ABOUT THE XPERT MTB/RIF TEST

The 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 and training needs, and can be housed in non-conventional laboratories.

UPDATED WHO RECOMMENDATIONS
AS OF OCTOBER 2013

For diagnosis of pulmonary TB and rifampicin resistance:

Strong recommendation:
• Xpert MTB/RIF should be used as the initial diagnostic test in adults and children presumed to have MDR-TB or HIV-associated TB

Conditional recommendations (recognising major resource implications):
• Xpert MTB/RIF may be used as the initial diagnostic test in adults and children presumed to have TB
• Xpert MTB/RIF may be used as a follow-on test to microscopy in adults presumed to have TB but not at risk of MDR-TB or HIV-associated TB, especially in further testing of smear-negative specimens

For diagnosis of extrapulmonary TB and rifampicin resistance:

Strong recommendation:
• Xpert MTB/RIF should be used as the initial diagnostic test in testing cerebrospinal fluid specimens from patients presumed to have TB meningitis

Conditional recommendation:
• Xpert MTB/RIF may be used as a replacement test for usual practice (including conventional microscopy, culture, and/or histopathology) for testing of specific non-respiratory specimens (lymph nodes and other tissues) from patients presumed to have extrapulmonary TB

For all WHO TB diagnostics policy documents: http://www.who.int/tb/laboratory/policy_statements/

KEY WHO RESOURCES

• Policy update: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance: Xpert MTB/RIF for the diagnosis of pulmonary and extrapulmonary TB in adults and children.
• Xpert MTB/RIF implementation manual: technical and operational ‘how-to’; practical considerations
• Mapping of country and partner implementation sites (in map at right, red countries have available information).
• Periodically updated list of scientific literature on use of Xpert MTB/RIF, including its evaluation, cost-effectiveness, and utility for diagnosis of extrapulmonary and paediatric TB.

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For more information: http://who.int/tb/laboratory/mtbrifrollout
ROLL-OUT OF THE XPERT MTB/RIF RAPID TB TEST

Since the time of the initial WHO recommendation of Xpert MTB/RIF in December 2010, 110 high-burden and low/middle-income countries (see dark blue countries in map) have procured 3,553 GeneXpert instruments and 8.8 million Xpert MTB/RIF cartridges in the public sector under concessional pricing, as of 30 September 2014.

TIMELINE – FROM CONCEPT TO IMPLEMENTATION

May 2006 – FIND and the University of Medicine and Dentistry of New Jersey partner with Cepheid to develop a novel TB test, with funding from the US NIH and the Bill & Melinda Gates Foundation (BMGF).

May 2009 – Demonstration studies underway.

September 2010 – 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 recommends Xpert MTB/RIF.

August 2012 – A public-private partnership between the US President’s Emergency Plan for AIDS Relief (PEPFAR), the US Agency for International Development (USAID), UNITAID, and Bill & Melinda Gates Foundation allows for a drop in price of the Xpert MTB/RIF test cartridge from 16.86 USD to 9.98 USD.

May 2013 – Expert Group reviews updated evidence base on use of Xpert MTB/RIF for diagnosis of pulmonary, extrapulmonary and paediatric TB and rifampicin resistance, and issues updated recommendations to WHO.

October 2013 – WHO updates recommendations on Xpert MTB/RIF, with an expanded scope of use.


TBXPERT PROJECT

The TBXpert Project will provide approximately 1.4 million Xpert MTB/RIF test cartridges and 237 GeneXpert instruments for the rapid detection of TB and rifampicin resistance in 21 recipient countries in 2013-2015. The USD25.9 million TBXpert Project is funded by UNITAID and executed by the WHO Global TB Programme and the Stop TB Partnership. To ensure country absorptive capacity and effective use of the technology, the TBXpert Project links a broad network of partners and existing initiatives for TB laboratory strengthening and innovative approaches to expand access to vulnerable populations in both the public and private sector. TBXpert Project partners include the Global Laboratory Initiative (GLI), TB REACH, the Global Drug Facility, the EXPAND-TB Project, Interactive Research and Development and the African Society for Laboratory Medicine.

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 rifampicin-resistant TB. This means people can be offered the proper treatment immediately.