en/)
3. CDC. A New Tool to Diagnose Tuberculosis: The Xpert MTB/RIF Assay. Accessed Feb 2015. [http://www.cdc.gov/tb/publications/factsheets/PDF/XpertMTB-RIFAssayFactSheet\\_Final.pdf](http://www.cdc.gov/tb/publications/factsheets/PDF/XpertMTB-RIFAssayFactSheet_Final.pdf)
4. Davis JL, et al. Impact of GeneXpert MTB/RIF on patients and tuberculosis programs in a low-burden setting. a hypothetical trial. Am J Respir Crit Care Med. 2014 Jun 15;189(12):1551-9.
5. Lippincott CK, 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):186-92.

For In Vitro Diagnostic Use.

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