National Laboratory Accreditation Assessment
For Clinical and Public Health Laboratories

1.0 INTRODUCTION

Laboratory services are an essential component in the diagnosis and treatment of persons infected with the human immunodeficiency virus (HIV), malaria, mycobacterium tuberculosis (MTB), sexually transmitted infections, and other microbiological diseases. Presently, the laboratory infrastructure and quality assurance (for all types of clinical laboratories) remains weak in Ethiopia. There is therefore an urgent need to strengthen laboratory services and systems. The establishment of national accreditation schemes will help countries to improve and strengthen the capacity of laboratories and to demonstrate technical competency as well as an ability to run a supporting quality system.

To strengthen laboratory systems of its member countries in a stepwise fashion, WHO-AFRO has established an accreditation scheme in accordance with its core functions of setting norms and standards and building institutional capacity. Accreditation provides documentation that the laboratory has the capability and the capacity to detect, identify, and promptly report all diseases of public health significance that may be present in clinical and research specimens. The national accreditation process further provides a learning opportunity, a pathway for continuous improvement, a mechanism for identifying resource and training needs, a measure of progress, and a link to the WHO-AFRO National Health Laboratory Service Networks.

2.0 Scope

This checklist specifies requirements for quality and competency aimed to develop and improve medical and health laboratory services to raise quality to uniform national standards using simple achievable WHO AFRO Accreditation.

The elements of this checklist are based on ISO standard 15189:2007(E) and, to a lesser extent, CLSI guideline GP26-A3.

3.0 Criteria for Accreditation

1. Test results are reported by the laboratory on at least 80% of specimens within turnaround time specified by WHO AFRO. Turnaround time to be interpreted as time from receipt of specimen in laboratory until results reported.
   This criterion must be met for all negative (uninfected) and positive (infected) specimens, including those that may need confirmatory testing according to WHO AFRO strategy used.

2. A sufficient number of tests are performed on a quarterly basis to maintain laboratory competency.
   The number of tests for each test type (e.g., HIV Serology, MTB Smear, etc.) required to meet this criterion will be determined by WHO AFRO.

3. Internal quality control (IQC) procedures are practiced for all testing methods used by the laboratory
   Ordinarily, each test kit has a set of positive and negative controls that are to be included in each test run. These controls included with the test kit are considered internal controls, while any other controls included in the run are referred to as external controls. QC data sheets and summaries of corrective action are retained for documentation and discussion with assessor.

4. The score on the two most recent WHO AFRO approved proficiency tests is 80% or better.
   Proficiency test (PT) results must be reported within 15 days of panel receipt to receive full credit. Unacceptable PT results must be addressed and corrective action taken. Laboratories that receive less than 80% on two consecutive PT challenges will lose their accreditation until such time that they are able to successfully demonstrate achievement of 80% or greater on two consecutive PT challenges.

   NOTE: A laboratory that has failed to demonstrate achievement of 80% or greater on the two most recent PT challenges will not be awarded any stars, regardless of the checklist score they received upon assessment.

5. Accreditation is provided in a 5 star tiered accreditation approach, based on an annual onsite assessment of laboratory operating procedures and practices.
   The inspection checklist score will correspond to the number of stars awarded to a laboratory in the following manner:

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 137 pts)	(138 – 160 pts)	(161 – 185 pts)	(186 – 211 pts)	(212 – 236 pts)	(237 – 250 pts)
< 55%	*55 – 64%*	65 – 74%	*75 – 84%*	*85 – 94%*	>95%

A laboratory that achieves less than the passing score on any one of the applicable criteria will work with the Regional Office Laboratory Coordinator to:

- Identify areas where improvement is needed.
- Develop and implement a work plan.
- Monitor laboratory progress.
- Provide for re-testing where required.
- Continue steps to achieve full accreditation.

4.0 Parts of the Assessment

This laboratory assessment consists of four parts.

Part I

Includes worksheets to determine and record laboratory performance for criteria 1-4 for the immediately preceding 12 months where data is complete. Selection of the most recent 12-month period, rather than the most recent calendar year as a basis for calculation, provides an assessment of current performance and permits inspection of laboratories at any time during the calendar year.

Part II

Provides a profile of the laboratory and serves to identify resource needs.

Part III

The assessment checklist contains for evaluation of laboratory operating procedures and practices for Criteria 5.

Part IV

Summarizes the findings of the accreditation assessment results

PART I: LABORATORY PERFORMANCE over PREVIOUS 12 MONTHS			
Date from:		Date to:	
Criteria 1	Are more than 80% of test results reported within the WHO-specified turnaround time (TAT)?	Number of Specimens tested	% reported within WHO specified TAT
1.1	HIV antibody Screening tests (e.g., EIA, rapid test) results reported within WHO AFRO specified TAT:		
1.2	HIV antibody Confirmatory tests (e.g., WB, IFA) results reported within WHO AFRO specified TAT:		
1.3	CD4 cell test results reported within WHO AFRO specified TAT		
1.4	Malaria-related specimens reported within WHO AFRO specified TAT:		
	Mycobacterium tuberculosis-related specimens reported within WHO AFRO specified TAT:		
1.5	Smear		
1.6	Culture		
1.7	Drug Susceptibility		
	1st Other disease of public health significance, please specify _____		
1.8	1st Other specimens reported within WHO AFRO specified TAT for this disease:		
	2nd Other disease of public health significance, please specify _____		
1.9	2nd Other specimens reported within WHO AFRO specified TAT for this disease:		
COMMENTS AND RECOMMENDATIONS:			

Criteria 2	Is a sufficient volume of testing conducted to maintain competency? Total Number of Specimens Tested (previous 12 months)	#
2.1	Specimens tested for HIV from: Diagnosis:	
2.2	Specimens tested for HIV from: Surveillance:	
2.3	Specimens tested for HIV from: Special surveys:	
2.4	Specimens tested for HIV from: Other, please specify _____:	
2.5	Specimens tested for CD4 count for: Diagnosis	
2.6	Specimens tested for CD4 count for: Monitoring	
2.7	Specimens tested for CD4 count for: Other, please specify _____:	
2.8	Specimens tested for malaria from: Diagnosis:	
2.9	Specimens tested for malaria from: Surveillance:	
2.10	Specimens tested for malaria from: Special surveys:	
2.11	Specimens tested for malaria from: Other, please specify _____:	
2.12	Specimens tested for MTB from: Diagnosis:	
2.13	Specimens tested for MTB from: Surveillance:	
2.14	Specimens tested for MTB from: Special surveys:	
2.15	Specimens tested for MTB from: Other, please specify _____:	
	Other disease of public health significance, please specify _____	
2.16	Other specimens tested from: Diagnosis:	
2.17	Other specimens tested from: Surveillance:	
2.18	Other specimens tested for from: Special surveys:	
2.19	Other specimens tested for from: Other, please specify _____:	
	Other disease of public health significance, please specify _____	
2.20	Other specimens tested from: Diagnosis:	
2.21	Other specimens tested from: Surveillance:	
2.22	Other specimens tested for from: Special surveys:	
2.23	Other specimens tested for from: Other, please specify _____:	

COMMENTS AND RECOMMENDATIONS:

Criteria 3	Is routine internal quality control procedures routinely conducted for all test methods?	Frequency *(e.g., Daily, Weekly, Monthly)*
3.1	Monitoring of control values	
3.2	Monitoring with internal standards	
3.3	Monitoring quality of each new batches of kits	
3.4	Documentation of internal controls and kits validation	
COMMENTS and RECOMMENDATIONS		

