Laboratory Assessment

I. Objectives

General objective:

To rapidly assess the functional laboratory capacity for diagnosis of priority diseases for surveillance.

Specific objectives:

To employ a standardised tool for brief laboratory assessments to obtain easily available information about laboratory capability at all levels as part of the overall assessment of national surveillance systems.

To identify weaknesses in laboratory provision for priority disease detection and devise improvements ensuring that clinical specimens and information flow smoothly from district to provincial and national levels.

To enable the development of a plan of action to strengthen laboratory capacity for surveillance and control of priority diseases.

II. Key steps in carrying out the laboratory assessment:

Step I: Review of documentation and information in the country

1. Obtain pertinent documents from previous laboratory assessments performed in the country before assessment

2. National laboratory system (both public and private)

    a. Review the national laboratory services policy

    b. Description of organizational units within Ministry of Health (e.g. health centre, district, regional, national)

    c. Description of organizational units for other Ministries that have health care functions (e.g. Ministry of Education or Scientific Research). University medical schools often provide laboratory services and are valuable resources that should not be overlooked

    d. Description of laboratories in the private sector. These include both independent labs and those in private hospitals. If a national accrediting organization for

laboratories exists, consult this agency for information about the type and number of private laboratories.

Step II: Adaptation and modification of proposed generic questionnaire

The protocol recommends a generic tool for assessment, that needs to be modified for each level of the health system. This should take into account the degree of sophistication of the assessed level, as well as the type of laboratory facility to be assessed. These vary widely from country to country. Relevant questions would need to be identified for each level of laboratory assessed within the country. A careful review of each question is important and these should be modified or deleted as appropriate.

Train assessors in the use of the laboratory assessment tool and how to perform the associated brief laboratory inspection. The time spent administering the questionnaire and inspecting the laboratory may vary greatly, depending on the type of laboratory and the level of the health care system, and this should be taken into account.

***Step III*:** The field assessment

3.1. Using a representative sample of laboratories at each level in both public and private organizations, assess the following:

1. Building facilities and utility services
2. Laboratory equipment
3. Laboratory Staff
    a. Number (level of training)
    b. Supervision
4. Reagents
5. Tests performed
    a. Name of test
    b. Number per month
6. Laboratory management
    a. Hours of service
    b. Procedure manuals

c. Specimen collection, labelling and handling

d. Reporting procedures

e. Quality control procedures and programme

1) Internal and external quality assurance and proficiency programmes

2) Equipment maintenance and repair

3) Supply procurement and management

f. Safety.

3.2. Inspect the laboratory and complete the inspection form to validate data reported in the interview.

a. Accessioning and reporting

b. Manuals

c. Equipment and reagents

d. Safety.

Step IV: Data analysis and report writing

Analyse data from country-wide laboratory assessment in regard to:

a. Overall function of surveillance system

b. Identification of specific laboratories deserving detailed laboratory assessment with a view to delineating and enhancing their role in the surveillance system.

The report writing could be done as part of the overall national surveillance system assessment report or separately if required.

Note: Follow-up assessments can also measure qualitative and quantitative changes in types of tests performed, number of each test performed per month and changes in proficiency by examining quality control data from internal controls and results of testing panels from reference labs.

Laboratory Assessment Tool

Checklist for diagnostic laboratory assessment

General Information

Name of the laboratory	
Address of the laboratory Telephone/fax/e-mail	
Level of the laboratory	Health Facility Provincial/State/Regional National Community/District
Affiliation of the Laboratory (more than one may be applicable, e.g. Private and Academic)	Public Private Academic Institution NGO or Religious Institution
Name of head of Laboratory	
Name of Laboratory Director	

Building facilities and utility services

How is the state of the building good medium poor*		
Is the laboratory in a free-standing building or part of larger structure		
Does the laboratory perform tests for:		
Bacteriology Virology Mycobacteriology Parasitology Mycology		Yes No Yes No Yes No Yes No Yes No
Cell culture facility?		Yes No
Is the laboratory connected to hospital service?		Yes No
How many rooms with bench space are there in the laboratories checked above?		Number:
What % of the working day do you have the following services available?		
Electricity Running water Gas (including bottled)	<50% 50-95% 95-100% <50% 50-95% 95-100% <50% 50-95% 95-100%	
Is there a back-up power source in case of power failure (e.g. emergency generator)?		Yes No
If Yes, what systems are protected?		
Refrigerators/freezers Ventilation/AC Computers Other		Yes No Yes No Yes No Yes No Not applicable
What ventilation is provided?		
Windows Electrically-powered ventilation (exhaust, not fans) system or air-conditioning		Yes No Yes No
What types of communications systems are available?	tick all applicable	Number
Post	Yes No	
Telephone	Yes No	

