



## Improving tuberculosis diagnostic services

*"Tuberculosis (TB) is an airborne infectious disease that is preventable and curable. People ill with TB bacteria in their lungs can infect others when they cough. In 2005, 8.8 million people fell ill with TB and 1.6 million died. If persons with infectious TB are detected early and fully treated, they quickly become non-infectious and then cured. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), HIV-associated TB, weak health systems are major challenges"* (source: WHO).

### The Stop TB Strategy

Reversing the increase in the incidence of tuberculosis by 2015 is part of the Millennium Development Goals (MDG6, target 8) and to this end the World Health Organization (WHO) and its partners have set up the Stop TB Strategy. The main aims of the Stop TB Strategy are to:

- Achieve universal access to high-quality diagnosis and patient-centred treatment
- Reduce the human suffering and socioeconomic burden associated with TB
- Protect poor and vulnerable populations from TB, TB/HIV and multidrug-resistant TB
- Support development of new tools and enable their timely and effective use.

### The role of KIT Biomedical Research

At KIT Biomedical Research we are actively involved in improving TB diagnosis through laboratory strengthening and the development, improvement and evaluation of new and existing diagnostic tools and methods.

KIT Biomedical Research staff are active members of the Stop TB partnership TB Lab Strengthening and New Working Groups on.

### Diagnostic laboratory strengthening

Laboratory diagnosis is of prime importance for TB control and KIT Biomedical Research staff has the joint expertise to provide a range of activities that can help to strengthen the diagnostic laboratory services:

#### 1. Data management

A first step in any control program is the collection and analysis of reliable data. KIT Biomedical Research has experienced epidemiologists that can advice and train laboratory and control program staff in setting up data collection systems, analyzing the data and using the data to improve TB control. We also have expertise and experience in the use of geographical information systems (GIS) to this end. Together the International Institute for Geo-Information Science and Earth Observation (ITC) in Enschede we jointly organize courses on using GIS in disease control programmes.

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## 2. Setting up and improving laboratories

Well-designed, well-equipped and well-functioning laboratories are a prerequisite for high quality diagnostic services at all levels of the health care system. KIT Biomedical Research has a track record in advising local, national and international entities on how to set up or improve laboratory facilities. This includes not only technical aspects, such as equipment, consumables and the floor plan, but also other aspects such as staffing, management structure, integration into the TB control program and generating revenue.

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## 3. Quality systems

KIT Biomedical Research can provide training as well as technical assistance for all aspects of quality, including process analysis, quality assurance and self assessment. Knowledge about needs assessments, tools required to implement quality improvements and guidance in an intervention process can be obtained via courses or our staff can provide direct advice or assistance.

We speak from experience: KIT Biomedical Research harbors a WHO/FAO/OIE/ RIVM Leptospirosis Reference Laboratory and our quality management system has been accredited by CCKL on the basis of ISO 15189, the world-wide norm for medical laboratories which includes aspects such as the provision of advice to users of the laboratory service, the collection of patient samples, the interpretation of test results, acceptable turnaround times, how testing is to be provided in a medical emergency and the lab's role in the education and training of health care staff.

KIT has developed a training programme for laboratory managers and staff in which quality of laboratory services is looked at from a system approach, in which input, process and output requirements are all considered to be important and determined by both technical and human factors. The training programme enables laboratories in resource-constrained countries to improve the quality of their service, even up to the level of accreditation or certification. The programme consists of a series of courses covering all aspects of laboratory quality management.

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## **Development, improvement and evaluation of diagnostic tools and methods**

KIT Biomedical Research works on the development, improvement and evaluation of new and existing tools and methods for TB diagnosis, infection control, and epidemiology. Some examples of our activities are:

- Developing a Multiplex Ligation-dependent Probe Amplification (MLPA) assay for the one-step rapid molecular characterization of *Mycobacterium tuberculosis*, including the detection of markers for drug resistance. As well as providing information on primary drug resistance this assay allows more rapid strain identification, aiding for example identification and control of nosocomial spread.
- Development of non-invasive methods for detection of tuberculosis.
- Development of rapid innovative culture methods for drug sensitivity testing.
- Evaluating of commercially available diagnostic methods under routine TB control program circumstances.

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