Criteria 4	Has the laboratory achieved acceptable PT results of at least 80% on the two most recent PT challenges? And were the results reported within 15 days?		Score (% correct)
	HIV		%
4.1	Date of HIV panel receipt:	/ /	
4.2	Date of HIV test report:	/ /	
	CD4 Count		
4.3	Date of CD4 panel receipt:	/ /	
4.4	Date of CD4 test report:	/ /	
	Malaria		%
4.5	Date of malaria panel receipt:	/ /	
4.6	Date of malaria test report:	/ /	
	Mycobacterium tuberculosis		%
4.7	Date of MTB PT panel for smear receipt:	/ /	
4.8	Date of MTB PT panel for smear report:	/ /	
4.9	Date of MTB PT panel for culture receipt:	/ /	
4.10	Date of MTB PT panel for culture report:	/ /	
4.11	Date of MTB PT panel for drug susceptibility receipt:	/ /	
4.12	Date of MTB PT panel for drug susceptibility report:	/ /	
	1st Other disease of public health significance, please specify _____		%
4.13	Date of 1st Other panel receipt:	/ /	
4.14	Date of 1st Other test report:	/ /	
	2nd Other disease of public health significance, please specify _____		%
4.15	Date of 2nd Other panel receipt:	/ /	
4.16	Date of 2nd Other test report:	/ /	

COMMENTS AND RECOMMENDATIONS:

PART III: LABORATORY PROFILE

Date of Assessment				Date of Last Assessment			
Current Accreditation Status	Not Assessed	0 Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
Name(s) and Affiliation(s) of Assessor(s)							
Laboratory Name						Laboratory Number	
Laboratory Address :							
Laboratory Telephone		Fax			Email		
Head of Laboratory			Telephone (Head of Lab)			Personal? Work?	

Laboratory Level (check those that apply)				Laboratory Affiliation (check those that apply)			
	National		Regional / Provincial		Public		Academic
	Zonal		District		Private		NGO/Religious Institution

Laboratory Staffing Summary

Profession	*Number of Full Time Equivalents (FTEs)*	*Adequate for facility operations?*
Laboratory Technologist (degree)		Yes No Insufficient Data
Laboratory Technician (diploma)		Yes No Insufficient Data
Laboratory Assistant (certificate)		Yes No Insufficient Data
Data Clerk		Yes No Insufficient Data
Phlebotomist		Yes No Insufficient Data
Cleaner		Yes No Insufficient Data
Is the cleaner(s) dedicated for only laboratory? Yes No		*Has the cleaner(s) been trained in safe waste handling?* Yes No
Driver		Yes No Insufficient Data
Is the driver(s) dedicated for only laboratory? Yes No		*Has the driver(s) been trained in biosafety?* Yes No
Other		Yes No Insufficient Data

If the laboratory has IT specialists, accountants or non-laboratory-trained management staff this can be indicated when describing the organizational structure on the following page.

Does the laboratory have sufficient space, equipment, supplies, personnel, infrastructure etc. to execute the correct performance of each test and maintain the quality management system?	YES	NO

Laboratory Profile, Cont.

Days and Hours of Service

Sun	Mon	Tuesday	Wednesday	Thursday	Friday	Saturday

Does the laboratory provide on-call services? If so, how are they organized?

List the tests run as part of the on-call services?

Referral Network

List the names and types of health facilities the laboratory currently serves.	List the name and type of laboratories to which the laboratory refers specimens.

Is a back-up laboratory formally designated for specimen referral in the event of instrument breakdown or power cutoff? If so, list the name of the back-up laboratory.

AVAILABLE LAB TESTS											
Test Type	Sample Type	Method and Instrument	Average # of tests/ month	Competency Assessments conducted in the last year?		Is instrument currently operable? (Y / N)		Is a service contract in place? (Y / N)		Is instrument overdue for service? (Y / N)	
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N

AVAILABLE LAB TESTS											
Test Type	Sample Type	Method and Instrument	Average # of tests/ month	Competency Assessments conducted in the last year?		Is instrument currently operable? (Y / N)		Is a service contract in place? (Y / N)		Is instrument overdue for service? (Y / N)	
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N
				Y	N	Y	N	Y	N	Y	N

SPECIMEN RECEIVING SCHEDULE

Consulting the laboratory logbooks, list the average number of specimens received each day per test over the last four weeks. Note any significant variations that occur monthly in the space below.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

REFERRAL TESTING (if applicable)

List the types of tests that are referred from this laboratory to another facility for testing. *ISO 15189: 4.5.3*

Test	Laboratory Referred to

ORGANIZATIONAL STRUCTURE and REPORTING AUTHORITY

Provide an organizational diagram (organogram) for the laboratory and the reporting structure for the laboratory (or attach).

LABORATORY FLOORPLAN & LAYOUT

Briefly sketch the general layout of the laboratory (or attach). Include designation of PCR testing suite and/or BSL-3 area, if applicable.

PART III: LABORATORY ASSESSMENT

Laboratory assessments are an effective means to determine whether a laboratory is providing accurate and reliable results and is well-managed and adhering to good laboratory practices.

Assessors will complete this assessment by utilizing the methods below to evaluate laboratory operations with regard to the checklist items.

- Review laboratory records to verify that the laboratory quality manual, policies, logs, SOPs and other manuals are complete, current, accurate, and regularly reviewed.

- Observe laboratory operations to ensure:
  - practice matches written policy or procedure in all phases of laboratory testing;
  - processes are appropriate for the testing performed;
  - identified problems have been adequately investigated and resolved.

- Ask open ended questions to clarify documentation seen and observations made. Ask questions like, "show me how…" or "tell me about…" It is often not necessary to ask all the checklist questions verbatim. An experienced assessor can often learn the answers to multiple checklist questions through open ended dialogue with the laboratory staff.

- Follow a specimen through the laboratory from collection through registration, preparation, aliquoting, analyzing, result verification, reporting, printing, and post-test handling and storage of samples to determine the strength of a laboratory's systems and operations.

- Confirm that each result or batch can be traced back to a corresponding IQC run and that the IQC was passed. Confirm that IQC results are recorded for all IQC runs and reviewed for validation.

- Confirm EQA results and whether the results are understood and corrective action taken as required.

- Talk to clinicians to learn the users' perspective on the laboratory's performance. Clinicians often are a good source of information regarding the quality and efficiency of the laboratory.

ASSESSMENT SCORING

This laboratory strengthening checklist contains 111 items worth 250 points. Each item has been awarded a point value of either 2, 3 or 5 points—based upon relative importance and/or complexity. Responses to all questions must be either, "yes", "partial", or "no".

- Items marked "*yes*" receive the corresponding point value (either 2, 3 or 5 points). All elements of a question must be present in order to indicate "yes" for a given item and thus award the corresponding points.

  NOTE: items that include "tick lists" must receive all "yes" and/or "n/a" responses to be marked "yes" for the overarching item.

- Items marked "*partial*" receive 1 point.

- Items marked "*no*" receive 0 points.

When marking "partial" or "no", notes should be captured in the comments field to assist the laboratory with addressing these areas of identified need.

