



Laboratory Assessment Tool

Annex 1: Laboratory Assessment Tool / System Questionnaire

April 2012

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Table of content

General information	1
Coordination and management	2
Structure and organization	8
Regulations	13
Quality of laboratory system	16
Laboratory information management	24
Infrastructure	26
Human resources	27
Biorisk management	32
Gap analysis	36
Summary	39
Acronyms	40

General information

Country assessed	
Date of the assessment (DD/MM/YYYY)	
Name and contact details of the assessor	
List name/s, contact details and level/s of authority of key interviewed person/s	

Comments

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1. Coordination and management

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

Documents to
be collected

1; 2; 3; 4

Provide here the answer to the open question/s and/or insert any additional
information

Coordination

1.1	Does the relevant Ministry have a dedicated unit in charge of health laboratory coordination?			
1.2	<i>If yes, please provide name/s, terms of reference and contact details of the unit and responsible person/s</i>	X		
1.3	Is there an official decree/text establishing the health laboratory coordination unit and defining terms of reference?	X		
1.4	Has this unit a dedicated budget?			
1.5	Has this unit developed coordination mechanisms with disease-specific control programmes?			
1.6	Has this unit an oversight role of reference laboratory designation and operations?			
1.7	Does this unit participate in public health-related committees such as influenza preparedness committees, emergency committees, or immunization committees?			
1.8	Does the coordinating unit coordinate its activities with the Ministry of Agriculture or its relevant agencies?			

Annex 1: LAT/System - Coordination and management

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
1.9	Do the coordinating unit coordinate their activities with the Ministry of Environment or its relevant agencies?		
1.10	Does the coordinating unit coordinate its activities with the Ministry of Education about laboratory worker education?		
1.11	Has this unit an oversight role of private laboratory regulations and operations?		
1.12	Is the unit assisted by an advisory body (committee or commission)?		
1.13	<i>If yes, please provide terms of reference and composition of the body</i>	X	
1.14	Is there a national policy for health laboratory services defining the goals and objectives of the national laboratory system?	X	
If yes or partial, does the policy address:			
1.15	Laboratory service coordination and leadership?		
1.16	Laboratory service structure and organization?		
1.17	Laboratory service testing capacity?		

Annex 1: LAT/System - Coordination and management

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
1.18	Laboratory service networking mechanisms?		
1.19	Laboratory service role in public health?		
1.20	Laboratory service regulatory framework?		
1.21	Laboratory service quality assurance framework?		
1.22	Laboratory workforce?		
1.23	Laboratory equipment and reagent procurement and supplying systems?		
1.24	Laboratory service funding?		
1.25	Is there a strategic plan aiming at strengthening laboratory services or other strategic plan/s with a laboratory component?	X	
1.26	<i>If yes or partial, please briefly describe main components of the plan</i>		

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
1.27	Is the plan funded and implemented?		
1.28	Are there indicators to monitor laboratory services (as part of the strategic plan monitoring or separately from the plan)?	X	
1.29	<i>If yes or partial, please list these indicators</i>		

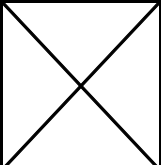
Funding

How are the laboratory services funded (for each source, specify percentage of funding)?			
1.30	Government or public health insurance		
1.31	User's fees		
1.32	Donors		
1.33	Other (specify)		

Annex 1: LAT/System - Coordination and management

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
1.34	Is there a specific budget assigned for public health laboratory activities (such as reference laboratories and networks operations)?		
1.35	Has a cost-effectiveness analysis been performed to select technically and financially appropriate laboratory technologies and methods?	X	
1.36	Are testing prices regulated?		
If yes, are testing prices recommended by:			
1.37	A national regulation/legislation?		
1.38	Public health insurance system (social security)?		
1.39	Private health insurance system?		