Fax	Yes No	
Satellite phone	Yes No	
E-mail (no. computers)	Yes No	
Internet (no. computers)	Yes No	

Laboratory equipment

Type and number of items available in your laboratory	Present	Number
Refrigerator	Yes No	
Freezing at –20°C	Yes No	
Freezing at –70°C	Yes No	
Microscope with oil-immersion objective	Yes No	
Slides and coverslips	Yes No	
Scale or balance	Yes No	
Candle jars	Yes No	
Other Anaerobe jar	Yes No	
Magnifying lens	Yes No	
Loop/needle handles	Yes No	
0.01and 0.001ml calibrated loops	Yes No	
Bunsen burner	Yes No	
If no Bunsen burner, Electric heater or alcohol lamp to sterilise loops and needles	Yes No	
Petri dishes (glass)	Yes No	
Petri dishes (disposable)	Yes No	
Test tube racks	Yes No	
Staining facilities-sink and slide rack	Yes No	
Adequate glassware for media preparation (flasks, graduated cylinders, etc.)	Yes No	
Wash bottles	Yes No	
pH paper	Yes No	
pH meter	Yes No	
Manual pipettes (e.g. Eppendorf)	Yes No	
Water distillation system	Yes No	
Low-speed centrifuge (hand or electrically powered)	Yes No	
Autoclave - manually controlled	Yes No	
Autoclave - electrically controlled	Yes No	
Hot air oven	Yes No	
Inverted microscope	Yes No	
Fluorescent microscope	Yes No	
Electron microscope	Yes No	
ELISA plate reader	Yes No	
Electrically-powered waterbath	Yes No	
Warm air incubator	Yes No	
CO_2 incubator	Yes No	

CO_2 tanks	Yes No	
Liquid nitrogen storage	Yes No	
ELISA washer	Yes No	
Safety cabinet- level 1 (operator protection. Open-fronted, unrecirculated airflow away from operator)	Yes No	
Safety cabinet- level 2 (protects operator and material from contamination. Open fronted, filtered supply and exhaust air)	Yes No	
Safety cabinet- level 3 (protects operator, material and environment from contamination-enclosed, negative pressure, HEPA filtered air supply and exhaust)	Yes No	
Are all equipment functioning? (Ask this question after each equipment item, if response is NO, record below)	Yes No	
If no, what items of equipment are not functioning?		

Laboratory staff and supervision for all microbiology and serology labs

Number of staff in each category	**Number**	**% of staff available in lab**
Supervisors — Medical/Scientific		
Supervisors — Technical		
Technologist/Technical (doing tests)		
Laboratory assistants (not doing tests)		
Clerical		
What is the highest level of microbiology training achieved by technical staff performing diagnostic tests? (state number of staff for each option)		
In-laboratory training only		
Diploma course or specific training course		
Degree level		
Other (briefly describe):		
Has training been conducted for your laboratory staff in the past year?	Yes No	
If Yes, indicate the type of training and the number of staff trained		
Formal training at national lab	Yes No	
Formal training on-site	Yes No	
International training	Yes No	
Laboratory staff supervision		
Who usually decides which tests to perform when the samples first arrive in the laboratory?		
The requesting clinician	Yes No	
The technician	Yes No	
Microbiologist/supervisor	Yes No	
Laboratory protocol	Yes No	
Who makes decisions about further testing if indicated?		
The technician	Yes No	
Microbiologist/supervisor	Yes No	
Are ALL tests reviewed before results sent for reporting?	Yes No	
If Yes, who reviews the results of tests (or test runs)?		