Assessment Score Sheet

Section	*Total Points*	*Assessed Score*
Section 1: Documents & Records (11 items)	25	
Section 2: Management Reviews (3 items)	12	
Section 3: Organization & Personnel (7 items)	20	
Section 4: Client Management & Customer Service (1 item)	10	
Section 5: Equipment (14 items)	32	
Section 6: Internal Audit *(1 item)*	5	
Section 7: Purchasing & Inventory *(15 items)*	31	
Section 8: Information Management *(6 items)*	14	
Section 9: Process Control and Internal & External Quality Assessment *(17 items)*	43	
Section 10: Corrective Action *(4 items)*	8	
Section 11: Occurrence/Incident Management & Process Improvement *(3 items)*	10	
Section 12: Facilities and Safety *(23 items)*	40	
TOTAL SCORE	250	

0 Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 137 pts)	(138 – 160 pts)	(161 – 185 pts)	(186 – 211 pts)	(212 – 236 pts)	(237 – 250 pts)
< 55%	*55 – 64%*	65 – 74%	*75 – 84%*	*85 – 94%*	>95%

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
1.0 DOCUMENTS & RECORDS					
1.1 Is there a system or procedure for document & record control and retention?	Y	P	N		2
Standard: A document control system should be in place to ensure that records and all copies of policies/procedures are current, read by personnel, authorized by proper authorities, reviewed annually, and immediately prior versions filed separately as per national policy. Laboratories should maintain a document control log listing all current policies and procedures and their locations. *ISO 15189: 4.3.1*					
1.2 Are documents & records properly maintained (including an up-to-date Master List) and easily accessible?	Y	P	N		2
Standard: An up-to-date Master List that comprehensively details all laboratory documents, policies, and procedures should be readily accessible in either hard copy or electronic form. These should be retrievable within a timely manner. If documents and records are maintained in electronic form they should be backed up on CD or other media. *ISO 15189:4.3.1, 4.3.2*					
1.3 Are policies and standard operating procedures (SOPs) for laboratory functions current and available and approved by an authorized person?	Y	P	N		3
Policies and/or SOPs for:	Tick for each item				
	Yes	No	N/A		
Writing SOPs for laboratory procedures					
Each testing procedure performed (*including QC guidelines, acceptability, what to do if QC out of range)*					
Laboratory Safety (*including biohazard waste, chemical storage & handling & spills, blood borne pathogens, accidental exposure/needle sticks, fire)*					
Method / Equipment Validation					
Equipment Maintenance					
Document & Record Control					
Specimen Collection & Processing					
Specimen pre- and post-test Storage					
Inventory Control & Procurement					
Communication of Test Results, including confidentiality					
Evaluating, selecting, and monitoring the performance of referral laboratories and consultants					
Quality Assurance, including collection and keeping of quality records					
Resolution of complaints and other feedback from clinicians, patients, and other parties					
Policies and procedures to avoid conflicts of interest and commercial, financial, political or other pressures that might affect the quality and integrity of operations.					
Employee communication of concerns about test quality and laboratory safety					
Are SOPs reviewed and updated at least once a year?					

Are SOP changes documented and communicated to staff immediately?					
Standard: Standard Operating Procedures (SOPs) should be established and maintained up-to-date for all testing procedures within the laboratory, safety and waste disposal, document control, specimen collection and processing, inventory control, procurement, and quality assurance. SOPs should be reviewed for accuracy and relevance on an annual basis. All policies and procedures should be approved by an authorized person. *ISO 15189: 4.1.6, 4.2.1, 4.3.2, 4.8, 4.12, 4.12.1, 5.4.4*					
1.4 Are policies and SOPs easily accessible / available to all staff?	Y	P	N		2
Standard: SOPs should be available in the laboratory (hard or soft copy) and easily accessible to all staff. Testing SOPs should be available in hard copy at each bench.					
1.5 Is there documentation that all staff have read and understood the policies and SOPs that relate to their responsibilities in the laboratory?	Y	P	N		2
Standard: All staff must understand and implement the policies, processes, programs, procedures and instructions that pertain to their responsibilities and tasks within the laboratory. This may be reflected by a signatures page for each policy and SOP that indicates the staff members who have read the SOP and the date of their reading. ISO 15189: 4.1.6, 5.2.8					
1.6 Is there a current laboratory *quality manual* containing the quality management system's policies & procedures that is understood and implemented by all staff?	Y	P	N		3
Does the quality manual include the following elements?	Tick for each item				
	Yes	No	N/A		
Quality policy statement, including scope of service, standard of service, objectives of the quality management system, and management commitment to compliance.					
Description of the quality management system and the structure of its documentation.					
Reference to supporting procedures, including technical procedures.					
Describe the roles and responsibilities of the laboratory manager, quality manager, and other personnel to ensure compliance?					
Evidence of at least annual management review and approval.					
Standard: A quality manual should be available that summarizes the laboratory's quality program, includes policies that address all areas of the laboratory service, and identifies the goals and objectives of the quality program. The quality manual should include policies (processes and procedures) for all areas of the laboratory service and should address all of the quality system essentials (QSE). ISO 15189: 4.2.3, 4.2.4					
1.7 Is a laboratory *safety manual* available, accessible, and up-to-date?	Y	P	N		3
Does the safety manual include guidelines on the following topics?	Tick for each item				
	Yes	No	N/A		
Blood and Body Fluid Precautions					
Hazardous Waste Disposal					
Hazardous Chemicals / Materials					
MSDS Sheets					
Personal protective equipment					
Vaccination					
Post-Exposure Prophylaxis					
Fire Safety					
Electrical safety					
Biosafety level guides					
Universal safety precautions					
1.8 Are procedures dated when put into use and when discontinued?	Y	P	N		2
Standard: The document control log should capture the date the policy/procedure went into service, schedule of review, the identity of the reviewers, and the date of discontinuation. *ISO 15189: 4.3.1, 4.3.2*					
1.9 Are invalid or discontinued policies and procedures removed from use and retained	Y	P	N		2

according to schedule?					
Standard: Discontinued policies/procedures should be retained in a separate file for the period of time required by laboratory and or national policy. *ISO 15189: 4.3.1, 4.3.2*					
1.10 Are results and technical and quality records archived in accordance with national guidelines?	Y	P	N		2
Standard: Testing results and technical and quality records should be archived according to national guidelines and laboratory procedures. *ISO 15189: 4.13.1, 4.13.2, 4.13.3*					
1.11 Are archived records and results retrievable in a timely fashion?	Y	P	N		2
Standard: Archived patient results must be easily, readily, and completely retrievable within a time frame consistent with patient care needs. *ISO 15189: 5.8.6*					
SECTION 1: DOCUMENTS & RECORDS Subtotal					25

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
2.0 MANAGEMENT REVIEWS					
2.1 Is a workplan and budget in place for the laboratory that supports the laboratory's testing operations and maintenance of the quality system?	Y	P	N		2
Standard: Laboratories should be involved in the development of the workplan and budget for their activities. The workplan should reflect the findings of management reviews in its goals, objectives, and actions. Not all labs will have budgetary authority as higher levels of management may have direct control for budget making. If the laboratory does not develop these guiding documents itself, it must communicate with upper management effectively about these areas, including providing a forecast of needs.					
2.2 Does the laboratory supervisor routinely perform a documented review of all quality records?	Y	P	N		5
Are the following included in management review?	Tick for each item				
	Yes	No	N/A		
Follow-up of action items from previous management reviews					
Changes in volume, type of work the laboratory undertakes, suitability of reference intervals and client handbook					
Environmental monitoring logsheets					
Specimen rejection logbook					
Equipment calibration and maintenance records					
IQC records across all test areas					
EQA results					
Turnaround Time					
Quality indicators and internal audit results					
Results of assessment(s) by external bodies					
Customer Complaints and Feedback					
Reports from managerial and supervisory personnel					
Occurrence/incidence logs and corrective action reports					
Results of improvement projects					
Operational procedures (for potential sources of non-conformance and opportunities for improvement)					
Evaluation of referral laboratories					
Evaluation of suppliers					
Quality Management System (at least once a year)					
Documentation of review and action planning with staff for resolution and follow-up review					

Standard: There must be documentation that the head of laboratory or a designee reviews the quality program regularly. The review must ensure that recurrent problems have been addressed, and that new or redesigned activities have been evaluated. *ISO 15189: 4.1.5, 4.15.1,4.15.2, 4.15.3, 4.15.4*					
2.3 Does the laboratory identify and undertake quality improvement projects?	Y	P	N		3
Standard: Action plans for improvement should be developed, documented, and implemented in response to management review, internal audits, and routine review of quality indicators and occurrence/incident logs. Management should evaluate the effectiveness of actions taken to ensure needed changes are implemented. *ISO 15189:4.12.1, 4.12.2, 4.12.3. 4.12.4, 4.12.5.*					
2.4 Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?	Y	P	N		2
Standard:					
SECTION 2: MANAGEMENT REVIEW Subtotal					12

