# TUBERCULOSIS LABORATORY ASSESSMENT TOOL

**(3rd draft)**

# WORLD HEALTH ORGANIZATION

## Preface

A dependable laboratory service is an essential component of the DOTS strategy. The promotion of DOTS expansion resulting in an increasing demand of quality laboratory services. In order to meet quantitative and qualitative demands of quality laboratory services by NTPs, the DOTS Expansion Working Group (DEWG) established the Subgroup on Laboratory Capacity Strengthening in August 2002. The subgroup consists at the moment of members from the supranational TB Reference Laboratories (SRL) in 21 different countries and other international and national organizations.

The establishment of the Laboratory Subgroup of DEWG aims at assisting the countries with high TB burden to strengthen the laboratory capacity in order to provide accurate and reliable services for TB control programme through integration of the laboratory network functions and the regular operations of the NTP; implementing systematic and efficient quality assurance schemes; developing training curricula and establishing good laboratory practices including standard operating procedures; and developing operational research capacity including drug resistance surveillance.

## Terms of reference of the Subgroup on Laboratory Capacity Strengthening of DOTS Expansion Working Group

To assist the DEWG members, in particular the NTP managers of endemic Countries, to:

1. Improve the quality of sputum smear microscopy at all levels of the laboratory network, mycobacterial culture, and drug susceptibility testing (DST) at national reference and intermediate level laboratories;
2. Implement quality assurance for sputum smear microscopy, culture and DST;
3. Implement external quality assessment programs for sputum smear microscopy, culture and DST;
4. Improve bio-safety conditions in TB laboratories;
5. Develop curricula and training tools to cover the above-mentioned laboratory functions;
6. Develop operational research capacity; and
7. Implement Good Laboratory Practices (GLP) including Standard Operating Procedures

## Introduction

Expansion of the DOTS strategy requires reinforced tuberculosis laboratory services because diagnosis and treatment monitoring by sputum smear microscopy are key components of the DOTS. To provide dependable laboratory services, the laboratories should be organized efficiently and the procedures should be carefully selected, taking account programme efficiency, and performed only by well-trained workers under a systematic, effective, and sustainable quality assurance programme.

In order to meet the growing demands of dependable laboratory services as a result of DOTS expansion, the DEWG partners established the Subgroup on Laboratory Strengthening in August 2002. An assessment of the organizational features of the existing laboratory network will serve as a basis for strengthening the laboratory component of NTP.

This TB laboratory assessment tool is designed for use by external consultants to evaluate the current situation of TB laboratory networks in the 22 high TB burden countries and other high incidence countries for future planning to strengthen laboratory capacity for TB control.

The document covers the minimum required information. Depending on the specific circumstances in the country under assessment, additional data may be collected. It recommends the assessment focus on the following issues.

1. Structural, functional and policy profile of the TB laboratory network
2. Quality assurance programme
3. Laboratory performance analysis
4. Human resource development
5. Procurement of equipment and supplies
6. Safety measures and practices
7. Data management
8. Budget requiring to make the laboratory network function in place

**Terminology in quality assurance**
Quality assurance (QA): System designed to continuously improve the reliability and efficiency of laboratory services, including internal quality control, external quality assessment, and quality improvement.
Quality control (QC): A systematic internal monitoring of working practices, technical procedures, equipment, and materials, including quality of stains.
External quality assessment (EQA): A process which allows participant laboratories to assess their capabilities by comparing their results with those in other laboratories in the network (intermediate and central laboratory) through panel testing and blinded rechecking. EQA also includes on-site evaluation of the laboratory performance.
Reference: *Association of Public Health Laboratories (APHL). External quality assessment for AFB smear microscopy. APHL and Centers for Disease Control and Prevention, 2002.*

## I. Basic information on the country to be assessed

1. The name of country:

2. Population: Rural population = %

3. TB patients notified in the previous year (2002):

| Cases | Pulmonary TB | | | Extrapulmonary TB (Bacteriologically proven cases) | Total |
|---|---|---|---|---|---|
| | Smear + | Smear – | Subtotal | | |
| New cases | | | | ( ) | |
| Retreatment cases | | | | ( ) | |
| Total | | | | ( ) | |

If the national level data is not available, it can be replaced with regional or local data with clear description of the source.

