Laboratory Assessment Comprehensive Checklist

Assessment conducted by_____

Laboratory: _____

District *or* Administrative Unit: _____

Laboratory Supervisor/Head of Laboratory: _____

Date(s) of Visit: _____

Number of Lab Personals: _____

Persons Met:

Name	Title	Qualification

1. Physical Structure

Does the lab have sufficient area? Yes No

Does the lab building in good condition?

Exterior Yes No (If no, prepare a separate observation report.)

Interior Yes No (If no, prepare a separate observation report.)

2. 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

3. Standard Operating Procedures

Standard Operating Procedures?	Yes	No
Manual of Methods?	Yes	No
Quality Assurance Plans?	Yes	No
Safety Guidelines?	Yes	No
Safety Equipment?	Yes	No
Infectious Waste Disposal Guidelines?	Yes	No
Specimen Rejection Policy Plan?	Yes	No

4. Staff Training

Has there been any change in staff since last supervisory visit?	Yes	No
Has new staff received proper training?	Yes	No
Is training requirements are defined for each staff?	Yes	No
Staff participated in refresher training within past two years?	Yes	No
Have any problems been identified through rechecking indicating?	Yes	No
Is there a need for additional training/refresher course?	Yes	No

Explain any need for additional training

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5. Laboratory Safety

Observe and Question	Indicator		
Are GLP followed in the lab.	No eating, drinking, smoking. No mouth pipeting	Yes	No

Where is TB work performed?	TB work is performed in an area separate from other laboratory procedures	Yes	No
	There are separate tables for smear preparation and microscopy	Yes	No
Where is HIV work performed?	There are separate tables	Yes	No
Does the laboratory have adequate ventilation? If smears are performed in front of an open window, are technicians aware of airflow direction and potential for danger?	There is adequate & safe ventilation	Yes	No
Which disinfectant is used?	An approved disinfectant active against TB is used	Yes	No
Have there been any shortages of disinfectant supply in the past three months?	An adequate supply of disinfectant is available	Yes	No
How often work areas are cleaned with disinfectant?	Work areas are cleaned at least daily	Yes	No
How wire loops are cleaned?	A sand bucket with Lysol or 70% ethanol is used to clean wire loops prior to flaming	Yes	No
How are used slides disposed of? Are slides ever reused?	Used slides are properly disposed of (boiled or buried) If slides are reused, are they properly disinfected and cleaned, and never reused for AFB microscopy.	Yes	No
How used sputum containers are disposed of? Are sputum containers ever reused? (Supervisor should check waste disposal site to ensure proper burial)	Sputum containers used only one time. Used containers are burned or properly buried.	Yes	No
		Yes	No
Observe biohazard waste bin	A biohazard waste bin with a lid is	Yes	No

	available		
Are workers wearing lab coats?	Lab coats are worn while working in the laboratory	Yes	No
Are lab coats removed prior to leaving the laboratory?	Lab coats are not worn outside the laboratory	Yes	No
Are gloves used in the laboratory? Are they used properly?	If gloves are available, they are used in accordance with safe work practice recommendations	Yes	No
Is supply of PPE sufficient?	Enough to last three months	Yes	No
Do workers wash their hands after working with sputum?	Proper hand washing procedures are followed	Yes	No
Does laboratory appear clean and in good working order?	Lab is clean, layout is adequate to ensure safe practices	Yes	No
Are electrical wiring exposed?		Yes	No
Are eye wash station and safety shower available?		Yes	No

Explain any problems or deficiencies

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6. Specimen collection, labeling and handling

Collection of Samples

Observe and Question	Standard	Yes	No
		Yes	No

Is lab technician responsible for collecting specimens?	If yes, complete all questions in this section	Yes	No
Ask technician how he draws a blood sample: Observe Adequate use of skin disinfections? Use of disposable syringe? Use of disposable needle? How needle is discarded?		Yes	No
How sample are labeled? Numbering system?		Yes	No
Ask the technician to describe the instructions for producing sputum that are given to patient	Patients receive adequate instruction to produce sputum rather than saliva	Yes	No
Is the quality of specimen checked?	Specimen is evaluated visually for presence of sputum	Yes	No
When the patient produces saliva, is a repeat specimen collected?	Smears are not prepared from specimens recognized as saliva. Repeat specimens are requested.	Yes	No
How many pre-treatment specimens are routinely collected for diagnosis? How many specimens are routinely collected for treatment follow-up?	Three specimens are routinely collected, following IUATLD and WHO guidelines for Spot, Morning & Spot collection.	Yes	No
How samples are transported to the Lab (Reference Lab)?		Yes	No

Explain any problems or deficiencies

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7. Equipment

Does lab have sufficient equipment to perform HIV test?	Yes	N o
Does lab have calibration, maintenance program/ Data?	Yes	No