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
3.0 ORGANIZATION & PERSONNEL					
3.1 Do work schedules show task assignments & coordination of work among lab staff?	Y	P	N		2
Standard: Work schedules and tasks should be prioritized, organized, and coordinated based upon personnel skill level, workloads, and the task completion timeframe?					
3.2 Are daily routine work tasks established, assigned (duty roster or workstation assignments) monitored and supervised by qualified professional staff?	Y	P	N		2
Standard: Daily routines should be prioritized, organized and coordinated to achieve optimal service delivery for patients. Staff should be properly supervised and mentored by experienced and qualified staff.					
3.3 Are lines of authority and responsibility clearly defined for all lab staff, including the designation of a supervisor and deputies for all key functions?	Y	P	N		2
Standard: An up-to-date organizational chart and/or narrative description should be available detailing the external and internal reporting relationships for laboratory personnel. ISO 15189: 5.1.1, 4.1.5j					
3.4 Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality management system?	Y	P	N		3
Standard: A quality manager (however named) with authority for overseeing the quality management system should be in place. This quality manager should report directly to the level of laboratory management at which decisions are made on laboratory policy and resources. ISO 15189: 4.1.5i					
3.5 Are Personnel Files present?	Y	P	N		3
If files are present, do they document the following:	Tick for each item: Yes	No	N/A		
Employee Orientation					
Education & Training (e.g., degrees/certificates)					
Written job description, with documentation that staff member received a copy of their job description					
Letter of employment or appointment					
Review of job-relevant SOPs					
Documented review of safety manual, evidence of safety training					
Review of procedure for employees to communicate concerns about test quality and laboratory safety					
Registration with professional board					
Training record documenting trainings received, including vendor training received on-site					
Periodic Performance Review – including Observation, Competency Assessment, Coaching / Feedback, on-the-job training					
Documentation of employee recognition (i.e., employee of the month, letter of commendation, etc.)					

Human Resource (HR) Data – (vaccination status, injuries, accident history, etc.)					
Standard: Personnel files should be maintained for all current staff. Documentation should include job description, qualifications, training, experience, SOP review, competency assessment records, periodic performance review records, and records of vaccination, injuries, or workplace accidents. *ISO 15189: 5.1.2*					
3.6 Is there a system for competency assessment of staff (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated?	Y	P	N		3
Standard: Newly hired lab staff should be assessed for competency before performing independent duties and again within six months. All lab staff should be regularly assessed for testing competency at least once a year. Staff assigned to a new section should be assessed before fully assuming independent duties. When deficiencies are noted, retraining and reassessment should be planned and documented. If the employee's competency remains below standard, further action might include supervisory review of work, re-assignment of duties, or other appropriate actions. Records of competency assessments and resulting actions should be retained in personnel files and/or quality records. Records should show which skills were assessed, how those skills were measured, and who performed the assessment.					
3.7 Does the laboratory have adequate training policies, procedures, and/or training plan, including cross training within the laboratory team, one-on-one mentoring, and/or off-site external training?	Y	P	N		2
Standard: In line with national laboratory training plans, each laboratory should have functional training policies and procedures that meet the needs of laboratory personnel through both internal and external training. ISO 15189: 4.12.5, 5.1.6, 5.1.9					
3.8 Are staff meetings held regularly?	Y	P	N		3
Do meetings include the following items:	Tick for each item				
	Yes	No	N/A		
Are problems and complaints discussed?					
Are SOPs routinely reviewed?					
Are systemic and or recurrent problems and issues addressed including actions to prevent recurrence?					
Are results reviewed of prior corrective actions?					
Are improvement topics/projects discussed and evaluated?					
Are employees recognized for exemplary performance (i.e., employee of the month, letter of commendation, etc.)?					
Are reports and updates relayed from lab attendance at meetings with clinicians regarding the use of lab services and/or attendance at clinical rounds?					
Are meeting notes recorded and monitored for progress on issues?					
Standard: The laboratory should hold regular staff meetings to ensure communication within the laboratory. Meetings should have recorded notes to facilitate review of progress over time. ISO 15189: 4.1.6, 5.2.8					
SECTION 3: ORGANIZATION & PERSONNEL Subtotal					20

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
4.0 CLIENT MANAGEMENT & CUSTOMER SERVICE					
4.1 Do staff with appropriate professional qualifications provide clients with advice and/or training regarding required types of samples, choice of examinations, repeat frequency, and interpretation of results?	Y	P	N		2
Standard: Professionally qualified staff should provide advice on sample type, examination choice, frequency and results interpretation. ISO 15189:4.7.1; 4.12.5					
4.2 Is there a laboratory handbook for clinicians' use that includes information on services offered, quality assurance, laboratory operations, and sample collection and transport, agreed turnaround times, etc.?	Y	P	N		2
Standard: The laboratory should provide its clients with a handbook that outlines the laboratory's hours of operation, available tests, specimen collection instructions, packaging and shipping directions, and expected turnaround times. ISO 15189: 4.7, 4.12.5, 5.5.6					
4.3 Is timely written notification provided to clients when the laboratory finds it necessary to change the examination procedures?	Y	P	N		2
Standard: Written notice should be provided to clients in the event that it is necessary to change examination procedures. If the specimen necessary for testing will be different new collection procedures should be included. The client handbook should be updated accordingly. ISO 15189: 4.4.4					
4.4 Are collaborative laboratory and patient care improvement projects implemented between organizations, work groups, or relevant professions?	Y	P	N		2
Standard:					
4.5 Is there a tool for regularly evaluating client satisfaction and is feedback utilized to improve services?	Y	P	N		2
Standard: The laboratory should measure the satisfaction of client clinicians and patients regarding its services, either on an ongoing basis or through episodic solicitations. ISO 15189: 4.8, 4.15.2					
SECTION 4: CLIENT MANAGEMENT & CUSTOMER SERVICE Subtotal					10

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
5.0 EQUIPMENT					
5.1 Is equipment installed and placed as specified in the operators' manuals and uniquely labeled or marked?	Y	P	N		2
Standard: ISO 15189: 5.3.3					
5.2 Are newly introduced equipment and methods validated on-site and are records documenting validation available?	Y	P	N		2
Standard: Newly introduced methods or equipment should be validated onsite to ensure that their introduction yields performance equal to or better than the previous method or equipment. Validation may be done versus the method or equipment being replaced or the prevailing gold-standard. An SOP should be in place to guide method validation.					
5.3 Is current equipment inventory data available on all equipment in the laboratory?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Name of equipment					
Manufacturer					
Condition received (new, used, reconditioned)					
Serial number					
Date of purchase					
Date of entry into service					
Standard: ISO 15189: 5.3.4					
5.4 Is relevant equipment service information readily available in the laboratory?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Service contract information					
Contact details for service provider					
Performance and maintenance records					
Last date of service					
Next date of service					
Current location					
Standard: Maintenance records must be maintained for each item of equipment used in the performance of examinations. ISO 15189: 5.3.4					
5.5 Is non-functioning equipment removed from the laboratory and storage area?	Y	P	N		2
Standard: ISO 15189: 5.3.7					
5.6 Is routine calibration of laboratory equipment – including pipettes, centrifuges, balances, and thermometers – scheduled, indicated on the equipment, and verified?	Y	P	N		2
Standard: A comprehensive calibration program should be in place that routinely provides for the calibration of all relevant laboratory equipment. ISO 15189: 4.2.5, 5.3.2, 5.3.9					