Only the technician performing the test	Yes No	
Another member of the technical staff	Yes No	
A supervisor/medical microbiologist	Yes No	
Are ALL tests reviewed before results sent for reporting?	Yes No	
If Yes, who reviews the final report before it is sent to the requesting clinician or other appropriate recipient?		
Only the technician performing the test	Yes No	
Another member of the technical staff	Yes No	
A supervisor/medical microbiologist	Yes No	

Reagents

What proportion of your reagents do you obtain from:	
A commercial supplier	%
From another laboratory	%
Prepared in-house	%
What type of water is used for preparation of media and reagents?	
Deionized	Yes No
Distilled	Yes No
Distilled and deionized	Yes No
Tap water	Yes No

Tests performed at the laboratory

*The following table lists a number of diseases and diagnostic tests. Please note which tests are performed in your laboratory. For each disease, note whether or not you test any of the named specimens by any of the listed tests. (If you do not perform any tests for meningitis, for example,**tick** in the "No" column for all. If you perform a Gram stain on CSF for meningitis, but none of the other tests, **tick** in the " Yes" column for Gram stain, and "No" for the other meningitis tests.) Please give the approximate number/month of each test you perform.*

Disease	**Specimen type**	**Assay Performed**	**Yes**	**No**	**Number/ Month**
Meningitis	CSF	a. Cell count			
		b. Latex agglutination			
		c. Gram stain			
		d. Culture			
		e. Identification tests			
		f. A-M susceptibility			
	S. pneumoniae	Optochin disks			
	N. meningitidis	Sugar fermentations			
	H. influenzae	X, V, XV factors			
	Blood	Blood Culture and tests b, e, f above			
Dysentery	Faeces	Microscopy of wet preparation			
		Culture			

		Identification tests			
		A-M susceptibility			
Watery diarrhea (cholera)	Faeces	Microscopy of wet preparation			
		Culture-TCBS			
		Culture-Alk. Peptone			
		Serotyping			
Plague	Bubo aspirate, sputum, blood	Stain			
		Culture			
		A-M susceptibility			
Tuberculosis	Sputum, CSF	Z-N staining			
		Rhodamine/Auramine staining and fluorescent microscopy			
		Culture			
		A-M Susceptibility			
Malaria	Blood	Thick/Thin film microscopy			
Measles	Serum	IgM by EIA			
		Other serological test			
	Throat swab, conjunctival swab	Virus isolation			
Yellow fever	Serum	IgM			
	Blood, post-mortem liver	Virus isolation			
FUO/PUO (suspect typhoid or brucellosis)	Blood, faeces	Culture Identification tests A-M susceptibility			
	Serum	Serological tests (Widal, brucella agglutinins)			
Hepatitis	Serum	Anti-HAV IgM			
		Anti-HBc IgM			
		Anti-HbsAg			
		Anti-HCV IgM			
		Anti-HEV IgG			
Viral haemorrhagic fevers (any)	Serum	IgM			
	Serum, other tissue specimens	Virus detection			
Acute flaccid paralysis	Faeces	Virus isolation			
		Virus typing			

HIV	Serum	IgG by EIA			
	Blood	Viral load			
		Virus isolation			

Laboratory management

What are the normal hours/days of service of the laboratory?	
Number of days per week	<5 5 6 7
Hours per day	<6 6-10 11-23 24
If no 24-hour service, is out-of-hours or emergency service available?	Yes No
If there is 24-hour service, number of staff at the following times:	Number
5 PM to 12 AM	
12 AM to 7 AM	
How does the laboratory inform existing or potential clients about the services it offers?	
Verbally only (informal)	Yes No
Printed list/Brochure	Yes No
Does the technical staff have access to typed or written protocols (Standard Operating Procedures) for performing each test?	Yes No