Observe and Question	Standard		
Does microscope SOP exists?		Yes	No
Is microscope present? Are adequate numbers of microscopes available?	At least one functional microscope is available Sufficient number of microscopes is available to manage workload	Yes	No
Is the microscope functioning properly?	Supervisor can observe a clear image when looking through the microscope at a random smear.	Yes	No
Is the stage mechanism functioning?	Stage can be moved properly	Yes	No
Is adequate light source present?	Functional light bulb and electricity, or microscope is located near adequate light source	Yes	No
How is maintenance on the microscope performed?	Microscope is under maintenance contract or there is evidence of routine maintenance.	Yes	No

Explain any problems or deficiencies

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8. Laboratory Reagents

Observe and Question	Indicator

Are all staining reagents available? Have there been any shortages of reagents within the last three months? (*Adequate supply is defined as available current supply and no shortages over the past three months.) Observe that all reagents in use are within expiration date Observe that Immersion Oil has acceptable viscosity (not too thick or too thin) (Will require training of non-lab supervisor)	Reagent	Available	Within expiration date	Adequate Supply*
	Grams stain Carbol Fuchsin Iodine Decolorizer	Yes No Yes No Yes No Yes No	Yes No Yes No Yes No Yes No	Yes No Yes No Yes No Yes No
	Methylene Blue	Yes No	Yes No	Yes No
	Sulphuric Acid 25% Or Acid Alcohol 3%	Yes No	Yes No	Yes No
	Immersion Oil	Yes No	Yes No	Yes No
	Xylene	Yes No	Yes No	Yes No

Explain any problems or deficiencies

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9. Laboratory Supplies

Observe and Question	Indicator			
	Material	Available	Good Condition/ With in expiration date	Adequate Supply *

Are the following items available? Is the type of sputum containers in use approved? Check to determine that slide boxes are adequate design (slides are stored standing up to drain oil and without touching each other) and number (sufficient boxes to store the number of slides required for adequate sampling) Have there been any shortages of supplies within the past three months? (*Adequate supply is defined as available current supply and no shortages over the past three months.) A clean water supply should be available. Water	HIV Kits Slides Frosted Slides	Yes No Yes No Yes No	Yes No Yes No Yes No	Yes No
	Slide Boxes	Yes No	Yes No	Yes No
	Sputum Containers approved	Yes No		Yes No
	Diamond Pencil (or) Pencils (use with frosted slides)	Yes No Yes No	Yes No	 Yes No
	Wire Loops or Sticks	Yes No Yes No	Yes No	Yes No Yes No
	Funnel	Yes No	Yes No	
	Filter Paper	Yes No		Yes No
	Staining Racks	Yes No	Yes No	Yes No
	Spirit Lamp or Bunsen Burner	Yes No	Yes No	
	Fuel for spirit lamp Or Gas for burner	Yes No		Yes No
	Lens Tissue	Yes No		Yes No
	Red Pen for recording Positive Results	Yes No		
	Water supply	Yes No	Yes No	Yes No

should be stored in bottles free of environmental contaminants including bacteria and fungus. Water from stagnant containers should not be used.	Balance (for weighing reagents)	Yes No	Yes No	

Explain any problems or deficiencies

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10. Laboratory Request Form, Laboratory Register, Laboratory Reports

Observe and Question	Indicator	
Are the approved laboratory request forms used for every patient?	Approved laboratory request forms are used for every patient	Yes No
Are laboratory request forms submitted with complete information?	Laboratory request forms are submitted with complete information	Yes No
Is the laboratory register present, and all columns completed properly?	Laboratory register is present Laboratory register is properly complete and legible	Yes No Yes No
Are patient records in laboratory register consistent?	If no, how many patients has missing records	Yes No
When is result information entered into the laboratory register?	Results entered into register daily	Yes No
Are laboratory results recorded on the request form?	Laboratory results are recorded directly onto the form	Yes No
How soon are results reported to the treatment center or physician? Use of Telephone to report the result.	Same day Next day	Yes No Yes No Yes No
Record keeping, Duration Manual		Yes No

Electronic		Yes No

Explain any problems or deficiencies

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11. 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

12. Laboratory Training Needs

	Target	Training Priorities	Recommended Training Venue	Recommended Partner
Quality Assurance	Quality Assurance Officer	QA system theory, development and administration	APHL member laboratory/on-site QA training at NIB for pilot states	NIB/CDC/APHL
	Laboratory Director	Implementation	In-country workshops	NIB/CDC/APHL
Rapid HIV Testing	All Laboratory Technicians	QA/QC, procedure, interpretation	In-country workshops	ICMR/CDC
HIV Antibody				
CD4				
Viral Load				
Sexually Transmitted Diseases				

(other than HIV)				
Tuberculosis				
Opportunistic Infections				

Any Other Observation/ recommendation/ training requirement.