WA##_Deliverable Date*_Lab Name_Audit Type_Lab_Audit_Report_Audit Start Date*
*date format=20YYMMDD

NIAID/DAIDS CRSS Team

PPD

NIAID HIV and Other Infectious Diseases Clinical Research Support Services (CRSS)
Contract No. HHSN272201700078C

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No. HHSN272201700078C, entitled NIAID HIV and Other Infectious Diseases Clinical Research Support Services (CRSS).

NIAID/DAIDS CRSS Team

PPD

Laboratory Audit Visit of

Harmonized ID (HID)	Laboratory Name - Address

Conducted by PPD

Audit Type: Tuberculosis

Audit Date(s):

Final Report Issued:

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WA##_Deliverable Date*_Lab Name_Audit Type_Lab_Audit_Report_Audit Start Date*
*date format=20YYMMDD

Tuberculosis (TB) Laboratory Checklist

Laboratory Report Summary

Study Site Name/Number/Location	
Visit Date(s)	
Audit Requestor	
Laboratory Auditor	
Principal Investigator	
Laboratory Name	
Laboratory Type	
Laboratory Management	
Quality Assurance Unit Manager	
Safety Officer	
Date(s) Last Audited	
Protocol(s) Supported by DAIDS	
DAIDS Network/Non-Network Affiliation(s)	

Comments:

Laboratory Activities

Indicate below all the activities performed in the laboratory and report in the "Comments" section the methods used to perform each activity.	
Acid-Fast Bacillus (AFB) Microscopy	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐
Mycobacterial Culture	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐
Mycobacterial Identification	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐
Drug Susceptibility Testing (DST)	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐
Storage of Mycobacterial Isolates	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐

Shipment of Mycobacterial Isolates	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐
Other	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐
Are reference laboratories used for further processing of TB specimens? (If "Yes," describe these.)	Yes ☐ No ☐ DAIDS Related? ☐ Comments ☐

Comments:

I. Safety

A.	**Laboratory Safety**	
1.	Are procedures involving propagation and manipulation of grown TB cultures, including mycobacterial identification and susceptibility testing, performed in a BSL-3 facility? (If "No," skip to Question 2.)	Yes ☐ No ☐ Comments ☐
	a. Is a procedure available to verify that the air pressure in the BSL-3 laboratory is lower than that of adjacent areas?	Yes ☐ No ☐ Comments ☐
	b. Are other procedures, such as specimen processing for mycobacterial smear and culture, performed in a BSL-2 facility?	Yes ☐ No ☐ Comments ☐
2.	For facilities performing propagation and manipulation of grown TB cultures in a BSL-2 laboratory, is negative air pressure and other BSL-3 practices such as the use of respiratory protection, closed gowns and other PPE implemented to minimize exposure risk?	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Safety Practices**	
1.	Are the following procedures performed in a Class II biosafety cabinet to protect personnel from aerosols?	
	a. Receipt and unpacking of specimens from secondary packaging	Yes ☐ No ☐ Comments ☐
	b. Filling and decanting of centrifuge tubes	Yes ☐ No ☐ Comments ☐
	c. Opening of the centrifuge buckets and removal of tubes	Yes ☐ No ☐ Comments ☐
	d. Preparation and drying of AFB smears from concentrated and liquefied specimens	Yes ☐ No ☐ Comments ☐
	e. Manipulation of viable cultures known or suspected of containing mycobacteria	Yes ☐ No ☐ Comments ☐
2.	Is the biosafety cabinet disinfected before and after each use? (If "Yes," describe the method used.)	Yes ☐ No ☐ Comments ☐

