

The Global Laboratory Initiative of the Stop TB Partnership



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Activities

Lack of Laboratory Services is a Barrier to the Control of TB and DR TB

- **Only ~53% of all new cases and 63% of new smear-positive cases are detected**
- **AFB smear-based testing is inadequate in high HIV settings**
- **Only 15% of MDR TB cases lab confirmed**
- **Many XDR TB cases are not detected due to the lack of second-line DST**

The Way Forward in Lab Strengthening

- **Promote the need to strengthen labs**
- **Support the Global Laboratory Initiative**
- **Coordinate with all partners**
- **Pursue endorsement and transfer of new technology and policy making**
- **Promote research into new diagnostics**
- **Favor integrated technology and broad laboratory network development**

Stop TB Partnership Workgroups

- **Implementation Workgroups**
 - DOTS Expansion
 - TB/HIV
 - MDR TB
 - **Global Laboratory Initiative**
- **Research Workgroups**
 - New Diagnostics
 - New TB Drugs
 - New TB Vaccines

GLI Structure & Governance

WHO Stop TB
Department

Stop TB Partnership



GLI Secretariat

GLI Core Group

Evaluates, approves, governs projects; Advises GLI Secretariat

GLI Partners Committee

Advises and approves strategic agenda of GLI; Monitors project progress

Subgroup

TB Supranational Reference Laboratory Network

Technical WG



Laboratory strengthening

Human resource development strategy

Laboratory accreditation

Other

Priority projects and activities
Time limited
Partner approach

GLI Mission

To serve as a platform of coordination and communication for TB lab strengthening, in the areas of:

- **Global policy guidance**
- **Laboratory capacity development**
- **Interface with other laboratory networks, enabling integration**
- **Standardised lab quality assurance**
- **Coordination of technical assistance**
- **Effective knowledge sharing**
- **Advocacy and resource mobilisation**

GLI Strategic Priorities

- **Establish GLI partnership projects**
- **Develop templates for country-specific roadmaps for laboratory strengthening**
- **Develop human resource strategies**
- **Develop appropriate and adequate laboratory biosafety standards**
- **Develop a TB lab accreditation system**
- **Move new diagnostics into countries**

WHO-Endorsed Molecular Tests for TB

- **Molecular Line Probe Assay (LPA)**
 - regional or national level laboratory
 - smear-positive sputum or MTB cultures
- **Xpert MTB/RIF**
 - sub-district/district hospital level laboratory
 - smear positive or negative sputum or processed sputum pellet



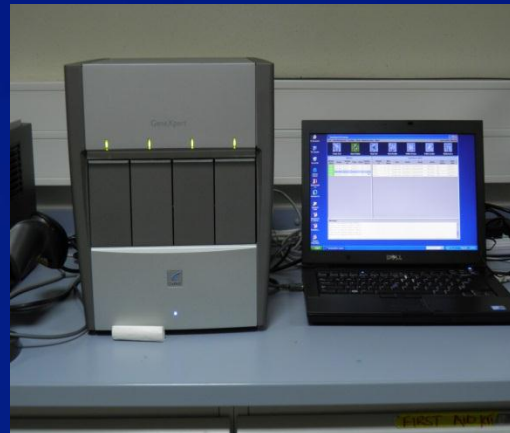
Cepheid Xpert[®] MTB/RIF Assay - I

- Hemi-nested PCR assay targeting *rpoB*
- Based on molecular beacon technology
- Detects *M. tuberculosis* directly from sputum specimens
- Simultaneously detects rifampin resistance



Cepheid Xpert[®] MTB/RIF Assay - II

- Requires minimal training and facilities
- Simple sputum processing steps
- Automated amplification and detection
- Includes internal amplification control
- Closed system