Specimen collection, labelling and handling

Proportion of samples collected on site	<20% 20-50% 50-80% >80%	
Does the laboratory use standardised request forms to order laboratory tests?		Yes No
Do request forms contain **ALL** of the following patient information: specimen source, date and time of collection, type of test requested?		Yes No
Do request forms provide details or a link which enable the lab to contact the patient?		Yes No
Are specimens that are received labelled with the patient's name and unique identifiers?		Yes No
Does the laboratory provide a unique accession number for all specimens?		Yes No
Does the laboratory have a logbook/electronic record of all specimens sent for diagnostic testing?		Yes No
Are specimens discarded after testing, or are they stored?		Discarded Stored
Are standard criteria used for discarding specimens with prolonged transit times (time of collection to time of processing in lab)?		Yes No
Does the laboratory during evening/night shifts accept specimens?		Yes No
If Yes, how are the following samples handled?		
Specimen	**Plated immediately**	***If no*, held at (*tick* one)**
CSF	Yes No	4≡ Ambient temp. 35≡
Blood culture	Yes No	4≡ Ambient temp. 35≡
Urine	Yes No	4≡ Ambient temp. 35≡
Does you laboratory refer bacteriology isolates or serum samples to the Ministry of Health or a reference laboratory?		Yes No
If Yes, reason for referral (***tick*** all)		
Confirmation		Yes No
Identification of Unknown ? organism		Yes No
Test not performed on site		Yes No

If Yes, then by what method?	
By regular post service	Yes No
By special messenger	Yes No
Courier service	Yes No
Other (describe):	
If Yes, number of sample sent per month?	
Types of transport media used (***tick*** all that apply)	
Trans-isolate	Yes No
Amies	Yes No
Stuart	Yes No
Cary and Blair	Yes No
Blood agar slants	Yes No
Viral transport medium	Yes No
Other (describe):	

Reporting procedures

Are records kept of the number and type of tests performed and results?	Yes No
Does the laboratory use standardised forms to report lab results?	Yes No
Does the laboratory have a list of diseases that are supposed to be reported to the Ministry of Health?	Yes No
If no, does the lab staff know what diseases should be reported?	Yes No
Does the lab provide regular reports of patients with notifiable diseases to any of the following Ministry of Health offices/institutions? (***tick*** all that apply)	
District Health Office	Yes No
State Health Office	Yes No
Central Laboratory	Yes No
National Communicable Disease Program	Yes No
If reports are submitted, how frequently?	
Weekly	Yes No
Monthly	Yes No
Quarterly	Yes No
Other	Yes No
If reports are submitted, by what means are they sent?	
Line list	Yes No
Telephone	Yes No
FAX	Yes No
Other (describe):	
Do you keep register of persons with notifiable diseases?	Yes No
If Yes, is the register computerised?	Yes No
If computerised, are back-up copies (hard copies or disc) of data made and archived?	Yes No
Quality control procedures and programs	

Is information gathered about laboratory turn-around times for specimens (time from receipt of specimen to issue of the report)?	Yes No
Does the laboratory use any system for internal quality control?	Yes No
Are internal controls included in each test run?	Yes No
If Yes, is the performance of these internal controls recorded and monitored over time?	Yes No
Does the laboratory participate in any external quality assurance or proficiency schemes?	Yes No
If Yes, what programs?	
Bacteriology Unknown ?s	Yes No
HIV/Hepatitis panels	Yes No
Antimicrobial susceptibility	Yes No
Other (specify)	Yes No
Does your laboratory keep records of deliveries of reagents and materials?	Yes No
Does your laboratory have a system for regularly monitoring of quantities of reagents and materials so that there is warning if stocks become low?	Yes No
Does the laboratory have problems obtaining and maintaining most supplies of essential reagents and materials?	Yes No
If Yes, what is the most important reason for not maintaining an adequate stock of reagents and supplies?	
Information about how to obtain materials	Yes No
Long delay ordering and delivery of materials	Yes No
Lack of funds	Yes No
Inconsistent demand for test from physicians	Yes No
Is the functioning of ALL electrical or mechanical equipment routinely monitored and recorded (e.g. microscope calibration, checking temperatures of refrigerators or incubators, calibration of pipettes or handling devices, autoclave function, etc.)?	Yes No
Are calibration, maintenance and service records kept?	Yes No
Safety	
Does the laboratory staff receive training in laboratory safety?	Yes No
Is there a safety manual easily accessible to the laboratory the staff?	Yes No
What methods are used for solid waste disposal?	
Autoclaving	Yes No
Incineration	Yes No
Burial with no pre-treatment	Yes No
Other (briefly describe):	
What methods are used for liquid waste disposal?	
No treatment	Yes No
Autoclaving	Yes No
Chemical disinfection	Yes No
Other (briefly describe):	
Is there a safety officer	Yes No
Is there a safety SOP	Yes No
Are new staff offered immunisation	Yes No