5.7 Is routine preventive maintenance performed on all equipment and recorded according to SOPs?	Y	P	N		2
Standard: ISO 15189: 4.2.5, 5.3.2					
5.8 Is equipment routinely serviced according to schedule and documented in appropriate logs?	Y	P	N		2
Standard: ISO 15189: 4.2.5, 5.3.2					
5.9 Is stock of expendable parts present on site?	Y	P	N		2
Standard:					
5.10 Is equipment malfunction resolved by cause analysis and performing corrective action or issuing a repair order?	Y	P	N		2
Standard: ISO 15189: 5.3.7, 4.9					
5.11 Are repair orders monitored to determine if the service is completed?	Y	P	N		2
Standard: ISO 15189: 5.3.10					
5.12 Are there back-up procedures for equipment failure (including SOPs for handling specimens during these times, identification of a back-up lab for testing, and referral procedures)?	Y	P	N		2
Standard: Contingency plans must be in place, in the event of equipment failure, for the completion of testing. In the event of a testing disruption, planning may include the use of a back-up instrument, the use of a different testing method, the referral of samples to another laboratory, or the freezing of samples until testing is reestablished.					
5.13 Is all equipment checked and documented as properly functioning before being put back into use after being out of control of the laboratory?	Y	P	N		2
Standard: All equipment should receive thorough documented checks to ensure proper functioning before being returned into service, following its absence from the laboratory. ISO 15189:5.3.10					
5.14 Are the equipment manufacturer's operator manuals readily available to testing staff?	Y	P	N		2
Standard: ISO 15189: 5.3.5					
5.15 Are equipment specifications and maintenance needs routinely communicated to upper management?	Y	P	N		2
Standard: ISO 15189: 4.6.1					
5.16 Has the laboratory provided uninterrupted testing services, *with no disruptions due to equipment failure in the last year (or since the last assessment)?*	Y	P	N		2
Standard:					
SECTION 5: EQUIPMENT Subtotal					32

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
6.0 INTERNAL AUDIT					
6.1 Are internal audits addressing areas important to patient care routinely conducted at the intervals defined in the quality manual?	Y	P	N		5
	Tick for each item				
	Yes	No	N/A		
Are internal audits conducted by the head of lab, quality officer, or designated qualified personnel?					
Are the personnel who conduct internal audits trained and competent in auditing?					
Is care taken to ensure that auditing staff do not audit their own activities?					
Is cause analysis performed for non conformities/noted deficiencies?					
Are internal audit findings documented and presented to the laboratory team.					
Are blinded characterized samples routinely distributed for testing to determine accuracy?					
Are recommendations and/or corrective actions prescribed and an action plan developed with clear timelines?					
Is there documented follow-up of recommendations/corrective actions?					

***Standard:** Internal audits should be conducted at least annually. Investigation of individual problems may not reveal trends or patterns. Errors and incident reports should be reviewed periodically to determine whether systemic problems are responsible for errors and/or incidents.*
ISO 15189: 4.2.4, 4.10.3, 4.14

SECTION 6: INTERNAL AUDIT Subtotal	5

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
7.0 PURCHASING & INVENTORY					
7.1 Is there a system for accurately forecasting needs for supplies and reagents?	Y	P	N		2
Standard:					
7.2 Are supply & reagent specifications periodically reviewed and approved suppliers identified?	Y	P	N		2
Standard: ISO 15189: 4.6.1					
7.3 Is a list available with complete contact information for approved manufacturers/suppliers?	Y	P	N		2
Standard: Each laboratory should keep a comprehensive and up-to-date list of manufacturers/suppliers that includes full contact details to expedite ordering, tracking, and follow-up. ISO 15189: 4.6.4					
7.4 Are budgetary projections based on personnel, test, facility and equipment needs, and quality assurance procedures and materials?	Y	P	N		2
Standard: ISO 15189: 5.1.4.i					
7.5 Does management review supply request forms?	Y	P	N		2
7.6 Are all orders tracked until delivery and inspected, receipted, and labeled with date of receipt when checked in?	Y	P	N		2
Standard: All incoming orders should be inspected for condition and completeness, receipted and documented appropriately and the date received in the laboratory and the expiry date for the product should be clearly indicated. ISO 15189: 4.6.1					
7.7 Is an inventory control system in place?	Y	P	N		3
Criteria and procedures for	Tick for each item: Yes	No	N/A		
Acceptance and rejection of consumables					
Recording of lot number, date of receipt, and date placed into service					
Storage of consumables					
Standard: ISO 15189: 4.6.1, 4.6.3 CAP GEN 61900					
7.8 Are inventory records complete and accurate, with minimum and maximum stock levels denoted?	Y	P	N		2
Standard: ISO 15189: 4.6.3					
7.9 Is the consumption rate monitored?	Y	P	N		2
Standard:					
7.10 Are stock counts routinely performed?	Y	P	N		2

Standard:					
7.11 Are storage areas set up and monitored appropriately?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Is the storage area well organized and free of clutter?					
Are there set places labeled for all inventory items?					
Are hazardous chemicals stored appropriately?					
Is adequate cold storage available?					
Is temperature monitoring conducted according to MSDS instruction?					
Is the ambient temperature monitored routinely?					
Is storage in direct sunlight avoided?					
Is the storage area adequately ventilated?					
Is the storage area clean and free of dust and pests?					
Standard: ICAP GEN 62000 & 62100					
7.12 Is First-Expiry-First-Out (FEFO) practiced?	Y	P	N		2
Standard: To minimize wastage from product expiry, inventory should be organized in line with the First-Expiry-First-Out (FEFO) principle. Place products that will expire first in front of products with a later expiry date and issue stock accordingly to ensure products in use are not past their expiry date. Remember that the order in which products are received is not necessarily the order in which they will expire.					
7.13 Are expired products disposed of properly?	Y	P	N		2
Standard: Expired products should be disposed of properly. If safe disposal is not available at the laboratory the manufacturer/supplier should take back the expired stock at the time of their next delivery.					
7.14 Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiry dates.	Y	P	N		2
Standard: All reagent and test kits in use, as well as those in stock, should be within the manufacturer-assigned expiry dates. Expired stock should not be entered into use and should be documented before disposal.					
7.15 Has the laboratory provided uninterrupted testing services, *with no disruptions due to stock outs in the last year (or since the last assessment).*	Y	P	N		2
Standard: Testing services should not be subject to interruption due to stock outs. Laboratories should pursue all options for borrowing stock from another laboratory or referring samples to another testing facility while the stock out is being addressed.					
SECTION 7: PURCHASING & INVENTORY Subtotal					31

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
8.0 INFORMATION MANAGEMENT					
8.1 Are test results legible, technically verified, and confirmed against patient identity?	Y	P	N		2
Standard: ISO 15189: 5.8.3					
8.2 Are testing personnel identified on the requisition and record?	Y	P	N		2
Standard:					
8.3 Are test results recorded in a logbook or electronic record in a timely fashion?	Y	P	N		2
Standard:					
8.4 Are test results traceable to the equipment used for testing?	Y	P	N		2
Standard: It is important that the laboratory has the ability to trace specimen results to a specific analytical system or method. Proficiency testing specimens would also fall under specimen results.					
8.5 Is there a system for reviewing for clerical errors?	Y	P	N		2
Standard: ISO 15189: 5.8.3					
8.6 Are archived results—paper or data-storage media—properly labeled and stored in a secure location accessible only to authorized personnel?	Y	P	N		2
Standard:					
8.7 Are there documented procedures for the prevention of the loss of test result data in the event of hardware/software failure or theft?	Y	P	N		2
Standard: The laboratory should have a procedure to protect essential data in the event of equipment failure and/or an unexpected destructive event. These procedures could include flood and fire safe storage of data, periodic backing up and storing of information, and off-site storage of backup data,					
SECTION 8: INFORMATION MANAGEMENT Subtotal					14