Xpert[®] MTB/RIF Improves TB Testing

One Xpert[®] MTB/RIF test

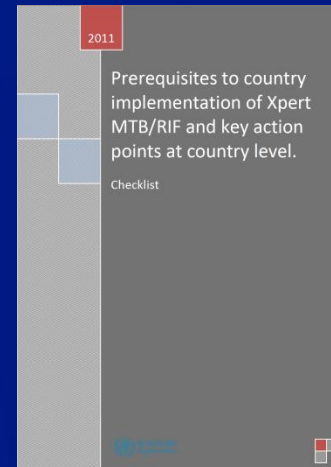
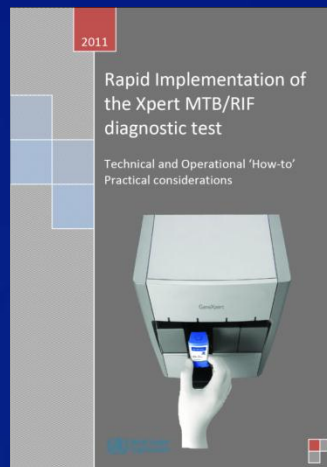
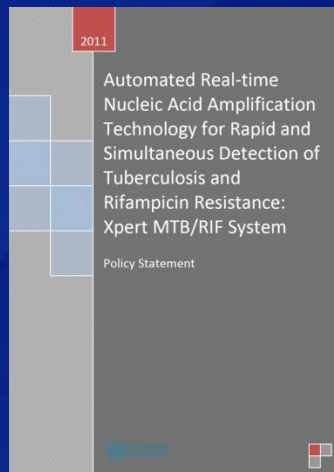
- **is about as sensitive and specific as one LJ culture**
- **can increase TB case detection by 40% over direct smear microscopy alone**
- **takes only 2hrs to complete**
- **detects MTB and RIF resistance**
- **does not require sophisticated BSL-3 facilities or specialized laboratory expertise**

WHO Recommendations – 2013

- **Xpert should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in persons presumed to have pulmonary MDR TB or HIV-associated TB**
- **Xpert may be used as a follow-on test to microscopy in persons, where MDR TB or HIV is of lesser concern, especially in further testing of smear-negative specimens**
- **Xpert may be used rather than conventional microscopy, culture and DST as the initial diagnostic test in all persons presumed to have TB**

Guidance and Training Materials

- WHO Policy Framework for Implementing TB Diagnostics
- WHO Rapid Implementation of the Xpert[®] MTB/RIF Diagnostic Test
- TB CARE Xpert Implementation Guide
- GII Xpert Workshop-in-a-Box training manual



