

# On-Site Evaluation Comprehensive Checklist- Draft

Laboratory: \_\_\_\_\_

District or Administrative Unit:

\_\_\_\_\_

Laboratory Supervisor/Head of Laboratory: \_\_\_\_\_

Date of Visit: \_\_\_\_\_

Number of Lab Personals: \_\_\_\_\_

Current Lab Staff Qualifications: \_\_\_\_\_

\_\_\_\_\_

Does the lab have sufficient area?                    Y    N

Does the lab building in good condition?

Exterior    Y    N    (If no, prepare a separate observation report.)

Interior    Y    N    (If no, prepare a separate observation report.)

## 1. Standard Operating Procedures

Are written standard operating procedures for laboratory methods and equipment available and accessible?                    Y    N

If no, explain: \_\_\_\_\_

\_\_\_\_\_

## 2. Staff Training

Has there been any change in staff since last supervisory visit?                    Y    N

Has new staff received proper training?                    Y    N

Is training requirements are defined for each staff?                    Y    N

Staff participated in refresher training within past two years?                    Y    N

Have any problems been identified through rechecking indicating there is a need for additional training/refresher course?                    Y    N

Explain any need for additional training \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### 3. Laboratory Safety

Observe and Question	Indicator	
Are GLP followed in the lab.	No eating, drinking, smoking. No mouth pipeting	Y N
Where is TB work performed?	TB work is performed in an area separate from other laboratory procedures	Y N
	There are separate tables for smear preparation and microscopy	Y N
Where is HIV work performed?	There are separate tables	Y N
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	Y N
Which disinfectant is used?	An approved disinfectant active against TB is used	Y N
Have there been any shortages of disinfectant supply in the past three months?	An adequate supply of disinfectant is available	Y N
How often are work areas cleaned with disinfectant?	Work areas are cleaned at least daily	Y N
How are wire loops cleaned?	A sand bucket with Lysol or 70% ethanol is used to clean wire loops prior to flaming	Y N
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.	Y N
How are used sputum containers disposed of? Are sputum containers ever reused? (Supervisor should check waste disposal site to ensure proper burial)	Sputum containers used only one time.	Y N
	Used containers are burned or properly buried.	Y N
Observe biohazard waste bin	A biohazard waste bin with a lid is available	Y N
Are workers wearing lab coats?	Lab coats are worn while working in the laboratory	Y N
Are lab coats removed prior to leaving the laboratory?	Lab coats are not worn outside the laboratory	Y N
Are gloves used in the laboratory? Are they used properly?	If gloves are available, they are used in accordance with safe work practice recommendations	Y N
Is supply of PPE sufficient?	Enough to last three months	Y N
Do workers wash their hands after working with sputum?	Proper hand washing procedures are followed	Y N
Does laboratory appear clean and in good working order?	Lab is clean, layout is adequate to ensure safe practices	Y N
Are electrical wiring exposed?		Y N
Are eye wash station and safety shower available?		Y N

Explain any problems or deficiencies

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Action required \_\_\_\_\_

**4. Equipment**

<b>Does lab has sufficient equipment to perform HIV test</b>	Y	N
<b>Does lab has calibration, maintenance program/ Data</b>	Y	N

Observe and Question	Standard		
Does microscope SOP exists?		Y	N
Is microscope present?	At least one functional microscope is available	Y	N
Are adequate numbers of microscopes available?	Sufficient number of microscopes is available to manage workload	Y	N
Is the microscope functioning properly?	Supervisor can observe a clear image when looking through the microscope at a random smear.	Y	N
Is the stage mechanism functioning?	Stage can be moved properly	Y	N
Is adequate light source present?	Functional light bulb and electricity, or microscope is located near adequate light source	Y	N
How is maintenance on the microscope performed?	Microscope is under maintenance contract or there is evidence of routine maintenance.	Y	N