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
9.0 PROCESS CONTROL and INTERNAL & EXTERNAL QUALITY ASSESSMENT					
9.1 Are environmental checks / temperature logs complete, accurate, and regularly reviewed?	Y	P	N		2
Are the following environmental checks performed daily?	Tick for each item: Yes	No	N/A		
Room temperature					
Freezers					
Refrigerator					
Incubators					
Water Bath					
Standard:					
9.2 Have acceptable ranges been defined for all temperature dependent equipment with procedures that detail what to do when temperatures are out of range?	Y	P	N		2
***Standard:** Acceptable ranges should be defined for all temperature dependent equipment and procedures should be available with instruction as to what action(s) should be taken when temperatures are out of range.*					
9.3 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample collection?	Y	P	N		2
Standard: ISO 15189: 5.4.2					
9.4 Are adequate specimen collection and receiving procedures in place?	Y	P	N		3
	Tick for each item: Yes	No	N/A		
Are specimens labeled with time, date, patient ID, and collector's initials?					
Are all test requests accompanied by an acceptable and approved test requisition form?					
If not a 24 hour lab, is there a documented method for handling of specimens received after hours?					
Are all samples received or referred to a higher level laboratory accompanied by a sample delivery checklist or transmittal sheet?					
Are received specimens evaluated according to acceptance/rejection criteria?					
Are specimens logged appropriately upon receipt in the laboratory (including date, time, and name of receiving officer)?					
When samples are split, can the portions be traced back to the primary sample?					
Is a two-identifier system in use and is each sample assigned a unique identifying number?					
Are procedures in place to process "urgent" specimens and verbal requests?					
Are specimens delivered to the correct workstations in a timely manner?					
***Standard:** Pre-analytical procedures must be in place, disseminated and understood by all relevant staff, and followed by all personnel to ensure quality testing processes.* ISO 15189: 5.4.1, 5.4.5, 5.4.7, 5.4.8, 5.4.10, 5.4.11, 5.4.13					

9.5 Are specimens stored appropriately prior to and following testing and disposed of in a safe manner?	Y	P	N		2
Standard: Specimens should be stored under the appropriate conditions to maintain the stability of the specimen. Specimens no longer required should be disposed of in a safe manner, according to biosafety regulations. ISO 15189: 5.2.9, 5.4.14, 5.7.3					
9.6 Are specimens packaged appropriately and transported to referral laboratories within acceptable timeframes?	Y	P	N		2
Standard: ISO 15189: 5.4.6 CAP GEN 40511, 40512					
9.7 Are referred specimens tracked properly, using a logbook or tracking form?	Y	P	N		2
Standard: ISO 15189: 4.5.3					
9.8 Is there a reagent logbook for lot number and dates of opening that reflects verification of new lots?	Y	P	N		2
Standard: ISO 15189: 4.6.2, 5.5.3					
9.9 Is each new lot number or new shipment of microbiology media checked for sterility and its ability to support growth before being incorporated into patient testing?	Y	P	N		2
Standard: ISO 15189: 4.6.2					
9.10 Are SOPs for specific testing present and easily accessible at the workbench?	Y	P	N		3
	Tick for each item				
	Yes	No	N/A		
Does the SOP include procedures that ensure specimen integrity and prevent mixing of samples?					
Is intermixing of test contents prohibited, unless otherwise specified?					
Where appropriate, is there a procedure for performing grading and reporting microscopic examinations – e.g., blood or urine?					
Standard: ISO 15189: 5.5.3					
9.11 Is internal quality control (IQC) performed, documented, and reviewed prior to release of patient results?	Y	P	N		3
	Tick for each item				
Is the quality of stains verified by routinely performing positive and negative controls?					
If a device contains an internal control area, is the internal control area determined to be acceptable before interpreting the test area?					
Does QC for qualitative testing include a positive and negative control and is appropriate follow-up taken on indeterminate results?					
If QC is unacceptable, is there a process for Investigation and corrective action?					
If using a point-of-care (POC) testing device, do they receive and document regular visits to check the accuracy of the POC device(s)?					
Standard: ISO 15189: 4.2.2, 5.6.1 PPD Lab Report V.5					
9.12 Is the laboratory result report(s) in a standard form determined to be acceptable in consultation with clients?					2

	Tick for each item				
	Yes	No	N/A		
Is the laboratory issuing the report clearly identified?					
Does the report contain the patient's name, address, and the hospital/destination of the report?					
Is the name of the person requesting the test indicated on the report?					
Is the type of sample received and the test requested included in the report?					
Are the date and time for specimen collection, receipt of specimen, and release of report indicated?					
Does the report indicate reference ranges for each test?					
Is the result reported in SI units?					
Is there space for interpretation of results and indicating when the specimen received was unsuitable for testing?					
Does the result contain the name of the person releasing the report and the signature of the person accepting responsibility for its content?					
9.13 Are QC results monitored for biases, shifts, and trends, i.e. Levy-Jennings charts? And are violations followed by timely troubleshooting/corrective action?	Y	P	N		3
Standard: ISO 15189: 5.8					
9.14 Are test results validated, interpreted and released by appropriately authorized personnel?	Y	P	N		3
Standard: ISO 15189: 5.7.1, 5.8.13					
9.15 Are test requests crosschecked with test results thereby assuring completion of all tests?	Y	P	N		2
Standard: A standard procedure should be followed for crosschecking all results. In instances where there is a LIS (laboratory information system) daily printing of the pending reports list should be done routinely to cross-check the completion of all tests within the defined turnaround times. ISO 15189: 5.7.1					
9.16 Is there a procedure for result reporting including use of standardized abbreviations, reporting of critical results, verbal/phone results, delayed results, corrected /amended laboratory results, and reporting unsatisfactory samples?	Y	P	N		3
Standard: ISO 15189: 5.8.7, 5.8.8; 5.8.14, 5.8.15, 5.8.16					
9.17 Are graphical tools (charts and graphs) used to communicate quality findings and identify trends?	Y	P	N		2
Standard: Use of graphical displays of quality data communicates more effectively than tables of numbers. Examples of graphical tools commonly used for this purpose include Pareto charts, cause-and-effect diagrams, frequency histograms, trend graphs, and flow charts. ISO 15189: 4.11.1					
9.18 Does the laboratory participate in an External Quality Assessment (EQA) scheme or inter-laboratory comparison?	Y	P	N		3
Are the following criteria met?	Tick for each item				
	Yes	No	N/A		
Do the EQA samples come from providers who are accredited or WHO AFRO approved?					
Are EQA specimens handled and tested In the same fashion as patient testing?					

Is cause analysis performed for poor EQA results?				
Is corrective action documented for poor EQA results?				
Standard: *The laboratory should handle, analyze, review, and report results for proficiency testing in manner similar to regular patient testing. Investigation and correction of problems identified by unacceptable proficiency testing should be documented. Acceptable results that show bias or trends suggest a problem should also be investigated.* ISO 15189: 4.2.2, 5.6.4, 5.6.5, 5.6.7				
SECTION 9: PROCESS CONTROL and INTERNAL & EXTERNAL QUALITY ASSESSMENT Subtotal				43

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
10.0 CORRECTIVE ACTION					
10.1 Do the environmental checks / temperature logs document action taken on unacceptable results?	Y	P	N		2
Standard: ISO 15189: 4.10.1					
10.2 Are out-of-control runs reviewed and submitted to troubleshooting and cause analysis?	Y	P	N		2
Standard: ISO 15189: 4.10, 5.6.7					
10.3 Is corrective action taken on out-of-control runs documented in the occurrence log, with results withheld, if indicated by the level of control violated?	Y	P	N		2
Standard: ISO 15189: 4.9.1, 5.6.7				PPD Lab Report V.B.1	
10.4 Are discordant results tracked and appropriate corrective action taken?	Y	P	N		2
Standard: ISO 15189: 5.6.1					
SECTION 10: CORRECTIVE ACTION Subtotal					8