Equipment and supply management

1.40	<i>Please describe the procurement system/s for public laboratories (centralized or decentralized purchasing and storage, bulk or small purchasing, quality of supplies, suppliers' location, etc.) and provide all necessary documents</i>	X		
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	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
1.41	X	X	
1.42			
1.43			
1.44			
1.45			

Comments

2. Structure and organization

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

Documents to
be collected

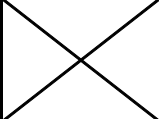
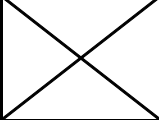
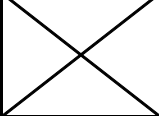
1; 2; 3; 4

Provide here the answer to the open question/s and/or insert any additional
information


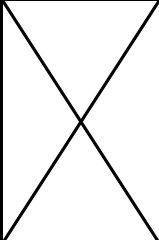


Structure

2.1	Is organizational structure of the laboratory services clearly defined with lines of authority?			
2.2	<i>If yes, please provide and comment any related charts or documents</i>	X		
2.3	Are the laboratories organized in a tiered system with different levels of functions?			
2.4	Is there an inventory or directory of laboratories performing clinical testing (health centre, hospital, public health, academic, research, etc.) in the country?	X		
2.5	Does this inventory take into account private clinical laboratories?			
2.6	<i>What kind of information is recorded for each laboratory (contact details, testing capacity, staff number, etc.)?</i>			

Documents to be collected 1; 2; 3; 4 Provide here the answer to the open question/s and/or insert any additional information

<i>Please estimate the number of laboratories within the following definitions:</i>			
2.7	<i>Central/national/reference laboratories</i>		
2.8	<i>Intermediate laboratories (regional or provincial level)</i>		
2.9	<i>Peripheral laboratories (district or health centre level)</i>		

Reference laboratories

2.10	Are reference laboratories identified for priority diseases or public health threats?		
2.11	<i>If yes or partial, please provide the list of reference laboratories (e.g. TB, HIV)</i>	X	
2.12	Are these reference laboratories officially designated (e.g. by directive, by regulation, by national authorities)?	X	
2.13	Are reference laboratories part of a national early warning system in place for public health events/outbreaks?		

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
2.14	Do representatives from reference laboratories routinely participate in outbreak or public health event preparedness and management meetings?		
2.15	Do representatives from reference laboratories routinely participate in field investigations during public health events (e.g. outbreaks)?		

Networking mechanisms

2.16	Are laboratories organized in network/s for clinical testing purposes (e.g. access to specialized or confirmatory testing that is not available at the patient location)?		
2.17	<i>If yes or partial, please describe for each network: member laboratory names or types, networking mechanisms (especially how samples and data are shared across the networks), documentation developed (SOPs, testing algorithm, reports forms) and funding sources</i>	X	
2.18	Are laboratories organized in networks for public health or surveillance purposes?		
2.19	<i>If yes or partial, please describe for each network: member laboratory names or types, networking mechanisms (especially how samples and data are shared across the networks), documentation developed (SOPs, testing algorithm, reports forms) and funding sources</i>	X	

Annex 1: LAT/System - Structure and organization

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
2.20	Are private laboratories part of the surveillance network/s?		
2.21	<i>If yes, is participation of private laboratories mandatory, imposed by law, through contractual agreement, etc.?</i>		
2.22	Are these network/s officially designated (e.g. by directive, by regulation, by national authorities)?		
2.23	Are reference laboratories members of international networks?		
2.24	<i>If yes or partial, please provide the list of laboratories and networks</i>		
2.25	Are there standardized reporting form/s for laboratory data within and across network/s?	X	
2.26	Is there a stock of emergency sample collection and transport supplies (personal protective equipment, sample collection material, transport media)?		

Documents to be collected 1; 2; 3; 4 Provide here the answer to the open question/s and/or insert any additional information

If yes, where are they positioned/stored?			
2.27	Central/reference level		
2.28	Intermediate level		
2.29	Peripheral level		

Comments

3. Regulations

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
3.1 Do public laboratories need to be registered or licensed to operate?			
3.2 Do private laboratories need to be registered or licensed to operate?			
3.3 <i>Please describe any registration and/or licensing criteria</i>	X	X	
3.4 If applicable, is the license/work authorization delivered after an initial on-site visit?			
3.5 If applicable, is the license/work authorization periodically reviewed?			
3.6 <i>How is the compliance with licensing criteria ensured (describe any inspection or control mechanism)?</i>		X	

Documents to
be collected

1; 2; 3; 4

Provide here the answer to the open question/s and/or insert any additional
information

Are the following areas regulated (as part of licensing mechanism or separately):

3.7	Laboratory facilities?			
3.8	Equipment?			
3.9	Staff?			
3.10	In vitro diagnostic medical device qualification?			
3.11	Sample transportation?			
3.12	Testing methods?			
3.13	Data management?			
3.14	Biorisk management measures?			