3.	Are slides heat fixed before staining to reduce aerosols? (If "Yes," describe the method used.)	Yes ☐ No ☐ Comments ☐
4.	Is there daily decontamination of benchtops?	Yes ☐ No ☐ Comments ☐
5.	Is laboratory waste autoclaved before disposal? (Where applicable, list the areas exposed to laboratory waste during the transport of unautoclaved material.)	Yes ☐ No ☐ Comments ☐
6.	Is an annual TB surveillance program in place for laboratory personnel?	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Safety-Related Incidents**	
1.	Are there procedures available for documenting or reporting safety incidents?	Yes ☐ No ☐ Comments ☐
2.	Is there documentation of all safety-related incidents? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
3.	Is the documentation reviewed and signed monthly by the laboratory management?	Yes ☐ No ☐ Comments ☐
4.	Is there a mechanism to evaluate safety incidents?	Yes ☐ No ☐ Comments ☐
5.	Is prophylaxis treatment available (e.g., hepatitis B vaccinations and post-pathogen exposure options)?	Yes ☐ No ☐ Comments ☐
6.	Does a Physician provide a documented review of all exposure events?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Safety Data Sheets (SDS) or Material Safety Data Sheets (MSDS)**	
1.	Are SDS or MSDS on file or available online? (If "No," skip to Section E.)	Yes ☐ No ☐ Comments ☐
2.	Are SDS or MSDS readily available to all laboratory personnel?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Safety Training**	
1.	Is there an initial and ongoing safety training program with documented participation of all laboratory personnel? (If "Yes," briefly describe the training and list the provider as well as the frequency of training.)	Yes ☐ No ☐ Comments ☐
2.	Is a respirator training program in place?	Yes ☐ No ☐ Comments ☐
3.	Is respiratory fit testing performed annually and documented?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Safety Policies**	
1.	Is a written Standard Precautions Policy available?	Yes ☐ No ☐ Comments ☐
2.	Is a written policy for fire safety available?	Yes ☐ No ☐ Comments ☐
3.	Are there written Biosafety policies and procedures specific for the TB Laboratory?	Yes ☐ No ☐ Comments ☐
4.	Is a written Chemical Hygiene/Hazardous Materials Plan available?	Yes ☐ No ☐ Comments ☐
5.	Is there a written policy for the handling and disposal of biohazardous materials and regulated medical waste? (If "Yes," list what mechanism is used for disposing biohazardous waste.)	Yes ☐ No ☐ Comments ☐
6.	Is an Infectious Spill procedure posted in the TB laboratory?	Yes ☐ No ☐ Comments ☐
7.	Are policies, procedures, and practices in place for use of dry ice (solid carbon dioxide)?	Yes ☐ No ☐ Comments ☐
8.	Is an emergency preparedness policy available?	Yes ☐ No ☐ Comments ☐
9.	Are safety policies and procedures readily available to all personnel?	Yes ☐ No ☐ Comments ☐
10.	Is there evidence of review within a two-year interval of all safety policies and procedures by laboratory management?	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Is safety equipment such as eyewashes, safety showers, fire extinguishers, sharps containers, spill kits, smoke detectors/fire alarms, hand washing sinks, and basic first aid kits present in the laboratory? (If "Yes," provide the frequency of documented functional checks for the equipment.)**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Personal Protective Equipment (PPE)**	
1.	Is PPE (gloves, gowns, masks/respirators, eye protectors, etc.) available to laboratory personnel?	Yes ☐ No ☐ Comments ☐
2.	Is PPE correctly worn and utilized by laboratory personnel?	Yes ☐ No ☐ Comments ☐
3.	Is PPE maintained in a sanitary and reliable condition in all technical work areas in which blood and body substances are handled and in circumstances during which exposure is likely to occur?	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Emergency Evacuation**	
1.	Does the laboratory have a documented and workable evacuation plan that is available to all laboratory employees and visitors?	Yes ☐ No ☐ Comments ☐
2.	Have all laboratory employees (and visitors, if appropriate) been properly trained in the evacuation plan/policy?	Yes ☐ No ☐ Comments ☐
3.	Are annual fire drills conducted with documented participation by laboratory personnel?	Yes ☐ No ☐ Comments ☐

Comments:

II. External Quality Assurance (EQA)

1.	Does the laboratory participate in any external proficiency programs for DAIDS-supported protocol-related assays? (If "Yes," list all EQA providers. If "No," list the analytes not covered.)	Yes ☐ No ☐ Comments ☐
2.	Does the laboratory have a written policy to address the following aspects of EQA: specimen handling and analysis, results review, and troubleshooting for unsatisfactory performance?	Yes ☐ No ☐ Comments ☐
3.	Is EQA documentation present and organized (e.g., investigation reports, SMILE Review, survey provider result and report, raw result data, attestation page, or other indication of who performed the testing)?	Yes ☐ No ☐ Comments ☐
4.	Are EQA specimens tested in the same manner as participant specimens?	Yes ☐ No ☐ Comments ☐
5.	Is there documented review by laboratory management of all EQA results?	Yes ☐ No ☐ Comments ☐
6.	Are EQA specimens rotated among personnel who routinely test participant samples?	Yes ☐ No ☐ Comments ☐