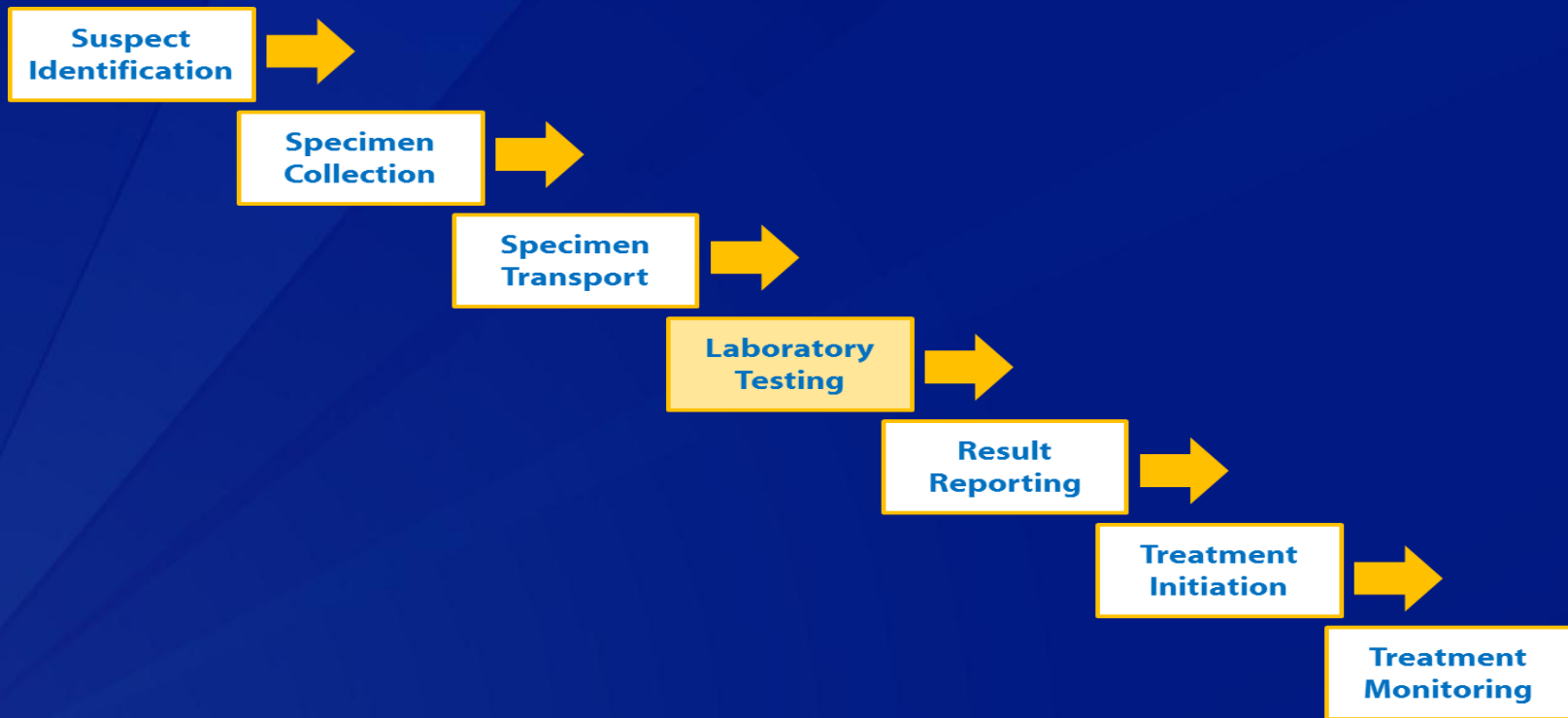
<http://www.stoptb.org/wg/gli/documents.asp>

Lessons from Early Implementers

- **Wide-scale implementation:**
 - **increases detection of bacteriologically positive cases and RIF-resistant cases**
 - **reduces time to diagnosis**
- **Diagnostic and treatment capacity need to be matched**
- **The private sector must be engaged**
- **Electronic recording and reporting improves impact of Xpert and monitoring and evaluation**
- **In-country partner collaboration, led by NTP, is critical to ensure a unified strategy and efficient use of resources**

To Realize the Potential of Xpert

- a systems approach is needed
- must strengthen entire path of workflow
- must be linked to drug access and program capacity



A Systems Approach

- **Involves a network of quality-assured laboratories**
- **Emphasizes access to services**
- **Uses quality management principles to ensure timely flow of specimens and information**
- **Uses appropriate methods to provide prompt, high quality results**
- **Relies on a well-trained workforce**

Scale-up PMDT Program in Parallel with Xpert MTB/RIF Scale-up

- **Laboratory capacity**
 - conventional culture and DST
 - other molecular methods – e.g. LPA
 - specimen referral and reporting of results
- **Treatment capacity**
 - hospital based and ambulatory care
 - patient support and palliative care
 - infection control
- **Second-line drug management**
 - Forecasting and ordering

Summary

- **Lack of lab services is a crucial barrier to an effective response to HIV/TB, and drug-resistant TB**
- **Molecular diagnostics may revolutionize TB lab services and help integrate testing for all diseases of public health importance**
- **Xpert MTB/RIF should be used as the initial diagnostic test in individuals suspected of having MDR-TB**
- **Must scale-up PMDT program in parallel with Xpert MTB/RIF scale-up**

Thank You

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of TB Elimination