4. Overall workload of smear microscopy for case-finding (2001 or 2002)

| | Numbers |
|---|---|
| No. of suspects examined | |
| No. of smears examined | |
| No. of positive smears found | |
| No. of smear positive cases found | |

If the national level data is not available, it can be replaced with regional or local data with clear description of the source.

5. NTP manager & head of the National TB Reference laboratory (NTRL) or equivalents:

| | NTP manager or equivalent | NTRL head or equivalent |
|---|---|---|
| Name | | |
| Address | | |
| Telephone | | |
| Fax | | |
| Email | | |

## 2. Structural and functional profile of the laboratory network for the NTP

TB laboratory services should be organized taking account of accessibility to entire population and provision of all the necessary services for efficient TB case-management. The NTP of some countries has built-in or fully integrated laboratory network, while in some countries TB laboratory services are integrated into the general health system or provided by completely independent organizations at all or certain levels. When the laboratory network has been dissociated from the NTP, it must be resolved by establishing good coordination to ensure functional integration of the network into NTP to obtain dependable TB laboratory services.

(1) Structural profile (public sector)

| | | Administrative levels (insert name of administrative unit if it is not applicable) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Central | | Intermediate | | Periphery | |
| | | National | Regional | Provincial | Prefectural | With laboratory | No laboratory |
| No. of health institutions for TB diagnosis & treatment | | | | | | | |
| No. of laboratories | | | | | | | |
| No. of laboratory staff at this level | MD/PhD | | | | | | |
| | Licensed technicians | | | | | | |
| | Other workers | | | | | | |
| Relationship of laboratory network with NTP* | | | | | | | |

*Relationship of every level of laboratory with NTP must be evaluated.

A= TB laboratory system fully integrated structurally (defined as budget, staff, and organization) and functionally (defined as operational) into the NTP

B= TB laboratory system separated structurally but functionally integrated through reporting mechanisms, supervision & QA

C= TB laboratory system separated structurally from the NTP but reporting to the NTP with supervision & QA of laboratory services undertaken by another agency (describe the over-all system in which TB laboratory system is placed)

D= Other relationship - describe

(2) Functional profile (public sector)

| Technical functions | | Administrative levels (insert name of administrative unit if it is not applicable) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Central | | Intermediate | | Periphery | |
| | | National | Regional | Provincial | Prefectural | With laboratory | No laboratory |
| Smear Microscopy* | Diagnosis | | | | | | |
| | EQA | | | | | | |
| Culture* | | | | | | | |
| Drug susceptibility testing* | | | | | | | |
| Other than TB works** | | | | | | | |

*Not number of tests but availability of the corresponding laboratory services or activities (yes or no).

**If available, specify

(3) Policy

a) Is there a national TB laboratory manual? If yes, is the laboratory manual included in NTP manual or another laboratory manual or a separate manual (please describe and attach)?
b) What is the national policy on standard procedures for smear microscopy?
- Smear preparation: direct smear / concentrated smear / both
- Stains: Ziehl-Neelsen carbol-fuchsin / Kinyoun carbol-fuchsin / fluorochromes
- Use of light microscopes / fluorescent microscopes (describe if use only at certain laboratories).

c) What is the national policy on culture?
- Purpose: routine diagnosis / DRS
- Culture performing laboratory: peripheral / intermediate / central
- Standard culture method: simple / concentration / rapid method

d) What is the national policy on drug susceptibility testing?
- Purpose: case-management / DRS
- DST performing laboratory: peripheral / intermediate / central
- Standard DST method: (describe)

**3. Method and system for implementation of quality assurance**

(1) Is there a national guideline (or protocol) of quality assurance of smear microscopy? If yes, is it in the NTP manual? in the laboratory manual? or a separate document?