Comments:

III. Organization and Personnel

A.	**Is an organizational chart inclusive of all laboratory personnel involved with DAIDS-supported protocol-related activities present?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Is there a policy/process for determining authorized designees? (If "Yes," please describe.)**	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Personnel Records**	
1.	Are personnel records kept? (If "Yes," describe how these records are organized and securely stored.)	Yes ☐ No ☐ Comments ☐
2.	Is a job description/delegation of duties documentation present for all laboratory personnel involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐
3.	For each laboratory position involved with protocol-related activities, is there a documented profile that lists requirements such as education, experience, and certification/license requirements?	Yes ☐ No ☐ Comments ☐
4.	Are education records maintained for all laboratory personnel involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐
5.	Are assay-specific training records available for all laboratory personnel involved with testing activities?	Yes ☐ No ☐ Comments ☐
6.	Have all personnel involved in processing and/or testing of DAIDS-supported protocol specimens completed DAIDS Good Clinical Laboratory Practice training? (If "No," indicate the total number of trained vs untrained personnel.)	Yes ☐ No ☐ Comments ☐
7.	Is documentation maintained, indicating the laboratory has assessed the competency of each employee to perform his/her assigned duties in accordance to the requirements for waived and non-waived testing? (If "Yes," report the methods utilized to assess competency and the frequency of evaluation.)	Yes ☐ No ☐ Comments ☐
8.	Are personnel identification lists (signature/initial/code) present to verify responsible personnel?	Yes ☐ No ☐ Comments ☐
9.	Has the laboratory defined and established a process for auditing personnel records?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Has the laboratory been certified by any regulatory/accrediting agency? (If "Yes," list the agency and date[s] of certification.)**	Yes ☐ No ☐ Comments ☐

Regulatory/Accrediting Agency	Date(s) of Certification

E.	**Does the laboratory have a policy that prohibits retaliation against personnel who communicate study integrity, testing quality, and/or safety concerns to laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Is there a mechanism for the leadership of the laboratory and the clinic to discuss laboratory performance?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Did the laboratory change location since the last audit visit?**	Yes ☐ No ☐ Comments ☐

Comments:

H. Have any new laboratory employees been hired since the last audit? (If "Yes," document the changes in personnel and management positions.)	Yes ☐ No ☐ Comments ☐

Comments:

IV. Testing Facility Operation

A. Is there a list of all DAIDS-supported testing activities performed in the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

B. Are turnaround times (TATs) present for all DAIDS-supported assays?	Yes ☐ No ☐ Comments ☐

Comments:

C. Is a master list of currently used SOPs maintained by the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

D. Standard Operating Procedures (List at least one example from each laboratory category)

Written Procedure Name	Review completed by laboratory management within two-year interval?	Laboratory management signature present?
1.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
2.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
3.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
4.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
5.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
6.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐

7.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
8.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
9.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
10.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐

Comments:

E. Is there a written document control plan that addresses topics such as procedural relevance, authorization process, reviews, revisions and discontinuation of procedures?	Yes ☐ No ☐ Comments ☐

Comments:

F. Are laboratory SOPs reviewed for accuracy and relevance within two-year intervals?	Yes ☐ No ☐ Comments ☐

Comments:

G. Does the laboratory have a system of documenting that all personnel are knowledgeable of the contents of the laboratory's SOPs?	Yes ☐ No ☐ Comments ☐

Comments:

H. Are the laboratory SOPs available in the work area?	Yes ☐ No ☐ Comments ☐

Comments:

I. Are superseded SOP versions identified as retired and archived in the laboratory? (If "Yes," explain the archiving process and provide the retention time.)	Yes ☐ No ☐ Comments ☐

Comments:

V. Test Method Validation and Verification

A. Has the laboratory documented diagnostic/clinical accuracy verification studies for all methods and/or revisions to established methods? (If "No," list the test[s] for which verification data are missing.)	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Has the laboratory documented precision verification studies for all methods and/or revisions to established methods? (If "No," list the test[s] for which verification data are missing.)**	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Has the laboratory documented diagnostic/clinical sensitivity verification studies for all methods and/or revisions to established methods? (If "No," list the test[s] for which verification data are missing.)**	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Has the laboratory documented diagnostic/clinical specificity verification studies for all methods and/or revisions to established methods? (If "No," list the test[s] for which verification data are missing.)**	Yes ☐ No ☐ Comments ☐

Comments:

VI. Laboratory Information Systems (LIS)

A.	**Is an LIS utilized in this laboratory? (If "No," skip to Section VII.)**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**LIS**	
1.	Are documented validation data present for the LIS?	Yes ☐ No ☐ Comments ☐
2.	Can accurate and complete copies be generated by the LIS?	Yes ☐ No ☐ Comments ☐
3.	Are computer time-stamped audit trails used by the LIS?	Yes ☐ No ☐ Comments ☐
4.	Is system access limited to authorized individuals?	Yes ☐ No ☐ Comments ☐
5.	Is there a written SOP for the operation of the LIS?	Yes ☐ No ☐ Comments ☐
6.	Is there a backup system for the LIS? (If "Yes," describe how data are stored.)	Yes ☐ No ☐ Comments ☐
7.	Is there a documented procedure that is followed in the event of LIS downtime?	Yes ☐ No ☐ Comments ☐
8.	Where applicable, is there ongoing validation of interface systems? (If yes, specify frequency.)	Yes ☐ No ☐ Comments ☐

9.	Are measures in place to ensure secure and confidential storage and transfer of participant data, including (if applicable) written procedures addressing data transfer?	Yes ☐ No ☐ Comments ☐
10.	Are calculated values reported with participant results reviewed every two years or when a system change is made that may affect the calculations?	Yes ☐ No ☐ Comments ☐

Comments:

VII. Laboratory Data Management System (LDMS)

A.	**Does this laboratory facility contain an LDMS? (If "Yes," provide the LDMS ID in the Comments Section; If "No," disregard the rest of Section VII and explain how specimen storage/shipping data are maintained.)**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**LDMS Reports Verified by the Auditor**	
1.	Primary Specimens Received Report	Yes ☐ No ☐ Comments ☐
2.	Storage Detail Report	Yes ☐ No ☐ Comments ☐
3.	Shipped Specimen Report–Detail	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Specimen Verification**	
1.	Can the participant identification (PID), date, protocol, derivative, and additive for specimens be verified with the LDMS?	Yes ☐ No ☐ Comments ☐
2.	Does the LDMS accurately reflect the number, type, and volume of all specimen aliquots as well as their storage location and shipping record?	Yes ☐ No ☐ Comments ☐
3.	Can the physical presence of specimens be verified with the LDMS Storage Detail Report?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Is the current LDMS manual available in the laboratory?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**LDMS Backup**	
1.	Is the LDMS backed up daily?	Yes ☐ No ☐ Comments ☐
2.	Is the LDMS backup device stored in a different location than the LDMS computer?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Is the LDMS connected to a backup power source?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Do laboratory SOPs include implementation and compliance with DAIDS-network mandates regarding LDMS usage?**	Yes ☐ No ☐ Comments ☐

Comments:

VIII. Quality Management

A.	**Quality Assurance**	
1.	Does the laboratory have a quality assurance/quality management program? (If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2.	Does the program include a documented operational plan to promptly record and investigate, correct (as appropriate), and trend nonconformities or other problems identified in in pre-analytic, analytic, post-analytic, and general laboratory systems?	Yes ☐ No ☐ Comments ☐
3.	Are key indicators of quality monitored and evaluated to detect problems and opportunities for improvement? (If "Yes," list the indicators.)	Yes ☐ No ☐ Comments ☐
4.	Are appropriate corrective actions and/or preventive actions (CAPAs) taken when opportunities for improvement are identified?	Yes ☐ No ☐ Comments ☐
5.	Is there evidence that CAPAs are monitored through resolution?	Yes ☐ No ☐ Comments ☐
6.	Is quality management documentation surrounding key indicators of quality and CAPAs reviewed by the laboratory management? (If "Yes," indicate the frequency.)	Yes ☐ No ☐ Comments ☐
7.	Does the laboratory have an internal auditing program?	Yes ☐ No ☐ Comments ☐