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
3.15	Laboratory related ethics?		
3.16	Are legislation and regulations regularly evaluated and updated to maintain relevance for evolving national and international needs?		

Comments

4. Quality of laboratory system

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

Documents to
be collected

1; 2; 3; 4

Provide here the answer to the open question/s and/or insert any additional
information

National standardization

4.1	Is there a national laboratory quality office for oversight of national laboratory quality programmes?	X		
4.2	<i>If yes, name and contact details of the office/responsible person/s</i>			
4.3	<i>Please briefly describe the national quality programme/s in place</i>			
4.4	Are national general quality norms/sets of standards established?	X		
If yes or partial, do they address these topics:				
4.5	Laboratory organization and management?			
4.6	Documentation and records?			

Annex 1: LAT/System - Quality of laboratory system

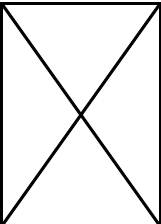

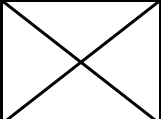

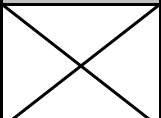

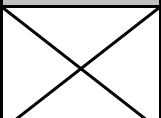

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.7	Specimen collection and transport?		
4.8	SOPs for specimen processing?		
4.9	Personnel and education requirements?		
4.10	Biorisk management?		
4.11	Equipment, reagents, reference materials, consumables management?		
4.12	Collaboration with referral laboratories?		
4.13	Internal quality control procedures?		
4.14	External quality assessment procedures?		
4.15	Data and information management?		

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.16	Are more specific quality standards available through membership of defined networks (e.g. TB, HIV)?		
In case laboratory services are organized in tiered network:			
4.17	Are minimal equipments standardized for each laboratory level?	X	
4.18	Are minimal staff number and qualifications standardized for each laboratory level?	X	
4.19	Are tests performed and methods standardized for each laboratory level?	X	
4.20	<i>Please describe how and by whom norms and standards are developed (e.g. by standardization body, professional societies, specialized networks, reference laboratories)</i>		

Quality assessment

4.21	Is there a national body in charge of laboratory inspection?		
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Annex 1: LAT/System - Quality of laboratory system

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.22	<i>If yes, please describe the inspection mechanism (frequency, procedures, sanctions, etc.)</i>		
4.23	Is there a national body in charge of laboratory certification (e.g. using ISO 9001)?		
4.24	<i>If yes, please provide name/s:</i>		
4.25	Is there a national body in charge of laboratory accreditation (e.g. using ISO 15189)?		
4.26	<i>If yes, please provide name/s:</i>		
4.27	If no, do laboratories use services of foreign national or regional accreditation bodies?		
4.28	<i>If yes, please provide name/s:</i>		
4.29	Are some laboratories accredited for disease-specific testing by WHO (e.g. polio, measles, HIV genotyping)?		

Annex 1: LAT/System - Quality of laboratory system

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.30	<i>Please provide number of laboratories certified or accredited and specify to which standard</i>		
4.31	Is there a specific national document which describes the registration procedure for in vitro diagnostic medical devices (IVD, i.e. kits and reagents)?	X	
4.32	Is there a national regulatory authority responsible for in vitro diagnostic device (e.g. reagents) qualification or registration?		
4.33	<i>If yes, please provide a summary of the qualification or registration mechanisms</i>	X	
4.34	Besides the inspection, certification or accreditation detailed above is any other kind of supervision organized?		
4.35	<i>If yes or partial, describe the supervision plan and procedures (e.g. through specific networks like TB control programme or surveillance programmes)</i>	X	
4.36	Are there standardized supervision checklists or procedures?	X	
4.37	When supervised, do the laboratories receive a report after each supervision?	X	

		Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.38	Are there indicators to measure the progress in laboratory test quality?			
4.39	<i>Please list these indicators</i>		X	
Does your country have a national EQA programme (proficiency-testing or rechecking) in the following areas:				
4.40	Bacteriology?			
4.41	Virology?			
4.42	Serology?			
4.43	Parasitology?			
4.44	Biochemistry			

Annex 1: LAT/System - Quality of laboratory system

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.45	Haematology?		
4.46	Anatomical pathology?		
4.47	Cytogenetic?		
4.48	Transfusion medicine?		
4.49	<i>Please describe the national EQA programme/s organization by providing for each: name of the programme, contact person/s, one line of description</i>		
4.50	If applicable, is participation in national EQA programmes/s mandatory for public laboratories?		
4.51	If applicable, is participation in national EQA programmes/s mandatory for private laboratories?		
4.52	<i>Percentage of public laboratories participating in the national EQA scheme (EQAS):</i>		

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
4.53 <i>Percentage of private laboratories participating in the national EQAS:</i>		X	
4.54 Are corrective actions organized when assessment result is poor?	X		

Comments

5. Laboratory information management

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
5.1	Does the MoH laboratory coordination unit collect any laboratory data?		
5.2	<i>If yes or partial, please describe which kind of data (tests ordered and/or performed, logistics data, scientific data, etc.) and data collection mechanisms</i>	X	
5.3	Are standardized forms available to collect these data?	X	
5.4	Does the MoH use a computerized Laboratory Information System (LIS) to collect and analyse data?		
5.5	Is this LIS connected to the MoH Health Information System?	X	
5.6	<i>If yes, describe how</i>		
5.7	Does the MoH laboratory coordination unit share data with other agencies or units?		

Documents to be collected

1; 2; 3; 4

Provide here the answer to the open question/s and/or insert any additional information

5.8 *If yes or partial, please describe which data and for which purpose*

5.9 Does the MoH laboratory coordination unit ensure feedback to the laboratory community?

5.10 *If yes, please describe the communication mechanisms and procedures (e.g. newsletter, website)*

Comments

6. Infrastructure

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

Documents to be collected 1; 2; 3; 4 Provide here the answer to the open question/s and/or insert any additional information

6.1	Are there any requirements in terms of building and facilities for laboratory operations (e.g. cold storage, containment requirements)?			
6.2	Is the facility infrastructure generally satisfactory throughout the country (i.e. ensuring quality of work and safety of staff)?			
6.3	Is there any national plan or project to build, renovate or upgrade laboratory facilities?			
6.4	<i>If yes, describe laboratory concerned, objectives and funding sources</i>		X	

Comments

7. Human resources

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

Documents to
be collected

1; 2; 3; 4

Provide here the answer to the open question/s and/or insert any additional
information

Staff

7.1	Is there an inventory of laboratory workers?	X		
7.2	Is the overall number of laboratory workers sufficient for the healthcare needs?			
7.3	Is the laboratory staff well distributed within the country in accordance with the needs?			
7.4	Is the education/training/experience of laboratory workers in accordance with the needs of the work?			
7.5	Is the salary of laboratory workers appropriate for the work?			
7.6	Are most laboratory workers national staff (as compared with workers from other countries)?			
7.7	Does the country graduate adequate number of trained personnel for its needs?			
7.8	Are there trained biomedical engineers/technicians (for specific laboratory equipment maintenance) inside the country?			

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
7.9	Is qualified staff easily maintained in laboratory in the country?		
7.10	<i>If no, please list the difficulties</i>		
7.11	Is the licensing/registration of laboratory workers organized?	X	
7.12	<i>If yes, please describe the licensing/registration requirements</i>		
7.13	<i>How many people are licensed/registered as laboratory workers?</i>		
7.14	If applicable, is continuous education/training mandatory to renew staff work authorization?		

Education

Are national specific degrees delivered for:			
7.15	Laboratory technicians?		
7.16	Post-graduate clinical pathologists?		

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
7.17	Post-graduate medical microbiologists?		
7.18	<i>If yes, please provide name/s of these degree/s and associated curricula:</i>		
7.19	Are these degrees mandatory for working in a medical laboratory?		
7.20	Are there interministerial mechanisms involving health and education ministries to review and adapt training curricula according to the needs?	X	
7.21	Do laboratory workers have access to suitable continuous education/training?		
Is continuous education available in the following areas:			
7.22	Specimen collection, packaging and transportation?		
7.23	Laboratory quality assurance?		
7.24	New laboratory diagnostic techniques?		

		Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
7.25	Data management?			
7.26	Epidemiological surveillance?			
7.27	Field Epidemiology and Laboratory Training Programme?			
7.28	Computer science applied to laboratory?			
7.29	Biorisk management?			
7.30	Laboratory management?			
7.31	<i>How are these courses provided (manufacturing companies, professional societies, distance learning, face-to-face, etc.)?</i>		X	

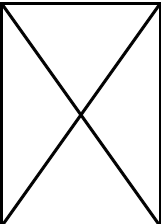

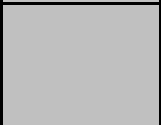
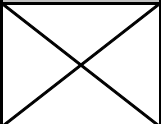
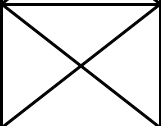
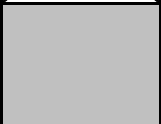

Comments

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8. Biorisk management

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

		Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
8.1	Does the relevant ministry have a dedicated unit in charge of biosafety/biosecurity at national level?			
8.2	<i>If yes, name and contact details of the unit/responsible person/s</i>	X		
8.3	Have biological risks and pathogens been identified, classified and listed at the national level?	X		
8.4	Does a national up-to-date legislation define minimal biosafety levels, measures or requirements for operation?			
8.5	<i>If yes, please describe them shortly and provide relevant documentation</i>	X		
8.6	Are specific policy or regulation for waste management and disposal available?			

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
8.7 <i>If yes, please describe them shortly and provide relevant documentation</i>	X		
8.8 Are inspections of laboratories performed by national authorities to evaluate compliance with biosafety requirement?			
8.9 Does the country have functional BSL-3 laboratories to deal with highly dangerous pathogens?			
8.10 <i>If yes, number of functional BSL-3 laboratories:</i>			
8.11 <i>Please also provide the number of functional BSL-4 laboratories:</i>			
8.12 Are the new facilities formally commissioned before opening?			
8.13 Can the biosafety cabinets (BSC) be certified by local certification bodies?			

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
8.14	Is there a specific national document for specimen packaging and transportation?	X	
8.15	If yes, is its application mandatory by law or decree?		
8.16	Are specific packages (like triple packages complying with P620 and P650 requirements) available?		
8.17	<i>If yes, from which source/s? Local suppliers, foreign suppliers, external assistance (e.g. NGO, UN)</i>		
8.18	Are national regulations in place and up-to-date for the transport of infectious substances (Categories A and B)?	X	
8.19	Do local carriers ensure the transport of infectious substances according to the national requirements?		
8.20	Are infectious substances (Categories A and B) imported or exported from/to other countries?		
8.21	Do central/reference laboratories have access to express courier service/s (e.g. DHL, FedEx, World Courier)?		
8.22	Do the people responsible for the shipment of specimens have access to training on infectious substance transport?		

	Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
8.23	If yes, are these trainings in line with United Nations regulations on the transport of infectious substances?		
8.24	Do laboratory staff have access to occupational/worker health services in all facilities?		
8.25	Is there a specific vaccination policy (pre-exposure prophylaxis) for laboratory workers (Hepatitis B and other relevant diseases)?	X	
8.26	Are vaccines that have been identified as mandatory provided to laboratory workers?		
8.27	Is post-exposure prophylaxis treatment provided to laboratory workers in all facilities?		

Comments

9. Gap analysis

What are the biggest needs/weaknesses of the national laboratory system?

Score from 0 (no gap) to 5 (high gap) for the items below and please provide comments for the area/s that display the biggest weaknesses (scores 4 and 5)

	0; 1; 2; 3; 4; 5	Comments
9.1 Financial resources for laboratory activities		
9.2 Human resources – qualifications and availability of suitable laboratory staff		
9.3 Equipment adequacy		
9.4 Reagent and consumable quality		
9.5 National guidelines on specific laboratory practices		
9.6 Collection of specimens		
9.7 Transportation of specimens		

Annex 1: LAT/System - Gap analysis

9.8	Laboratory organization, service delivery structure, and networking		
9.9	Regulatory framework		
9.10	Laboratory safety or security		
9.11	Quality assurance		
9.12	Recognition of importance of laboratory services		
9.13	Political commitment (national laboratory policies, budget, etc.)		
9.14	Other		
	<i>For other, please specify:</i>		

Comments

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Laboratory System Assessment Questionnaire Report

General comments on the assessment

Conclusions and recommendations

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Acronyms referred to in this document

BSC	Biosafety Cabinet
BSL	Biosafety Level
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
HIV	Human Immunodeficiency Virus
HR	Human Resources
ISO	International Organization for Standardization
IVD	In vitro diagnostic medical devices
LIS	Laboratory Information System
MoH	Ministry of Health
NGO	Non-Governmental Organization
SOP	Standard Operating Procedure/s
TB	Tuberculosis
UN	United Nations
WHO	World Health Organization