Explain any problems or deficiencies

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Action Required \_\_\_\_\_

**5. Laboratory Reagents**

Observe and Question	Indicator
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Are all staining reagents available?	Reagent	Available	Within expiration date	Adequate Supply*
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)	Grams stain	Y N	Y N	Y N
	Carbol Fuchsin	Y N	Y N	Y N
	Iodine	Y N	Y N	Y N
	Decolorizer ( )	Y N	Y N	Y N
	Methylene Blue	Y N	Y N	Y N
	Sulphuric Acid 25% Or Acid Alcohol 3%	Y N	Y N	Y N
	Immersion Oil	Y N	Y N	Y N
	Xylene	Y N	Y N	Y N

Explain any problems or deficiencies

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Action Required \_\_\_\_\_

## 6. Laboratory Supplies

Observe and Question	Indicator			
	Material	Available	Good Condition/ With in expiration date	Adequate Supply *
Are the following items available?	HIV Kits	Y N	Y N	Y N
Is the type of sputum containers in use approved?	Slides	Y N	Y N	
	Frosted Slides	Y N	Y N	
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)	Slide Boxes	Y N	Y N	Y N
	Sputum Containers approved	Y N		Y N
	Diamond Pencil (or) Pencils (use with frosted slides)	Y N	Y N	
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.)	Wire Loops	Y N	Y N	Y N
	or Sticks	Y N		Y N

A clean water supply should be available. Water should be stored in bottles free of environmental contaminants including bacteria and fungus. Water from stagnant containers should not be used.	Funnel	Y N	Y N	
	Filter Paper	Y N		Y N
	Staining Racks	Y N	Y N	Y N
	Spirit Lamp or Bunsen Burner	Y N	Y N	
	Fuel for spirit lamp Or Gas for burner	Y N		Y N
	Lens Tissue	Y N		Y N
	Red Pen for recording Positive Results	Y N		
	Water supply	Y N	Y N	Y N
	Balance (for weighing reagents)	Y N	Y N	

Explain any problems or deficiencies

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**Action Required** \_\_\_\_\_

### 7. 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	Y N
Are laboratory request forms submitted with complete information?	Laboratory request forms are submitted with complete information	Y N
Is the laboratory register present, and all columns completed properly?	Laboratory register is present	Y N
	Laboratory register is properly complete and legible	Y N
Are patient records in laboratory register consistent?	If no, how many patients has missing records	Y N
When is result information entered into the laboratory register?	Results entered into register daily	Y N
Are laboratory results recorded on the request form?	Laboratory results are recorded directly onto the form	Y N

How soon are results reported to the treatment center or physician?	Same day	Y	N
	Next day	Y	N
		Y	N
Record keeping, Duration Manual Electronic		Y	N
		Y	N

Explain any problems or deficiencies

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Action required \_\_\_\_\_

### 8. Storage of slides for External Quality Assessment

Observe and Question	Standard		
Does lab participate in EQA program?		Y	N
Are ALL slides kept as required by EQA program?	Slides are kept for EQA; supervisor is able to retrieve all slides identified from the laboratory register for EQA.	Y	N
Are slides kept in storage boxes?	Slides are kept in storage boxes	Y	N
Are slides cleaned with xylene before storage, or are slides stored in boxes so that oil can drain without contaminating other slides?	Slides are cleaned with xylene before storage, or are stored in boxes so that oil can drain without touching or contaminating other slides?	Y	N

Explain any problems or deficiencies

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Action Required \_\_\_\_\_

## 9. Workload

Number of samples last quarter		Number of AFB smears last quarter		Number of follow up AFB smears last quarter	
HIV Serology					
Total:		Total:		Total:	
# Pos:	# Neg:	# Pos:	# Neg:	# Pos:	# Neg:

Average number of smears read by each technician per day?