(2) Describe measures of quality control for smear microscopy at each level. (Specimen reception/handling; stains/staining; equipment function, etc)

Peripheral:
Intermediate:
Central:

(3) Describe the methods and system of external quality assessment (EQA) of smear microscopy? (EQA is a process to assess laboratory performance by outside agency and includes On-site evaluation, Panel testing, and Blinded rechecking)

(4) Results of smear microscopy EQA (2002).

a) Slide rechecking

| Rechecking mode | Results of peripheral laboratory reading | Number of slides rechecked | % of discordant results |
|---|---|---|---|
| Blinded | + | | |
| | - | | |
| Unblinded* | + | | |
| | - | | |

*If it is still implemented despite of that it is not recommended.

b) Panel testing

| Panel of slides | Slides in a panel | Number of slides read at peripheral laboratories | % of discordant results |
|---|---|---|---|
| Stained | + | | |
| | - | | |
| Unstained | + | | |
| | - | | |

(5) Supervisory visits (2002)

| Direction of supervision | | Planned | Done |
|---|---|---|---|
| Intermediate to periphery | By laboratory person | | |
| | By non-laboratory person | | |
| Central to periphery | | | |
| Central to intermediate | | | |

(6) Is supervisory visit (on-site evaluation) carried out with a check-list? If so, attach it. If not, what points are checked during supervisory visit?

(7) Describe the mechanism for feedback of the results of EQA or onsite supervision. (*at the intermediate level and national laboratories visited*)

(8) Are there mechanisms to ensure that corrective actions (QI) are taken and sustained after the feedback? (*at the intermediate level laboratories visited*)

(9) If culture examination is routinely performed, describe how QC and EQA for culture examination are implemented in brief.

(10) If DST is performed, describe how EQA for DST is implemented.

**4. Laboratory workload analysis**

(1) Volume of work done at different levels (2002)

| Level of laboratory (rename, if necessary) | Number of smears examined | | | | Cultures | | | Drug susceptibility tests (DST) |
|---|---|---|---|---|---|---|---|---|
| | Diagnosis | Folllow-up | EQA | Total | Diagnosis | Follow-up | Total | |
| National | | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Regional | | | | | | | | |
| Provincial | | | | | | | | |
| Prefectural | | | | | | | | |
| Peripheral | | | | | | | | |
| Total | | | | | | | | |

(2) Workload of laboratory workers at different levels (2002)

| | | Central | | Intermediate | | Peripheral |
|---|---|---|---|---|---|---|
| | | National | Regional | Provincial | Prefectural | |
| Smear microscopy | No. examined | | | | | |
| | No. workers | | | | | |
| | No. per worker | | | | | |
| Culture* | No. examined | | | | | |
| | No. workers | | | | | |
| | No. per worker | | | | | |
| DST* | No. examined | | | | | |
| | No. workers | | | | | |
| | No. per worker | | | | | |

*Culture & DST data can be analyzed only when these procedures are routinely performed.
**It is desirable to analyze population covered, number of suspects examined, and number of smear positive cases found per laboratory worker if possible.

(3) Routine use of rapid culture and DST techniques: if use, provide the number of tests done in 2001 or 2002.

(4) Routine use of molecular techniques to detect *M. tuberculosis* in clinical specimens or to test susceptibility to anti-TB drugs. If use, describe the techniques and the number of tests done in 2001 or 2002.

**5. Safety**

(1) Microscopy laboratories
Disinfectant(s) in use?
Disposal of used sputum containers, sticks, other contaminated materials?
Cleaning work place, how often? With what?
Use of hand basin?
Proper use of lab coats, globes, etc?

(2) Culture and drug susceptibility laboratory
Laboratory layout designed to control of airflow?
Use of centrifuges and their specification?
Use and maintenance of safety cabinet(s)?

(3) Any training of safe laboratory practices?

(4) Regular health check up of laboratory workers
Chest X-ray and sputum examination? If yes, how often?

**6. Human resource development**

(1) Is there a national training plan (describe and attach a copy).

(2) Give details of training of laboratory staff. Consider, pre-service and in-service training, and the various levels of service (central, intermediate and peripheral).
Who provides the training?
Where is it conducted?
How often is it conducted?
How long is the training?
What is the curriculum (attach)?
Are there training facilities and what equipment are used?
Describe the training materials available e.g. laboratory manual? training modules?
Do these reflect actual practice?

(3) Approximate proportion of laboratory workers receiving refresher training each year.

(4) How many staff was trained overseas from 2001 to 2002 (where, for how long, how funded). Are they still involved in TB laboratory work?

(5) Describe the number and status of educational institutions for laboratory workers.

(6) Approximate number of technicians newly licensed in a year.

(7) Describe turnover rates of laboratory staff at central, intermediate and peripheral levels.

(8) Distribution of the number of staff with TB laboratory work experience (years)

| | < 6 months | 6-12 months | 1-2 years | 2-5 years | ≥5 years |
|---|---|---|---|---|---|
| Central | | | | | |
| Intermediate | | | | | |
| Peripheral | | | | | |

(9) Describe the unmet resource requirements for human resources development, 2002 – 2003 at central, intermediate and peripheral levels.

**7. Procurement and distribution of supplies and equipment**

(1) Is there a plan for the procurement and distribution of supplies (laboratory reagents, consumables etc.) and equipment (microscopes, incubators, safety hoods etc.), 2001 - 2003 (if yes, attach)?

(2) Does NTP or Reference Laboratory expert(s) take part in the procurement system?

(3) Describe the system for procurement and distribution.

(4) Procurement of supplies and equipment for smear, culture, and drug susceptibility tests at different levels (please check relevant box, if no procurement leave blank):

| Laboratory procedure | | Central procurement | Intermediate procurement | Peripheral procurement |
|---|---|---|---|---|
| Smear microscopy | Supplies | | | |
| | Equipment | | | |
| Culture | Supplies | | | |
| | Equipment | | | |
| DST | Supplies | | | |
| | Equipment | | | |

*"Central procurement" means purchasing centrally and then distribution from the central to intermediate and peripheral locations. Describe, if necessary.

(5) What is budget for procurement and distribution of supplies and equipment, 2002 and 2003. Consider central, intermediate and peripheral levels separately (attach)?

(6) Who is responsible for procurement of supplies and equipment at central, intermediate and peripheral levels and what criteria are used in this process? Describe the system of recording and reporting for the status of supplies and equipment within the laboratory system. Is a standard form is used (attach).

(7) Have there been interruptions to laboratory work at central, intermediate and peripheral levels due to shortages of supplies and equipment?

(8) What mechanisms are in place to prevent interruption of work due to shortages of supplies and equipment? If there is a policy to keep a buffer stock of supplies and equipment, describe.

(9) Describe the maintenance system for equipment.

(10) What is the average lifespan of microscopes? What are the major causes of malfunction?

(11) Is the provision of supplies and equipment at different levels of the laboratory system appropriate for the functional activities of laboratories at these levels? If no, why not?

**8. Data management**

(1) Is a standard TB laboratory register book in use? (if yes, attach one)

(2) Is a standard TB-suspects registry book in use? (if yes, attach one)

(3) Is a standard laboratory request form in use? (if yes, attach one)

(4) On average, how often do laboratories report results to the clinic?

(5) On average, how long does it take for the laboratory report to be produced after the clinic has sent the patient or specimen to the laboratory (turnaround time)?

(6) How often are laboratories required to report on their performance (monthly, quarterly, 6-monthly or annually) and to which authorities do they send their reports? Are there standard reporting forms (if yes, attach one each)?

(7) How is feedback to laboratories received from supervisors and how are records on supervision kept (e.g. are notes of the feedback kept)?

## 9. Summary of the major findings on the constraints

| | Findings and conclusions |
|---|---|
| Policy | |
| Organization (coverage/relationship with NTP) | |
| Manpower (including training/supervision) | |
| Technical services (standard methods/operations) | |
| Procurement (equipment/supplies) | |
| Quality assurance of the services | |

## 10. Budget requiring to improve and strengthen the laboratory capacity

| | Central | Intermediate | Peripheral |
|---|---|---|---|
| Personnel | | | |
| Equipment | | | |
| Supplies | | | |
| Training | | | |
| Supervision | | | |
| Others (specify) | | | |