Comments:

B.	QC by Monitoring Consistency of Specimen Processing and Isolation of Mycobacteria	
1.	Does the laboratory periodically monitor the following parameters to ensure that processing and handling of cultures are consistent and within the normal limits established for the laboratory?	
	a. Total specimens processed	Yes ☐ No ☐ Comments ☐
	b. Total and percent AFB smear-positive and smear-negative	Yes ☐ No ☐ Comments ☐
	c. Total and percent AFB culture-positive from smear-negative and smear-positive specimens	Yes ☐ No ☐ Comments ☐
	d. Total and percent positive cultures belonging to the mycobacteria tuberculosis complex and nontuberculous mycobacteria	Yes ☐ No ☐ Comments ☐
	e. Average time to detection for AFB-positive cultures	Yes ☐ No ☐ Comments ☐
	f. Bacterial contamination rate (If "Yes," specify the acceptable rate of contamination.)	Yes ☐ No ☐ Comments ☐
	g. Records of personnel who processed specimens	Yes ☐ No ☐ Comments ☐
	h. Records of all specimens processed in a batch	Yes ☐ No ☐ Comments ☐
2.	Are procedures reviewed if a significant change or deviation is noted in the parameters above?	Yes ☐ No ☐ Comments ☐

Comments:

IX. Physical Facilities

1.	Is there a documented policy/procedure in place for access control into the laboratory?	Yes ☐ No ☐ Comments ☐
2.	Are the ventilation (and humidity, where applicable,) adequately controlled in all areas?	Yes ☐ No ☐ Comments ☐
3.	Are ambient room temperature readings (and humidity, where applicable) taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
4.	Have tolerance limits been established and documented for ambient room temperature (and humidity, where applicable)? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
5.	Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐
6.	Is there adequate, conveniently located space so the quality of work and safety of personnel are not compromised?	Yes ☐ No ☐ Comments ☐
7.	Is there adequate space for records and specimen storage?	Yes ☐ No ☐ Comments ☐

Comments:

X. Equipment

A. Is all equipment used for protocol-related laboratory activities listed on an inventory document?	Yes ☐ No ☐ Comments ☐

Comments:

B. Is all out-of-service/not-in-use equipment clearly identified as such?	Yes ☐ No ☐ Comments ☐

Comments:

C. Are there documented Preventive Maintenance (PM) and calibration plans for laboratory equipment indicated?	Yes ☐ No ☐ Comments ☐

Comments:

D. Has any DAIDS-related equipment been replaced, added, or removed since the last audit? (If "Yes," list the equipment.)	Yes ☐ No ☐ Comments ☐

Comments:

E. Laboratory Equipment

Verify the following as it applies to equipment used for study-specific laboratory activities: (List the manufacturer and model of the equipment, where applicable.)

1. Are freezers present? (If "No," skip to Question 2.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for temperature readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

2. Are refrigerators present? (If “No,” skip to Question 3.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐

b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings taken and documented? (If “Yes,” report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for temperature readings? (If “Yes,” list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

3. Are incubators present? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings and CO_2 levels (if applicable) taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for temperature readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

4. Are centrifuges present? (If "No," skip to Question 5.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Is calibration of speed, time, and temperature performed and documented for each centrifuge? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Are additional containment accessories such as safety buckets or containment rotors used with the centrifuge?	Yes ☐ No ☐ Comments ☐

Comments:

5. Are biosafety cabinets/hoods present? (If "No," skip to Question 6.)	Yes ☐ No ☐ Comments ☐
a. Does the biologic safety cabinet meet minimum requirements for mycobacteriology work? [*NOTE: Exhaust air from a Class I or Class II biological safety cabinet must be filtered through HEPA filters. Air from Class I and IIB cabinets should be hard-ducted to the outside. Air from Class IIA cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every 12 months.*]	Yes ☐ No ☐ Comments ☐

b. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
c. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
d. Has each cabinet/hood been certified? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
e. Are pressure or air flow rate readings documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
f. Have tolerance limits been established and documented for pressure or air flow readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐

Comments:

6. Is an automated mycobacterial detection system present? (If “No,” skip to Question 7.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are temperature readings monitored? (If ‘Yes’ report the frequency)	Yes ☐ No ☐ Comments ☐
c. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐

Comments:

7. Is PCR/molecular testing equipment present? (If "No," skip to Question 8.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

8. Are slide warmers present? (If “No,” skip to Question 9.)	Yes ☐ No ☐ Comments ☐
a. Is temperature verified and documented when in use?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed as required by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

9.	Are autoclaves present? (If "No," skip to Question 10.)	Yes ☐ No ☐ Comments ☐
a.	Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b.	Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c.	Are calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
d.	Are checks to verify effective autoclave sterilization, including use of heat-sensitive tape and biological indicators, performed and documented? (If yes, indicate the frequency).	Yes ☐ No ☐ Comments ☐

Comments:

10.	Are pipettors present? (If “No,” skip to Question 11.)	Yes ☐ No ☐ Comments ☐
a.	Are calibration/verification procedures performed for all pipettors? (If “Yes,” report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

11.	Are thermometers present? (If "No," skip to Question 12.)	Yes ☐ No ☐ Comments ☐
a.	Is a known standard thermometric device available (e.g., NIST certified)?	Yes ☐ No ☐ Comments ☐
b.	Have all non-certified thermometers been tested against a standard device? (If "Yes," describe the procedure performed.)	Yes ☐ No ☐ Comments ☐

Comments:

12.	Are balances present? (If "No," skip to Question 13.)	Yes ☐ No ☐ Comments ☐
a.	Are accuracy checks performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
b.	Are service and calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

13.	Are microscopes present? (If "No," skip to Question 14.)	Yes ☐ No ☐ Comments ☐
a.	Are daily and annual PM activities/services performed and documented?	Yes ☐ No ☐ Comments ☐
b.	If fluorescent microscopes are used for identification of AFB, does the laboratory record halogen lamp usage and replace the lamp prior to the end of life span as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

14.	Are timers present? (If "No," skip to Question 15.)	Yes ☐ No ☐ Comments ☐
	a. Are calibration procedures performed and documented?	Yes ☐ No ☐ Comments ☐

Comments:

15.	Are additional equipment used for protocol-related assays present? (If "Yes," report on PM and calibration activities where applicable.)	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Temperature Monitoring**	
1.	Is there a written policy/procedure in place, explaining how temperatures are monitored during the absence of laboratory personnel?	Yes ☐ No ☐ Comments ☐
2.	Is a computerized alarm system with setpoint temperature ranges utilized for continuous monitoring of temperature-sensitive equipment and ambient room temperature? (If "Yes," report the frequency of alarm testing; if “No,” specify the system used for continuous temperature monitoring.)	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Is there an SOP in place that describes backup power resources? (If yes, specify how backup power equipment is maintained, e.g., logs or SOPs that detail the frequency of maintenance).**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are maintenance, repair, and calibration records reviewed and signed monthly by laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

XI. Test and Control

A. Qualitative Tests

Name of Test	QC Material Type	QC Frequency

1.	Is there a written Quality Control (QC) program that clearly defines procedures for monitoring analytic performance, including the number and frequency of control tests, corrective action based on QC data, and related information?	Yes ☐ No ☐ Comments ☐
2.	Are records present documenting control results assayed with each test as described in the specific assay procedure? (If no QC records are present, skip to Question 4.)	Yes ☐ No ☐ Comments ☐
3.	Does the technologist performing the QC initial the records?	Yes ☐ No ☐ Comments ☐
4.	Has laboratory management reviewed and signed all QC records? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
5.	Are QC records available for the past 2 years and retrievable within 24 hours?	Yes ☐ No ☐ Comments ☐
6.	For qualitative assays, is a positive and negative control tested?	Yes ☐ No ☐ Comments ☐

Comments:

B.	**QC Failure/Corrective Action**	
1.	Is there documentation of corrective actions taken in response to QC failures? (If "No," skip to Section C.)	Yes ☐ No ☐ Comments ☐
2.	Has laboratory management reviewed and signed the records for QC failures? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Staining QC**	
1.	Is a known positive and negative smear processed and examined whenever new stains are introduced?	Yes ☐ No ☐ Comments ☐
2.	Is a staining QC log present? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
3.	Is a Corrective Action Log present for staining QC?	Yes ☐ No ☐ Comments ☐
4.	Are logs reviewed and signed by the laboratory management monthly?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Media QC**	
1.	Is laboratory-prepared and/or commercially acquired media in use?	Yes ☐ No ☐ Comments ☐
2.	Is each lot/batch of media quality controlled before use? (If "Yes," describe the QC procedure.)	Yes ☐ No ☐ Comments ☐
3.	Is a media QC log present?	Yes ☐ No ☐ Comments ☐
4.	Is a corrective action log present for media QC?	Yes ☐ No ☐ Comments ☐

5.	Are logs reviewed and signed by the laboratory management monthly?	Yes ☐ No ☐ Comments ☐
6.	Is adequate labelling information of media available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Mycobacterial QC Strains**	
1.	Are ATCC strains or equivalent used for QC?	Yes ☐ No ☐ Comments ☐
2.	Has the laboratory established and documented criteria for optimal growth, storage, and maintenance to ensure the viability of all microbial strains used in QC?	Yes ☐ No ☐ Comments ☐
3.	Is adequate labelling information of microbial strains available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Reagent/Testing Kits/Solutions**	
1.	Are all reagent/testing kits/solutions dated within the manufacturer's assigned expiration dates?	Yes ☐ No ☐ Comments ☐
2.	Are all reagents/testing kits/solutions properly stored as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
3.	Is adequate labelling information of reagents/testing kits/solutions available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

G.	**AFB Microscopy**	
1.	Is there a standardized method for reporting the average number of AFB observed microscopically in clinical specimens? (If "Yes," describe the method used.)	Yes ☐ No ☐ Comments ☐
2.	Is there periodic comparison of AFB microscopic observations between personnel to ensure accuracy and reproducibility in reporting results?	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Water Quality**	
1.	Does the laboratory require specific water types for certain testing procedures? (If "Yes," describe. If "No," skip to Section I.)	Yes ☐ No ☐ Comments ☐
2.	Is there a documented policy that defines standards and frequency of water testing? (If "Yes," include the testing performed.)	Yes ☐ No ☐ Comments ☐
3.	Are Certificates of Analysis maintained for commercially bottled purified water?	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Is there an established, documented inventory control system in operation for laboratory reagents and supplies?**	Yes ☐ No ☐ Comments ☐

Comments:

XII. Records and Reports

A.	**Are copies of network laboratory-specific manuals, protocols, and appendices available and retrievable within 24 hours?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Specimen Tracking Forms/Requisitions**	
1.	Are forms readily available and retrievable within 24 hours?	Yes ☐ No ☐ Comments ☐
2.	Are the forms retrievable for the entire protocol? (If "Yes," explain how archiving is accomplished and provide the retention time[s].)	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Is specimen chain of custody adequately documented?**	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Do the laboratory reports identify the laboratory performing the testing?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Is there a written policy/procedure that addresses the revision of laboratory reports?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Is a log or other appropriate record of result modifications reviewed at least monthly by laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Does the laboratory archive result data (result printouts, electronic records, etc.), QC records, package inserts, and Certificates of Analysis? (If "Yes," explain how archiving is accomplished and the duration in which data are archived. If "No," skip to Question H.)**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are the archived records accessible only to authorized personnel?**	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Are records protected from flood and fire?**	Yes ☐ No ☐ Comments ☐

Comments:

J.	**Are there established qualifications for staff assigned to releasing testing results? (If "Yes," verify the qualifications for at least one personnel releasing results in each laboratory area.)**	Yes ☐ No ☐ Comments ☐

Comments:

XIII. Specimen Transport and Management

A.	**Are there documented guidelines for specimen collection in the laboratory and areas dedicated for specimen collection?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Is there a documented policy/procedure for identifying and assessing the quality of specimens received in the laboratory?**	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Are specimen rejection criteria established? (If "Yes," describe how the specimen rejection is communicated to the clinic personnel.)**	Yes ☐ No ☐ Comments ☐

Comments:

D.	Specimen Transport	
1.	Is there a documented policy/procedure in place for transporting samples (e.g., transported in a sturdy, non-breakable, closable container labeled with the international symbol for biohazard)?	Yes ☐ No ☐ Comments ☐
2.	Is there a documented policy/procedure available addressing transportation within the facility?	Yes ☐ No ☐ Comments ☐
3.	Is there a documented policy/procedure available addressing transportation between off-site clinics and the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Are all fixed/stained specimen smears retained for potential re-evaluation until patient results are finalized and reported?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	Shipping/IATA Certification/Training	
1.	Is there a training plan in place for shipping certification?	Yes ☐ No ☐ Comments ☐
2.	Is there documentation of persons trained for shipping?	Yes ☐ No ☐ Comments ☐
3.	Are shipping certifications renewed every 2 years?	Yes ☐ No ☐ Comments ☐
4.	Is there a policy in place for shipping samples internationally?	Yes ☐ No ☐ Comments ☐

Comments:

XIV. Vertical Audit of SOP/Practice

Title of SOP	Procedure Observed	Person Observed

A.	Personnel Training and Competency Verification	
1.	Are training and competency evaluations documented for the personnel performing the test?	Yes ☐ No ☐ Comments ☐
2.	Is SOP user knowledge documented?	Yes ☐ No ☐ Comments ☐

Comments:

B.	Pre-Test Specimen Handling	
1.	Are specimens submitted for testing as required by the SOP?	Yes ☐ No ☐ Comments ☐

2.	Are specimens maintained at appropriate conditions (e.g., temperature) until testing can be performed?	Yes ☐ No ☐ Comments ☐
3.	Are all pre-testing specimen handling procedures performed per SOP?	Yes ☐ No ☐ Comments ☐
4.	Is PPE appropriately worn?	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Reagent Preparation and Storage**	
1.	Are reagents prepared in accordance with the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are reagents maintained at appropriate conditions until testing can be performed?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Test Set-Up**	
1.	Are tubes/plates pre-labeled prior to testing? (If "Yes," comment on how far in advance labeling occurs.)	Yes ☐ No ☐ Comments ☐
2.	Are tubes/plates labeled appropriately with sufficient identification to prevent mix-up?	Yes ☐ No ☐ Comments ☐
3.	Is appropriate equipment (e.g., pipettors or a vortex mixer) available at the start of the procedure to avoid delay?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Processing Phase**	
1.	Are appropriate conditions maintained to perform the assay (e.g., sterile, biohazard containment)?	Yes ☐ No ☐ Comments ☐
2.	Are reagents and samples added in the appropriate order and at appropriate times?	Yes ☐ No ☐ Comments ☐
3.	Are appropriate controls (i.e., positive and negative) available and tested?	Yes ☐ No ☐ Comments ☐
4.	Are QC samples tested in the same manner as test samples?	Yes ☐ No ☐ Comments ☐
5.	Is an incubation time required? (If "No," skip to Question 6.)	Yes ☐ No ☐ Comments ☐
	a. Is incubation performed appropriately?	Yes ☐ No ☐ Comments ☐
	b. Is incubation time documented?	Yes ☐ No ☐ Comments ☐
6.	Are additional steps followed as defined in the SOP?	Yes ☐ No ☐ Comments ☐
7.	Are samples maintained under appropriate conditions until analysis?	Yes ☐ No ☐ Comments ☐

WA##_Deliverable Date*_Lab Name_Audit Type_Lab_Audit_Report_Audit Start Date*
*date format=20YYMMDD

Comments:

F.	**Analysis Phase**	
1.	Is an analyzer required for this phase? (If "Yes," indicate the analyzer. If "No," skip to Question 2.)	Yes ☐ No ☐ Comments ☐
	a. Is the analyzer set up as required by the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are specimens analyzed by manual methods? (If "Yes," indicate the method. If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
3.	Are control results acceptable?	Yes ☐ No ☐ Comments ☐
4.	Are samples analyzed as defined in the SOP?	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Result Reporting**	
1.	Are results verified by alternate personnel?	Yes ☐ No ☐ Comments ☐
2.	Are results reported as defined in the SOP?	Yes ☐ No ☐ Comments ☐

Comments: