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Policy framework

World Health Organization

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Abbreviations

AFB	acid-fast bacilli
CRI	colorimetric redox indicator
DST	drug-susceptibility testing
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IGRA	interferon-gamma release assay
ISO	International Organization for Standardization
LED	light-emitting diode
LPA	line-probe assay
LTBI	latent TB infection
MDR-TB	multidrug-resistant tuberculosis
MODS	microscopic observation drug-susceptibility assay
MTBC	*Mycobacterium tuberculosis complex*
NAAT	nucleic acid amplification test
NRA	nitrate reductase assay
NTM	non-tuberculosis mycobacteria
PCR	polymerase chain reaction
QMS	quality-management system
*rpo*B	gene encoding for the ß-subunit of the DNA-dependent RNA polymerase of *Mycobacterium tuberculosis*
RR-TB	rifampicin-resistant tuberculosis
SLIPTA	stepwise laboratory quality improvement process towards accreditation
SLMTA	strengthening laboratory management towards accreditation
SOP	standard operating procedure
STAG-TB	Strategic and Technical Advisory Group for Tuberculosis
TB	tuberculosis
TST	tuberculin skin test
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Introduction

Tuberculosis (TB) laboratories play a critical part in national TB programmes, providing clinicians with invaluable information that is used to diagnose and guide the care of patients. Because of the specialized nature of the different technical procedures needed to diagnose TB, and the need for quality assurance and effective laboratory management, TB control programmes require a tiered network of laboratories in which different tiers use complementary diagnostic tools and mechanisms for referring specimens. Establishing, equipping and maintaining a laboratory network to ensure that there are timely and universal access to quality-assured diagnostics is challenging, complex and expensive, and the following core elements must be addressed simultaneously:

- planning for the implementation of diagnostic services;
- developing laboratory infrastructure and plans for maintaining the infrastructure, as well as implementing appropriate biosafety measures;
- developing schedules for equipment validation and maintenance;
- establishing mechanisms for specimen collection, transport and referral;
- establishing systems for managing

resistant TB and TB associated with HIV. An unprecedented effort to improve and expand the capacity of TB laboratories is under way, coordinated by the World Health Organization's (WHO's) Global TB Programme and with the active involvement of the Global Laboratory Initiative (GLI), a working group of the Stop TB Partnership (for more information, see http://www.stoptb.org/wg/gli).

The targets for laboratory strengthening in *The global plan to stop TB 2011–2015* include ensuring:[1]

- there is 1 microscopy centre per 100 000 population (for smear examinations for acid-fast bacilli [AFB]);
- there is 1 laboratory per 5 000 000 population to perform culture testing;
- that 50% of tests for drug resistance for new TB patients and more than 90% of tests for previously treated patients are done using rapid TB diagnostic tests.

However, with the roll-out of the Xpert MTB/RIF assay (Cepheid, Sunnyvale, CA, United States), the number of microscopy centres and facilities offering culture and drug-susceptibility testing (DST) will need to be adjusted depending on the extent of the roll-out in different settings and