



TUBERCULOSIS DIAGNOSTICS Xpert MTB/RIF Test

WHO ENDORSEMENT AND RECOMMENDATIONS

The new rapid TB test – known as Xpert MTB/RIF- is a fully-automated diagnostic molecular test. It has the potential to revolutionize and transform TB care and control. The test:

- simultaneously detects TB and rifampicin drug resistance
- provides accurate results in less than two hours so that patients can be offered proper treatment on the same day
- has minimal bio-safety requirements, training, and can be housed in non-conventional laboratories



Xpert MTB/RIF – a new diagnostic test that could “revolutionize and transform” TB care and control

WHO RECOMMENDATIONS

- **Strong recommendation:** Xpert MTB/RIF rapid test should be used as the initial diagnostic test in individuals suspected of MDR-TB or HIV/TB
- **Conditional recommendation:** Xpert MTB/RIF rapid test may be used as a follow-on test to microscopy in settings where MDR-TB and or HIV is of lesser concern, especially in smear-negative specimens (recognising major resource implications)

EXPECTED IMPACT

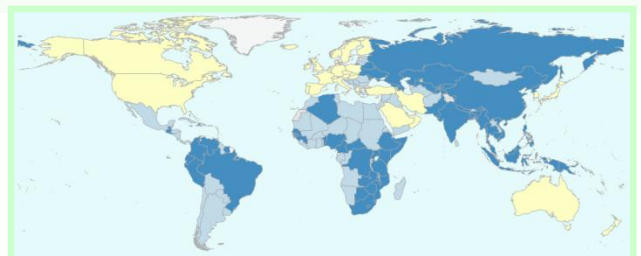
- a three-fold increase in the diagnosis of patients with drug-resistant TB
- a doubling in the number of TB/HIV cases diagnosed in areas with high rates of TB and HIV (compared to microscopy diagnosis)

- Xpert MTB/RIF was developed by FIND, Cepheid and the University of Medicine and Dentistry of New Jersey with funding from NIH, and the Bill and Melinda Gates Foundation.
- Scientific evidence was reviewed by WHO through an Expert Group and then WHO's Strategic and Technical Advisory Group for TB.
- FIND negotiated a 75% price reduction for the public sector of 145 countries plus NGOs and other non-profit agencies in these countries.

TIMELINE

- from concept to field implementation -

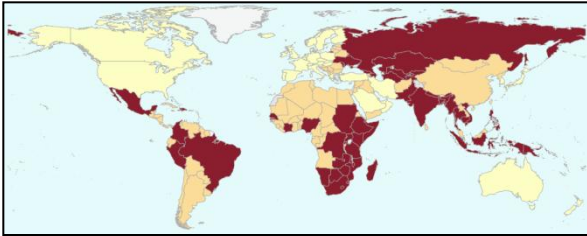
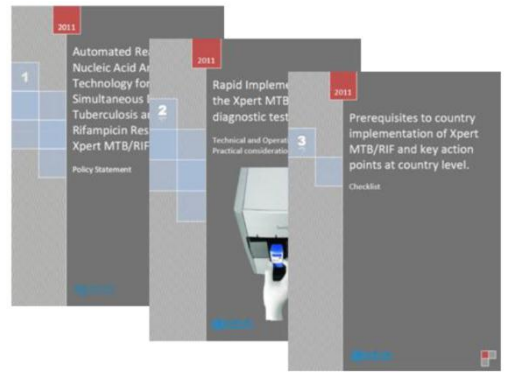
- May 2006** – FIND partners with Cepheid to develop a new and novel TB test
- April 2009** – the new Xpert MTB/RIF rapid test for TB receives CE IVD marking
- May 2009** – Demonstration studies underway
- September 2010** – New England Journal of Medicine publishes validation data; Expert Group issues strong recommendation to WHO based on scientific evidence; WHO's Strategic and Technical Advisory Group for TB further reviews evidence and makes policy recommendations
- December 2010** – After organization of a Global Consultation, **WHO endorses Xpert MTB/RIF**
- March 2012** – Since WHO endorsement, 61 countries around the world (see dark blue countries in map below) have procured 611 GeneXpert instruments and 863,790 Xpert MTB/RIF cartridges in the public sector under concessional pricing



ROLL OUT OF THE XPERT MTB/RIF RAPID TB TEST

Available WHO resources:

- Policy statement: *Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance: Xpert MTB/RIF*
- Rapid implementation of the Xpert MTB/RIF diagnostic test: *Technical and operational 'How-to' Practical considerations*- providing guidance on diagnostic algorithms, site selection, and operational considerations
- Checklist: *Prerequisites to country implementation of Xpert MTB/RIF and key action points at country level*



- Mapping of country and partner implementation sites and plans for procurements (see map at left, indicating red countries with available information)
- Post-marketing surveillance of operational problems
- Online data collection tool for facility-level data on routine use, allowing for refined global guidance

For information on all available WHO resources: <http://who.int/tb/laboratory/mtbrifrollout>

COSTS AND FUNDING

Projected price reductions based on increases in the number of tests			
Year	2011	2012	2014
Number of Tests (million)	0.6m	1.7 m	3.7 m
Price per Test	\$16.86	\$14.00	\$10.72
Average Price Reduction	75%	79%	84%

COSTS (from the *Global Plan to Stop TB 2011-2015*)

For MDR-TB: The cost of testing all MDR-TB retreatment cases and 20% of all new MDR-TB cases is US\$14 million, requiring less than 1% of current funding for TB control.

For HIV-associated TB: Testing all HIV-positive individuals suspected of having TB will cost US\$ 44 million, requiring 1-2% of current funding for TB control, and amounting to less than 1% of current expenditure on HIV care in several high TB-HIV burden countries.

WHY IS MDR-TB & TB/HIV DIFFICULT TO DIAGNOSE?

- The most widely used method to detect TB is the 125 year-old sputum smear microscopy test, which has a number of drawbacks, including low sensitivity (especially in HIV-positive individuals and children) and inability to determine drug-resistance.
- Conventional diagnosis of drug resistant TB relies on bacterial culture and drug susceptibility testing, a slow and cumbersome process. During this time patients may be inappropriately treated, drug-resistant strains may continue to spread, and resistance may become amplified.
- In contrast, the new Xpert MTB/RIF test is rapid, fully-automated and therefore not as susceptible to human error. It provides a highly accurate diagnosis in a single test that identifies both the presence of TB and drug-resistant TB. This means people can be offered the proper treatment immediately.