A1: On-Site Evaluation Comprehensive Checklist

Laboratory: _____

District or Administrative Unit: _____

Laboratory Supervisor/Head of Laboratory: _____

Date of Visit: _____

Number of Microscopists/ Technicians: _____

Current Laboratory Staff Qualifications: _____

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SECTIONS 1-9, and 14 MAY BE FILLED OUT BY LABORATORY OR NON-LABORATORY STAFF SUPERVISING THE CLINIC OPERATIONS. SECTIONS 10-13 ARE DETAILED LABORATORY EVALUATIONS THAT SHOULD ONLY BE COMPLETED BY TRAINED LABORATORY STAFF.

1. Standard Operating Procedures

Are written standard operating procedures for laboratory methods and equipment (e.g. NTP laboratory manual) available and accessible? Y N

If no, explain: _____

2. Laboratory Reagents

Observe and Question	Indicator			
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.)	Carbol Fuchsin	Y N	Y N	Y N
	Methylene Blue	Y N	Y N	Y N
Observe that all reagents in use are within expiration date	Sulphuric Acid 25% Or Acid Alcohol 3%	Y N	Y N	Y N
	Immersion Oil	Y N	Y N	Y N
Observe that Immersion Oil has acceptable viscosity (not too thick or too thin) (Will require training of non-lab supervisor)	Xylene	Y N	Y N	Y N

Explain any problems or deficiencies

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Action Required _____

3. Laboratory Supplies

Observe and Question	Indicator			
	Material	Available	Good Condition	Adequate Supply *
Are the following items available?	Slides Frosted Slides	Y N		Y N
Is the type of sputum containers in use approved by the NTP?	Slide Boxes	Y N	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)	Sputum Containers approved by NTP	Y N		Y N
	Diamond Pencil (or) Pencils (use with frosted slides)	Y N Y N	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 or Sticks	Y N Y N	Y N	Y N Y N
	Funnel	Y N	Y N	
	Filter Paper	Y N		Y N
A clean water supply should be available distilled water is recommended. Water should be stored in bottles free of environmental contaminants including bacteria and fungus. Water from stagnant containers should not be used.	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

Action Required

4. Laboratory Safety

Observe and Question	Indicator		
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
Does the laboratory have adequate ventilation? If smears are performed in front of an open window, are technicians aware of air flow direction and potential for danger?	There is adequate & safe ventilation	Y	N
Which disinfectant is used?	An NTP 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, the are 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. Used containers are burned or properly buried.	Y Y	N 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
Do workers wash their hands after working with sputum?	Proper handwashing 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

Explain any problems or deficiencies

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Action Required _____

5. Laboratory Request Form, Laboratory Register, Laboratory Reports

Observe and Question	Indicator	
Are the NTP approved laboratory request forms used for every patient?	NTP 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 Laboratory register is properly complete and legible	Y N Y N
Are patient records in laboratory register consistent with District Register? (Compare 10 patients from the Laboratory Registry and determine if all 10 patients are listed in the district register)	District TB cases appear in Laboratory register If no, how many patients are missing? _____	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?	Forms are sent back to the treatment center or physician within two working days. *All three results are sent back within two working days*	Y N Y N
Are three specimens routinely examined as recommended by IUATLD?	Three specimens, including spot, morning and spot are examined for diagnosis of TB.	Y N

Explain any problems or deficiencies

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Action Required _____

External Quality Assessment for AFB Smear Microscopy APHL, CDC, IUATLD, KNCV, RIT and WHO, 2003 (pgs 59-69)

6. Microscope

Observe and Question	Standard	
Is microscope present? Adequate number of microscopes available?	At least one functional microscope is available Sufficient number of microscopes is available to manage workload	Y N 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

Action Required

7. Storage of slides for External Quality Assessment

Observe and Question	Standard	
Are ALL slides kept as required by the NTP 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

Action Required

8. Staff Training

Has there been any change in staff since last supervisory visit?	Y	N
Has new staff received proper training, as required by the NTP?	Y	N
If training requirements are not defined by NTP, has each staff member participated in refresher training within past two years?	Y	N
Have results of rechecking been received by peripheral lab?	Y	N
Have results of rechecking or panel testing been acceptable?	Y	N
If no, have any problems been identified through Rechecking or Panel Testing indicating there is a need for additional training/refresher course?	Y	N

Explain any problems or deficiencies

Action Required

9. **Workload**

Number of smears last quarter		Number of suspects smears last quarter	Number of follow up smears last quarter	
Total:		Total:	Total:	
# Pos:	# Neg:		# Pos:	# Neg:

Average number of smears read by each technician per day? _____

THE FOLLOWING EVALUATION QUESTIONS SHOULD ONLY BE COMPLETED BY SUPERVISORY LABORATORY STAFF

10. **Collection of Sputum Samples**

Observe and Question	**Standard**	
Is lab technician responsible for collecting specimens?	If yes, complete all questions in this section If no, skip to section 11	Y N
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 Y N
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.	Y N

Explain any problems or deficiencies

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Action Required _____

11. Smearing 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 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 always 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 Y N
Are smears air dried completely prior to fixing?	Smears are completely *air dried* 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 maximum of* 10-12 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 Y N Y N Y N 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 *and* examine 100 fields	Y N
How many fields are examined to report a positive smear?	An adequate number of fields is 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 *NTP* 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 Each new batch of stain Never	

Explain any problems or deficiencies _____

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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 and/or Panel Testing

Have results of rechecking or panel testing been acceptable according to performance expectations set by NTP? Y N

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

Explain any need for corrective action _____

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14. On-Site Evaluation Summary

List any MAJOR problems identified during the on-site visit:
A. Operational Problems:

B. Technical Problems:

15. Name of person completing On-Site Evaluation: _____

Signature: _____

16. Signature of Laboratory Supervisor: _____