What protective clothing/equipment is available for laboratory staff? (***tick*** all)	
Gloves - latex	Yes No
Gloves - other	Yes No
Lab coats	Yes No
Safety glasses/visors	Yes No
Other (briefly describe):	
Are gloves worn for all manipulations of specimens, organisms, and reagents?	Yes No
If Yes, type of gloves	
Latex	Yes No
Other	Yes No
If no, are they worn	
Only for designated procedures OR	Yes No
By the decision of the technician performing a test?	Yes No
If the respondent has said ***Yes*** to any question for Antimicrobial (A-M) susceptibility testing, please indicate which method was used:	
Disk diffusion	Yes No
Agar dilution	Yes No
Broth dilution	Yes No
E-Test	Yes No
Any anti-TB susceptibility testing method	Yes No
Do use any internationally recognised standards for definitions of resistance/susceptibility (e.g., NCCLS, Stokes, DIN, SGRA)	Yes No
If Yes , then which one(s)?	

If the laboratory performs tests for any sexually transmitted diseases, e.g. syphilis, gonorrhoea, chancroid, please enter the information in the following table

Disease	**Specimen type**	**Assay performed**	**Number/Month**

If the laboratory performs any other virological assays using enzyme immunoassay, other serological assays, virus isolation or detection (including molecular tests, e.g., PCR), please list on the table below. Please append sheet if too numerous to fit on table

Disease	**Specimen type**	**Assay performed**	**Number/Month**

Laboratory Inspection

Laboratory Inspection

Inspect the laboratory and complete the following form. Be courteous by first asking permission to open refrigerators, freezers, media storage closets and incubators to examine items contained therein. Some of the information collected during a walk-through will be used to verify information provided on the questionnaire. Make additional Notes as required, e.g. general cleanliness and organization of the laboratory, staff activity level, workload (specimens and inoculated plates present), and special facilities. Obtain copies of standard forms where indicated.

Accessioning and reporting

Review accessioning logbook(s) if available. Roughly calculate the number of specimens submitted over a one-month period. Record number: *samples/month*		
Review forms submitted with specimens. What proportion of specimens received are labelled with the patient's name and unique identifiers?		<50% > 50%
Are copies of report forms available?		Yes No
If Yes, obtain copies of standardised reports forms that are used		
Manuals		
Type of manual	**Available**	**Date of last revision**
Test Procedures	Yes No	< 1 year 2-5 years > 5 years no date
Safety	Yes No	< 1 year 2-5 years > 5 years no date
Quality control	Yes No	< 1 year 2-5 years > 5 years no date
Equipment and reagents		
Briefly look to see if reported number and type of equipment items is consistent with those reported on the questionnaire. Are findings generally consistent with responses above?		Yes No
Inspect equipment to see if performance indicators (e.g., temperatures) are regularly recorded		
Equipment item	**Sheet present**	**Temps. Recorded (per cent complete)**
Refrigerators	Yes No	0% 1-50% >50%
Freezers	Yes No	0% 1-50% >50%
Incubators	Yes No	0% 1-50% >50%
Inspect prepared reagents, dehydrated media, antibiotic susceptibility disks and prepared media to see if dates are recorded for the date prepared or opened and to see if expiration dates have passed.		
Proportion of reagents labelled appropriately?		None < 50% >50%
Expiration dates found?		None < 50% >50%
For reagents with dates - percent outdated?		None < 50% >50%
Inspect bacteriological media, both prepared and dehydrated, and reagents for signs of deterioration, e.g. drying, discoloration, hemolysis		
Deterioration noted in bacteriological media		None < 50% >50%
Safety		
If biosafety hood is present, is it operational?		Yes No No hood

Is a certification/inspection sticker present?	Yes No Not applicable
If Yes, date of certification?	< 1 year >1 year Not applicable
Inspect laboratory for presence of biosafety equipment (gloves, sharps containers, safety glasses)	
Gloves present	Yes No
Sharps containers	Yes No
What proportion of staff are wearing gloves while performing procedures?	<1-50% >50% None Unknown
Inspect equipment used for the disposal of biological wastes, e.g. autoclaves, incinerator. Is the hazardous waste disposal system operational?	Yes No