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
11.0 OCCURRENCE / INCIDENT MANAGEMENT & PROCESS IMPROVEMENT					
11.1 Are laboratory occurrence reports completed, cause analysis performed, and corrective and preventive actions defined and taken on all reports to avoid recurrence?	Y	P	N		5
Standard: Errors and incidents should be documented, investigated, and corrected. Investigation of individual problems may not reveal trends or patterns caused by underlying system problem(s). For this reason the laboratory should periodically group errors and incident reports together for review. ISO 15189: 4.8 CAP GEN 20208					
11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities?	Y	P	N		5
Standard: Key indicators of quality must be monitored regularly and evaluated for opportunities to improve testing services. Indicators should be drawn from pre-analytic, analytic, and post-analytic phases and reflect activities critical to patient outcomes, those that correspond to a large proportion of the laboratory's patients, or areas that have been problematic in the past. These indicators should be compared against a benchmark from an acknowledged guideline. ISO 15189: 4.12.4, 5.8.11					
SECTION 11: OCCURRENCE/INCIDENT MGT, & PROCESS IMPROVEMENT Subtotal					10

*For each item, please circle either Yes (Y), Partial (P), or No (N). **All** elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.*

	Y	P	N	Comments	Score
12.0 FACILITIES & SAFETY					
12.1 Is the size of the laboratory adequate and is the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal workflow?	Y	P	N		2
Standard: The laboratory floor plan should be configured to promote high quality work, personnel safety, and efficient operations. ISO 15189: 5.2.2 CAP GEN 60000 PPD Lab Report VIII.1					
12.2 Are the client area and the testing areas of the laboratory distinctly separate and are incompatible testing activities effectively separated from one another?	Y	P	N		2
Standard: Client service areas (i.e., waiting room, phlebotomy room) should be distinctly separate from the testing areas of the laboratory. Client access should not compromise 'clean' areas of the laboratory. For biosafety reasons, microbiology and TB testing should be segregated in a separate room(s) from the general laboratory testing. ISO 15189: 5.2.6					
12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?	Y	P	N		2
Are the following criteria met:	Tick for each item				
	Yes	No	N/A		
Does the equipment placement / layout facilitate optimum workflow?					
Are all needed supplies present and easily accessible?					
Are the chairs/stools at the workstations appropriate for bench height and the testing operations being performed?					
Is needed reference material posted, i.e., critical values and required action, population reference ranges, frequently called numbers, etc.					
Standard:					
12.4 Is the physical work environment appropriate for testing?	Y	P	N		2
Is the workplace:	Tick for each item				
	Yes	No	N/A		
Free of clutter?					
Adequately ventilated?					
Free of excess moisture?					
Adequately lit?					
Climate-controlled for optimum equipment function?					
Where air-conditioning is installed, are filters checked, cleaned and/or replaced at regular intervals?					
Are wires and cables properly located and protected from traffic?					
Is there a functioning back up power supply (generator)?					
Is critical equipment supported by uninterrupted power source (UPS) systems?					

Is equipment placed appropriately, i.e. away from water hazards, out of traffic areas, etc.					
Is a contingency plan in place for continued testing in the event of prolonged electricity disruption?					
Are appropriate provisions made for adequate water supply, including deionized water (DI) or distilled water, if needed?					
Is clerical work completed outside the testing area?					
Is major safety signage posted and enforced?					

Standard: The laboratory space should be sufficient to ensure that the quality of work, the safety of personnel, and the ability of staff to carry out quality control procedures and documentation. The laboratory should be clean and well organized, free of clutter, well-ventilated, adequately lit, and within acceptable temperature ranges. Emergency power should be available sensitive instruments, temperature controlled storage, and other essential equipment to prevent damage and disruption due to unexpected power fluctuations and outages. Sensitive instruments should be equipped with surge controls. Distilled and de-ionized water should be available, if required.
ISO 15189: 5.2.5 & 5.2.10

12.5 Is the laboratory properly secured from unauthorized access with appropriate signage?	Y	P	N		2

Standard: The access of unauthorized persons to the laboratory should be strictly limited to avoid the unnecessary contact of individuals with contaminated areas, reagents, or equipment. Unnecessary traffic also disturbs workflow and can distract staff members.
ISO 15189: 5.2.7

12.6 Are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?	Y	P	N		2

Standard: Laboratory reagents and blood products should be stored separately when refrigerated or frozen.

12.7 Is the work area clean, free of leakage & spills and are disinfection procedures conducted and documented?	Y	P	N		2

Standard: The work area should be regularly inspected for cleanliness and leakage. An appropriate disinfectant should be used. At a minimum, all benchtops and working surfaces should be disinfected at the beginning and end of every shift. All spills should be contained immediately and the work surfaces disinfected.
ISO 15189: 5.2.10

12.8 Is a certified and maintained biosafety cabinet (or an acceptable alternative processing procedure) in use for all specimens or organisms considered to be highly contagious by airborne routes? (Biosafety cabinet should be recertified according to national protocol).	Y	P	N		2

Standard: A biosafety cabinet should be used for to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, biosafety cabinets require periodic maintenance and should be serviced accordingly.

12.9 Is sufficient waste disposal available and is waste separated into infectious & non-infectious waste, with infectious waste autoclaved, incinerated, or buried?	Y	P	N		2

Standard: Waste should be separated according to biohazard risk, with infectious and non-infectious waste disposed of in separate containers. Infectious waste should be discarded into containers that do not leak and are clearly marked with a biohazard symbol. Sharp instruments and needles should be discarded in puncture resistant containers. Both infectious waste and sharps containers should be autoclaved before being discarded to decontaminate potentially infectious material. To prevent injury from exposed waste, infectious waste should be incinerated, burnt in a pit, or buried.
ISO 15189: 5.2.10

12.10 Are hazardous chemicals / materials handled properly?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Are hazardous chemicals properly labeled?					
Are hazardous chemicals properly stored?					
Are hazardous chemicals properly utilized?					
Are hazardous chemicals properly disposed?					

Standard: All hazardous chemicals must be labeled with the chemical's name with hazard markings clearly indicated. Flammable chemicals must be stored out of sunlight and below their flashpoint, preferably in a still cabinet in a well-ventilated area. Flammable and corrosive agents should be separated from one another. Distinct care should always be taken to handle hazardous chemicals safety in the workplace. Used, outdated, old, or discolored chemicals should be discarded appropriately—some items can be poured down the sink, while others will require additional steps for their safe disposal.

12.11 Are 'sharps' handled & disposed of properly in 'sharps' containers that are appropriately utilized?	Y	P	N		2

Standard: All syringes, needles, lancets, or other bloodletting devices capable of transmitting infection must be used only once and discarded in puncture resistant containers that are not overfilled. Sharps containers should be clearly marked to warn handlers of the potential hazard and should be located in areas where sharps are commonly used.
ISO 15189: 5.2.10

12.12 Is fire safety attended to as part of the laboratory's overall safety program?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Are all electrical cords, plugs, and receptacles used appropriately and in good repair?					
Is an appropriate fire extinguisher available, in working condition, and routinely inspected?					
Is an operational fire alarm system in place in the laboratory with periodic fire drills?					

Standard: Electrical chords and plugs, power-strips, and receptacles should be maintained in good condition and utilized appropriately. Overcrowding should be avoided and chords should be kept out of walkway areas. An approved fire extinguisher should be easily accessible within the laboratory and be routinely inspected and documented for readiness. Fire extinguishers should be kept in their assigned place, not be hidden or blocked, the pin and seal should be intact, nozzles should be free of blockage, pressure gauges should show adequate pressure, and there should be no visible signs of damage. A fire alarm should be installed in the laboratory and tested regularly for readiness and all staff should participate in periodic fire drills.

CAP GEN 70200, 70250, 70300 PPD Lab Report X.E

12.13 Are safety inspections or audits conducted regularly and documented?	Y	P	N		2

Standard: Safety inspections or audits, using a safety checklist, should be conducted periodically to ensure the laboratory is a safe work environment and identify areas for redress and correction.

12.14 Is standard safety equipment available and in use in the laboratory?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Biosafety cabinet(s)					
Covers on centrifuge(s)					
Hand-washing station					
Eyewash station/bottle(s)					
Spill kit(s)					
First aid kit(s)					

Standard: It is the responsibility of laboratory management to ensure the laboratory is equipped with standard safety equipment. The list above is a partial list of necessary items. Biosafety cabinets should be in place and in use and all centrifuges should have covers. Hand washing stations should be designated and equipped and eyewash stations (or an acceptable alternative method of eye cleansing) should be available and operable. Spill kits and first aid kits should be kept in a designated place and checked regularly for readiness.

PPD Lab Report X.E

12.15 Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently *(for example: lab. coats, gowns, aprons, vision protection, gloves, closed shoes, etc. as applicable to the specific lab.)*	Y	P	N		2

Standard: Management is responsible to provide appropriate personal protective equipment—gloves, lab coats, eye protection, etc.— in useable condition. Laboratory staff must utilize personal protective equipment in the laboratory at all times. Protective clothing should not be worn outside the laboratory. Gloves should be replaced immediately when torn or contaminated and not washed for reuse..

12.16 Are laboratory personnel offered appropriate vaccination/s?	Y	P	N		2

Standard: Laboratory staff should be offered appropriate vaccinations--particularly Hepatitis B. Staff may decline to receive the vaccination, but should sign a declination form to be held in the staff member's personnel file.

12.17 Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known exposures?	Y	P	N		2

Standard: The laboratory must have a procedure for follow-up of possible and known percutaneous, mucus membrane, or abraded skin exposure to HIV, HBV, or HCV. The procedure should include clinical and serological evaluation and appropriate prophylaxis.

12.18 Are occupational injuries or illnesses documented in the safety / occurrence log? (Level II: 2.1, 2.3, 6.8)	Y	P	N		2
Standard: All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented.					
12.19 Are drivers/couriers and cleaners working with the laboratory trained in biosafety practices relevant to their job tasks?	Y	P	N		2
Standard: All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented.					
12.20 Is a trained safety officer designated to implement and monitor the safety program in the laboratory, including training of other staff?	Y	P	N		2
Standard: A safety officer should be designated to work with the laboratory manager to implement the safety program, monitor the ongoing safety conditions and needs of the laboratory, coordinate safety training, and serve as a resource for other staff. This officer should receive safety training.					
SECTION 12: FACILITIES & SAFETY Subtotal					40

SUMMARY

Noted Commendations

Noted Challenges

RECOMMENDATIONS

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 137 pts)	(138 – 160 pts)	(161 – 185 pts)	(186 – 211 pts)	(212 – 236 pts)	(237 – 250 pts)
< 55%	*55 – 64%*	65 – 74%	*75 – 84%*	*85 – 94%*	>95%

Laboratory Accreditation External Assessment Feedback Form, p.1

Date of Assessment *(DD-month-YYYY)*				Date of Last External Assessment *(DD-month-YYYY)*			
Current Accreditation Status	Not Assessed	0 Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars

Name(s) of Assessor(s) Affiliation(s) Signature(s)

1. _____ _____ _____

2. _____ _____ _____

Laboratory Name	Laboratory Number
Laboratory Address	
Laboratory Telephone / Fax	Telephone *(Laboratory Head)*
Head of Laboratory	Email

Laboratory Level *(check those that apply)*		Laboratory Affiliation *(check those that apply)*	
☐ Level IV National Lab.	☐ Level III a Regional Lab.	☐ Public	☐ Academic
☐ Level III b Federal Hosp.	☐ Level II a Regional Specialized Hosp.	☐ Private	☐ NGO/Religious Institution
☐ Level II b Zonal/District Hosp.			

Assessment Score Sheet

Section	*Total Points*	*Assessed Score*
Section 1: Documents & Records *(11 items)*	25	
Section 2: Management Reviews *(3 items)*	12	
Section 3: Organization & Personnel *(7 items)*	20	
Section 4: Client Management & Customer Service *(1 item)*	10	
Section 5: Equipment *(14 items)*	32	
Section 6: Internal Audit *(1 item)*	5	
Section 7: Purchasing & Inventory *(15 items)*	31	
Section 8: Information Management *(6 items)*	14	
Section 9: Process Control and Internal & External Quality Assessment *(17 items)*	43	
Section 10: Corrective Action *(4 items)*	8	
Section 11: Occurrence/Incident Management & Process Improvement *(3 items)*	10	
Section 12: Facilities and Safety *(23 items)*	40	
TOTAL SCORE	250	

Laboratory Accreditation External Assessment Feedback Form, p.2

Date of Assessment *(DD-month-YYYY)*	
Laboratory Name	Laboratory Number

PART IV: SUMMARY of ASSESSMENT FINDINGS		
Criteria 1	Test results on at least 80% of all specimens are reported within WHO AFRO specified turnaround time (time from receipt of specimen in laboratory until results reported):	YES / NO
Criteria 2	WHO AFRO required number of tests to retain competency performed annually:	No. of tests (annually)
	HIV serology	
	CD4 cell testing	
	Mycobacterium tuberculosis	
	Smear	
	Culture	
	Drug Susceptibility	
	Malaria	
	Clinical chemistry (no. of samples)	
	Hematology (no. of samples)	
	Bacterial identification (no. of samples)	
Crit. 3	Internal quality control (IQC) procedures are implemented daily for all tests included in Criteria 2:	YES / NO
Criteria 4	Results of the two most recent PT challenges are at least 80%:	YES / NO / n/a
	HIV serology	YES / NO / n/a
	CD4 cell testing	YES / NO / n/a
	Mycobacterium tuberculosis	
	Smear	YES / NO / n/a
	Culture	YES / NO / n/a
	Drug Susceptibility	YES / NO / n/a
	Malaria	YES / NO / n/a
	Clinical chemistry	YES / NO / n/a
	Hematology	YES / NO / n/a
	Bacterial identification	YES / NO / n/a
Crit. 5	Score on annual on-site inspection is at least 55% (at least 138 pts):	YES / NO

[n/a … not applicable]

Additional Comments/Notes

Laboratory Improvement Plan

Date of Assessment *(DD-month-YYYY)*				Date of Last Assessment *(DD-month-YYYY)*			
Current Accreditation Status *(circle)*	Not Assessed	0 Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
Name(s) of Assessor(s) Affiliation(s) 1. _____ _____ 2. _____ _____							
Laboratory Name					Laboratory Number		
Laboratory Address							
Laboratory Telephone		Fax			Telephone *(Laboratory Head)*		
Head of Laboratory				Email			
Signature							

	ACTION PLAN			
	Follow-Up Actions	Responsible Person(s)	Timeline	Status *(use this column for updates after the first Improvement Plan is developed)*
1				
2				
3				
4				
5				
6				

Laboratory Accreditation Internal Assessment Feedback Form

Date of Assessment *(DD-month-YYYY)*				Date of Last Assessment *(DD-month-YYYY)*			
Current Accreditation Status	Not Assessed	0 Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars

Name(s) of Assessor(s) Affiliation(s)

1. _____ _____

2. _____ _____

Laboratory Name	Laboratory Number
Laboratory Address	
Laboratory Telephone / Fax / Telephone *(Laboratory Head)*	
Head of Laboratory	Email

Laboratory Level *(check those that apply)*		Laboratory Affiliation *(check those that apply)*	
☐ Level IV National Lab.	☐ Level III a Regional Lab.	☐ Public	☐ Academic
☐ Level III b Federal Hosp.	☐ Level II a Regional Specialized Hosp.	☐ Private	☐ NGO/Religious Institution
☐ Level II b Zonal/District Hosp.			

Assessment Score Sheet

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Section 8: Information Management *(6 items)*	14	
Section 9: Process Control and Internal & External Quality Assessment *(17 items)*	43	
Section 10: Corrective Action *(4 items)*	8	
Section 11: Occurrence/Incident Management & Process Improvement *(3 items)*	10	
Section 12: Facilities and Safety *(23 items)*	40	
TOTAL SCORE	250	

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