



PEPFAR Perspectives on Xpert RIF/MTB



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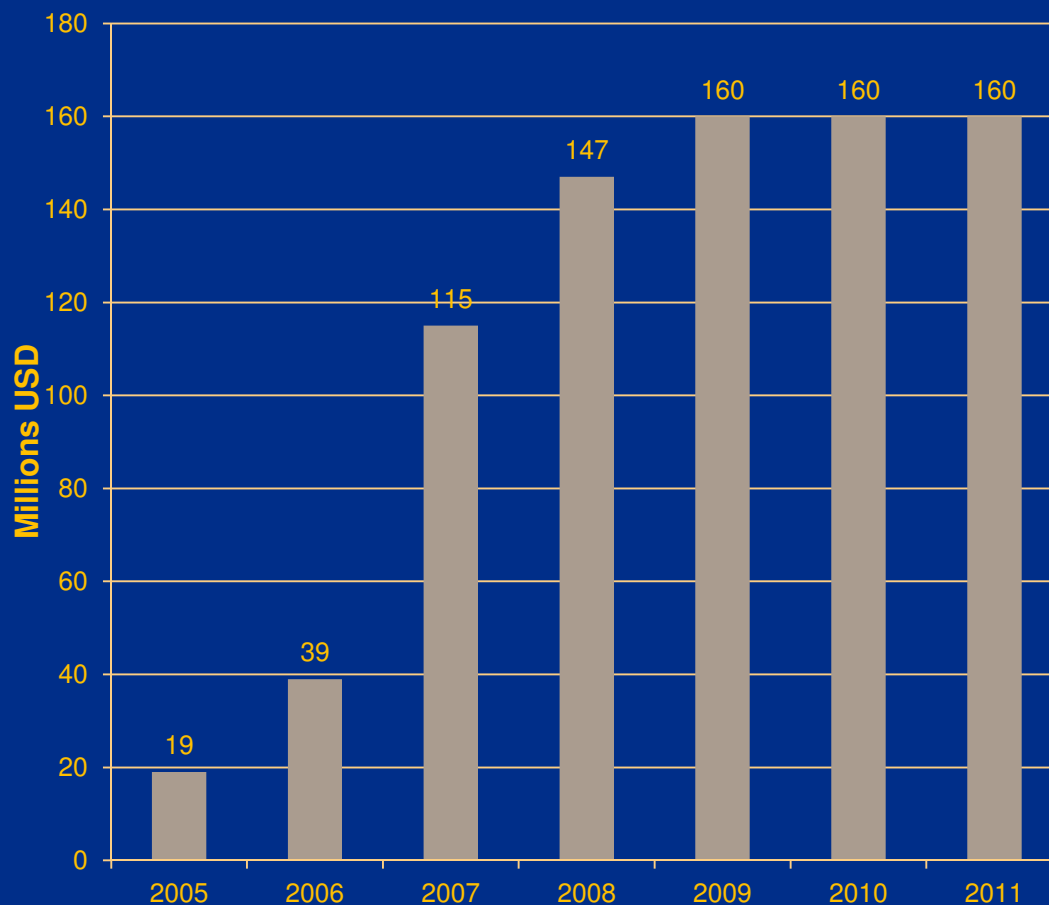
GLI Partners Meeting
Annecy, April 19, 2012



A Unified Response

PEPFAR Commitment to TB/HIV

- PEPFAR is leading a unified U.S. Government response to global TB/HIV
- PEPFAR supports national TB and HIV/AIDS programs that fully integrate TB/HIV services
- PEPFAR funding for TB/HIV programs has increased more than 800% over five years





Framework for PEPFAR TB/HIV Programming

WHO-recommended collaborative TB/HIV activities

A. Establish and strengthen the mechanisms for delivering integrated TB and HIV services

- A.1. Set up and strengthen a coordinating body for collaborative TB/HIV activities functional at all levels
- A.2. Determine HIV prevalence among TB patients and TB prevalence among people living with HIV
- A.3. Carry out joint TB/HIV planning to integrate the delivery of TB and HIV services
- A.4. Monitor and evaluate collaborative TB/HIV activities

B. Reduce the burden of TB in people living with HIV and initiate early antiretroviral therapy (the *Three I's for HIV/TB*)

- B.1. Intensify TB case-finding and ensure high quality antituberculosis treatment
- B.2. Initiate TB prevention with Isoniazid preventive therapy and early antiretroviral therapy
- B.3. Ensure control of TB infection in health-care facilities and congregate settings

C. Reduce the burden of HIV in patients with presumptive and diagnosed TB

- C.1. Provide HIV testing and counselling to patients with presumptive and diagnosed TB
- C.2. Provide HIV prevention interventions for patients with presumptive and diagnosed TB
- C.3. Provide co-trimoxazole preventive therapy for TB patients living with HIV
- C.4. Ensure HIV prevention interventions, treatment and care for TB patients living with HIV
- C.5. Provide antiretroviral therapy for TB patients living with HIV

WHO policy on collaborative TB/HIV activities
Guidelines for national programmes and other stakeholders





TB/HIV as part of AIDS Free Generation

Emphasis areas:

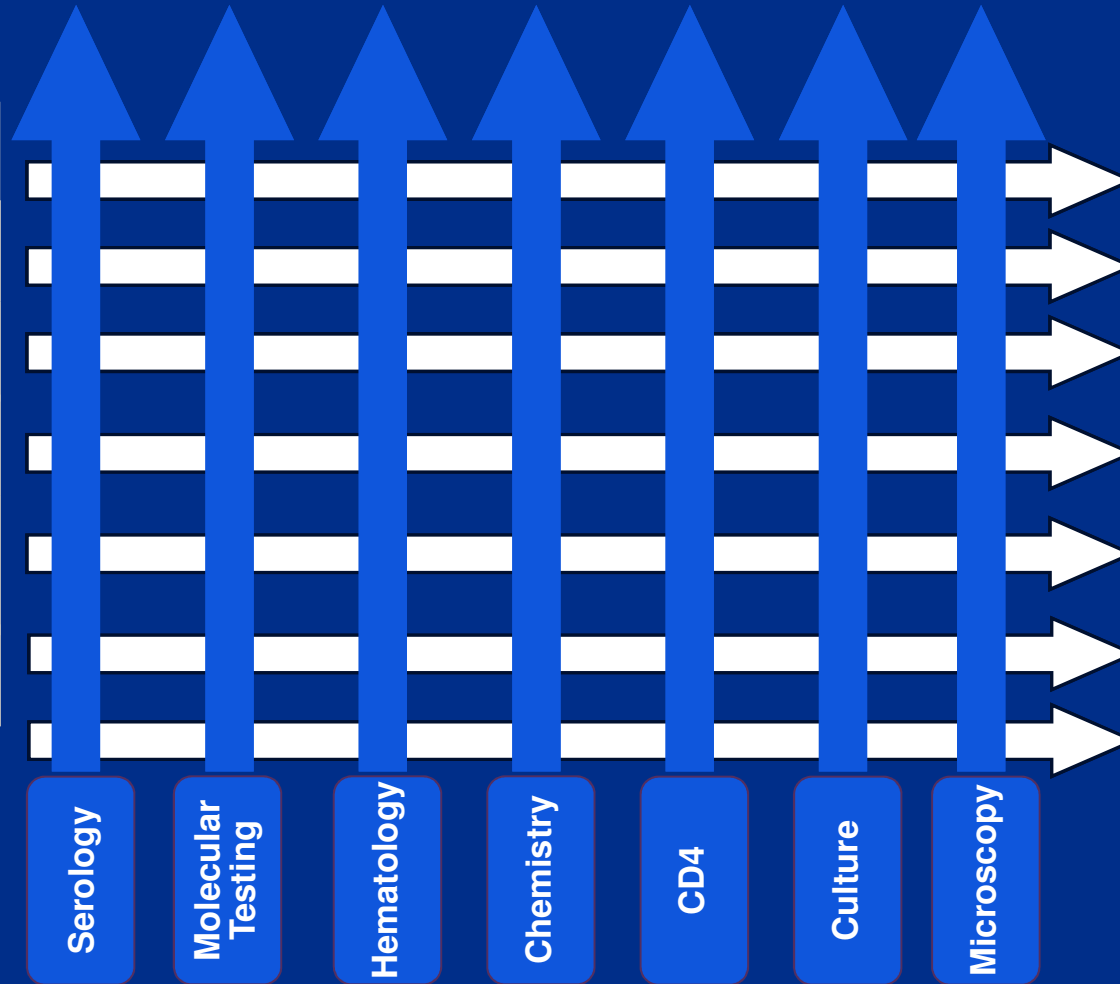
- HIV testing, beyond TB cases: TB patients' family members/contacts, TB suspects;
- Early ART for all HIV-infected TB patients;
- Ramping up of ART in TB clinics.
- TB screening and diagnosis in ANC and PMTCT settings, effective linkages to care and treatment
- PHDP (positive health, dignity and prevention).



PEPFAR Support for Laboratory Integration and Strengthening Systems

Laboratory Systems

Quality Management System
Training & Retention Systems
Equipment Maintenance Systems & Biosafety
Supply Chain Management Systems
Laboratory Information & Data Management Systems
Sample Referral Systems
Institutions & Policies



Laboratory Technologies

Strengthening
Laboratory Health Systems
Sustainability



National Laboratory Strategic Plans

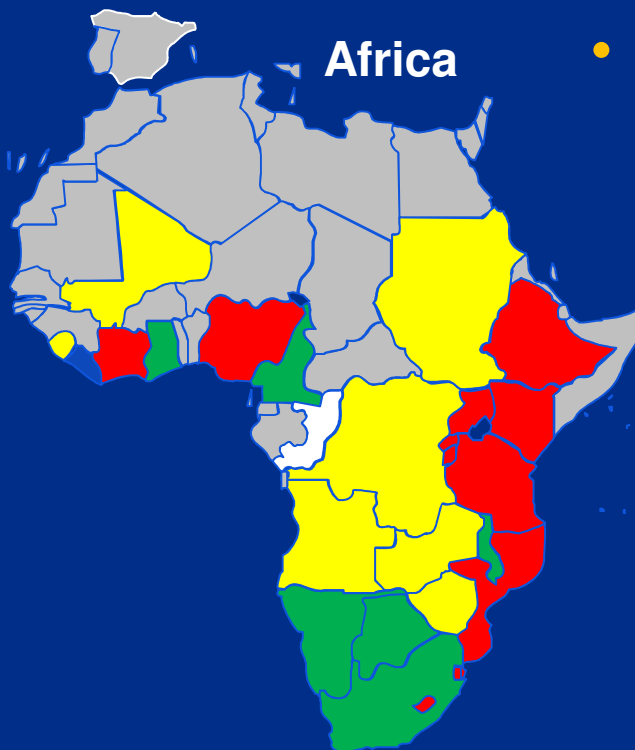
Caribbean Region



S E Asia



Africa



- 32 countries in various stages

2009

2010

2011

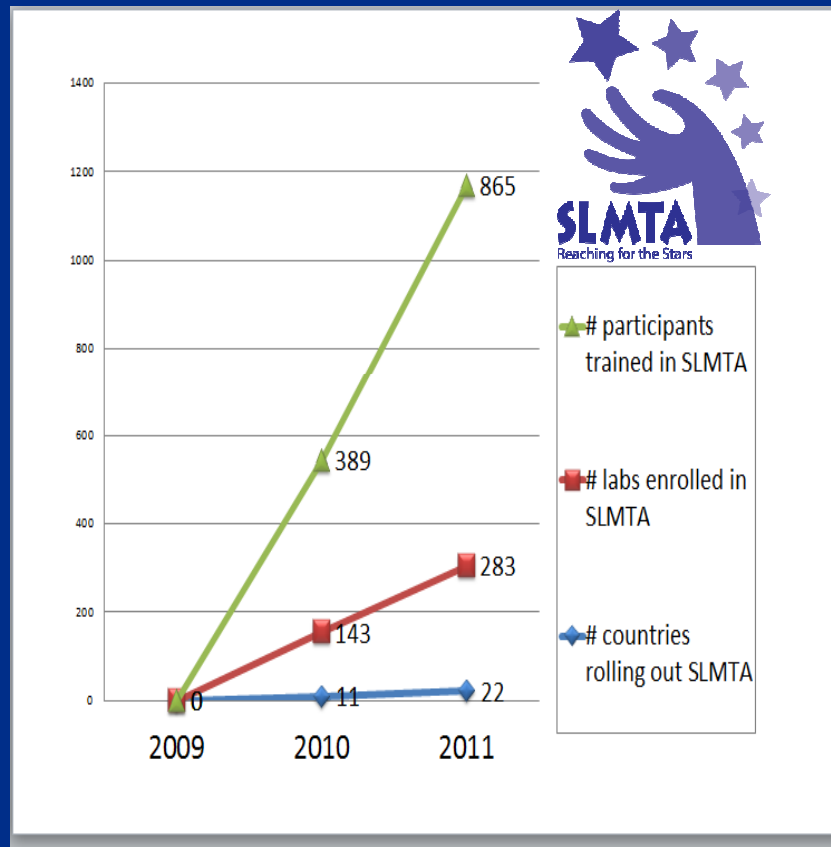
Guidance for Development of National Laboratory Strategic Plans

Helping to Expand Sustainable Quality Testing to Improve the Care and Treatment of People Infected with and Affected by HIV/AIDS, TB and Malaria

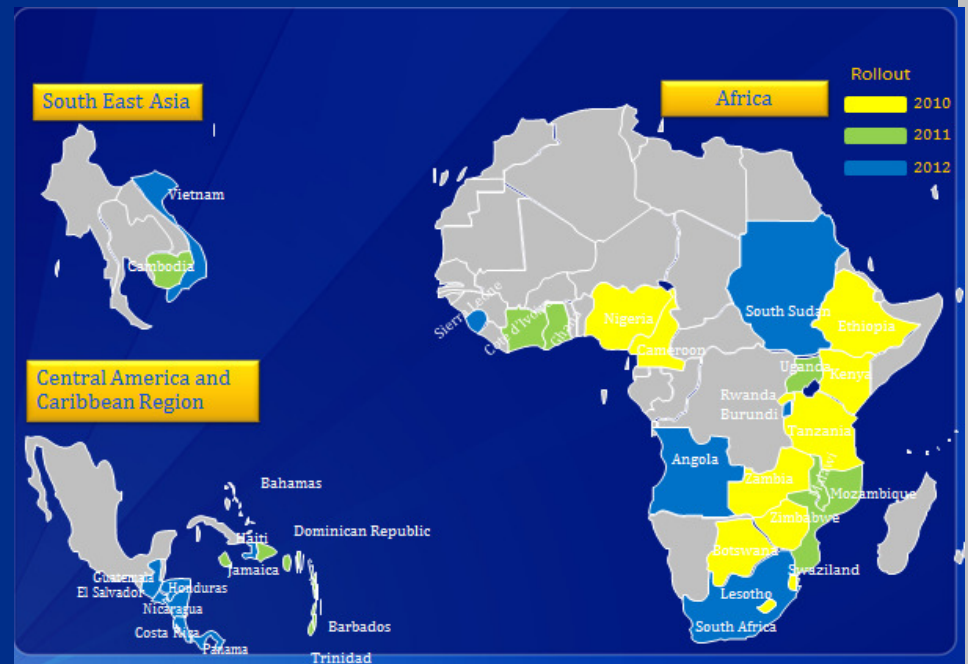




Strengthening Laboratory Management Toward Accreditation (SLMTA)



- 283 labs
- 22 countries





Results

- ❑ In FY 2011, PEPFAR-supported programs:
 - Screened more than 3.8 million PLWH for TB in HIV care or treatment settings
 - Started TB treatment for 230,800 patients enrolled in HIV care or treatment programs
- ❑ Support for more than over 13,500 facilities providing care and treatment services for PLWH in high TB prevalence settings
- ❑ Supported 4,884 facilities (laboratories) with capacity to perform clinical laboratory tests



USG Support for Xpert MTB/RIF

“...USAID, PEPFAR, and the U.S. Centers for Disease Control and Prevention (CDC), are committed to working together to support the rapid scale-up and appropriate use of this new technology.”

Amb E Goosby, Admin. R Shah, Director T Frieden





Resources ^{1,2}

- ❑ As of December 2011 (136):
 - Machines procured: 54
 - Machines planned: 82
 - Cartridges: ??

- ❑ 2010/11 supplemental funding
 - Planned (\$11M):
 - Machines: 100
 - Cartridges: 300,000 (3000 per machine, year 1)

- ❑ 2012 Country Operational Plans: TBD

1. Cartridge volume projected at current \$16.86 price
2. Includes PEPFAR-supported projects implemented via CDC and USAID

Implementation and
evaluation TA



Programmatic Xpert MTB/RIF Roll-Out: USG Approach

- ❑ Coordinated CDC, USAID, and OGAC approach
 - Close WHO collaboration
- ❑ Comprehensive package of support and technical assistance
 - Led by Ministry of Health
 - Assessment of priorities, gaps, and stakeholders
 - Development of an implementation and quality assurance plan
 - Preparation of testing sites and procurement of machines/tests
 - Training of laboratory and clinical staff
 - Supervision, monitoring and evaluation
- ❑ Emphasis on systems strengthening to address entire diagnostic cascade.

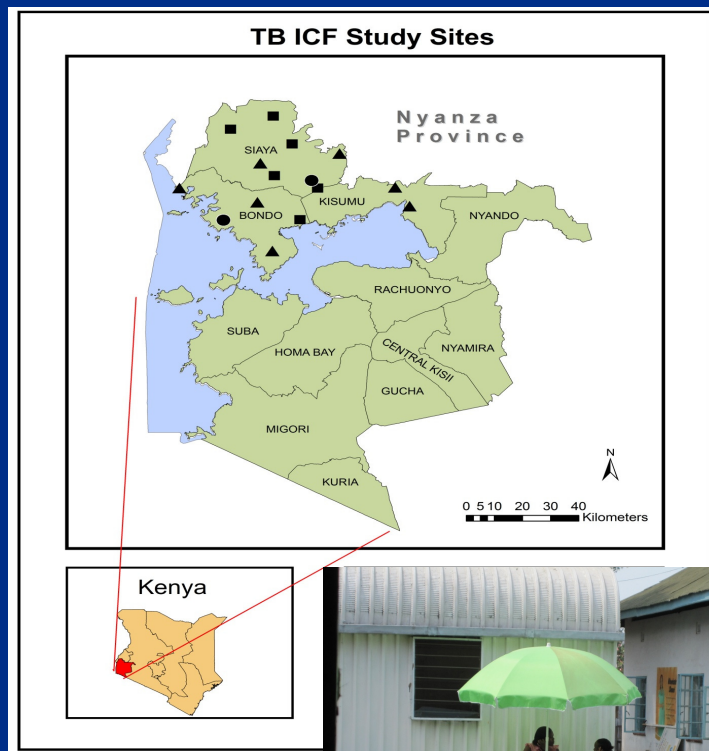


Programmatic Xpert MTB/RIF Roll-Out: USG Tools for Field Staff

- ❑ Phased Implementation and Evaluation of Xpert MTB/RIF: Principal considerations for USG-funded activities (available)
- ❑ Technical framework for Xpert MTB/RIF roll-out (draft)
- ❑ Guide to Xpert MTB/RIF introduction, validation, and quality assurance (draft/pilot)
- ❑ Laboratory and programmatic M&E indicators (draft/pilot)



Kenya ICF PHE and Diagnostics Study - 1



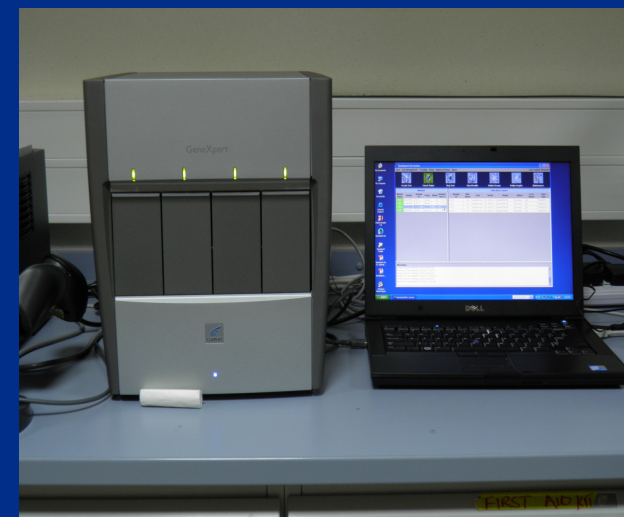
- ❑ **DGHA, DTBE, KEMRI/CDC, and NTLF collaboration**
- ❑ **Objectives**
 - To evaluate the performance of various diagnostic tests among HIV-infected persons in Kenya
 - To determine the performance of 3 clinical screening methods for ruling out TB in HIV-infected persons
 - To determine the prevalence and incidence of TB among HIV-infected persons



Kenya ICF PHE and Diagnostics Study - 2

□ Laboratory Strengthening

- Specimen collection and transport
- Microscopy center infrastructure
- KEMRI-CDC Kisian TB laboratory strengthening toward accreditation
- Biosafety
- New diagnostic implementation
- Result recording and reporting





Botswana XPRES Study - 1

- ❑ **DGHA, DTBE, BOTUSA, and MOH collaboration**
- ❑ **Objectives**
 - To compare sensitivity of Xpert-based TB diagnostic algorithm to pre-Xpert smear microscopy-based TB diagnostic algorithm among TB suspects
 - To evaluate the impact of the “Xpert package” on TB incidence during the first 6 months of ART



Botswana XPRES Study - 2

❑ Laboratory Strengthening

- Specimen referral and result reporting systems
- Testing site infrastructure
- Biosafety
- New diagnostic implementation
- Xpert MTB/RIF external quality assessment (EQA) program





Namibia 3 I's Scale-Up - 2



□ Laboratory Strengthening

- National TB Laboratory Strategic Plan
- Specimen referral and result reporting systems
- TB Reference Laboratory strengthening toward accreditation
- Biosafety
- New diagnostic implementation
- Laboratory information system
- LED smear microscopy external quality assessment (EQA) program
- Xpert MTB/RIF EQA program



Priorities for discussion

- ❑ **How can funders and technical agencies:**
 - Coordinate to hasten volume price reduction of cartridges?
 - Better share information and coordinated programming?
 - Effectively promote roll-out TA and EQA?
 - Effectively contribute to knowledge base?
 - Strengthen MOH leadership?
 - Further sustainability and assured ongoing funding for cartridges?
 - Further support GLI coordination?

THANK YOU



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