## 10. Collection of Samples

Observe and Question	Standard		
Is lab technician responsible for collecting specimens?	If yes, complete all questions in this section	Y	N
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?		Y	N
How sample are labeled? Numbering system?			
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	Y	N
Is the quality of specimen checked?	Specimen is evaluated visually for presence of sputum	Y	N
When the patient produces saliva, is a repeat specimen collected?	Smears are not prepared from specimens recognized as saliva. Repeat specimens are requested.	Y	N
How many pre-treatment specimens are routinely collected for diagnosis? <i>How many specimens are routinely collected for treatment follow-up?</i>	Three specimens are routinely collected, following IUATLD and WHO guidelines for Spot, Morning & Spot collection.	Y	N

Explain any problems or deficiencies

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## 11. Smear and Staining Procedures

Observe and Question	Standard		
Does technician verify that container is properly labeled?	Containers are labeled with the health center code and the patient identification on the side of the container, not on the lid.	Y	N
Are new slides used for sputum AFB smears? Are slides cleaned prior to use?	New slides are used for AFB microscopy. Slides are cleaned prior to use if greasy.	Y	N
How are slides labeled?	Slides are labeled with laboratory code, serial number and sequence identifier.	Y	N
How often is Carbol Fuchsin filtered?	Carbol Fuchsin is filtered before use	Y	N
How often is Methylene Blue filtered?	Methylene Blue is filtered at least once a month or more often if precipitate is noted in smears	Y	N
Is the wire loop cleaned in sand and sterilized by flaming after every smear? OR Is a new wooden stick used to prepare each smear?	The wire loop is sterilized by flaming after every smear OR A new wooden stick is used to prepare each smear	Y	N
Are smears air-dried completely prior to fixing?	Smears are completely <i>air dried</i> prior to fixing	Y	N
Are slides properly heat fixed?	Slides are heat fixed by passing 3-5 times through flame	Y	N
How many slides are usually stained in a batch?	A <i>maximum of 10-12</i> specimens are processed at one time	Y	N
What is the staining procedure used by the technician? How long are slides stained with CF and MB? How are slides decolorized?	Slides are stained with hot, steaming CF for 5 minutes Stain is not permitted to dry on the slide Slides are decolorized for 3 minutes, repeat decolorization is performed only when needed, slides are not over-decolorized Slides are counterstained with MB for 1 minute	Y	N
How often are microscope lenses cleaned with lens tissue?	Microscope objective is wiped with lens tissue after every slide examination	Y	N
How many fields are examined to report a negative smear?	The microscopist takes at least 5 minutes <i>and</i> examine 100 fields	Y	N
How many fields are examined to report a positive smear?	An adequate number of fields are examined to provide accurate quantitation. For high positives, this may be 20-50 fields, for low positives, 100 fields should be read.	Y	N
How are results reported?	Results are consistent with <i>WHO</i> recommendations for grading and reporting	Y	N
Are known positive and negative smears included as an internal control? Observe availability of sufficient quantity of control slides.	Control smears are included:	Daily	Never

Explain any problems or deficiencies



## 12. Onsite Rechecking

Laboratory supervisor should re-read at least three positive and negative smears during the on-site visit.

	Slide No.	Result Peripheral Lab	Result Supervisor	Staining AFB	Staining Background	Sputum or Saliva	Thickness and size of smear
+							
+							
+							
-							
-							
-							

Observations:	
Were results of supervisor consistent with laboratory result? Explain any problems:	Y N
Is staining of AFB and background acceptable? Explain any problems?	Y N
Does background material represent sputum? Explain any problems?	Y N
Are smears of proper thickness? Explain any problems?	Y N
Are smears of proper size? Explain any problems?	Y N

**13. Rechecking**

Have results of rechecking been acceptable *according to performance expectations?* Y N

If no, have any problems been identified through Rechecking or Panel Testing indicating there is a need for corrective action?  
Explain any need for corrective action \_\_\_\_\_

Has corrective action been adequately implemented? Y N

If no, explain \_\_\_\_\_

**14.** Who checks and signs report? Technician, senior lab person, Supervisor, lab manager, lab director, Pathologist

**16.** On-Site Evaluation Summary

List any MAJOR problems identified during the on-site visit:

A. Operational Problems:

B. Technical Problems:

Name of person completing On-Site Evaluation: \_\_\_\_\_

Signature: \_\_\_\_\_ Date \_\_\_\_\_