A Stepwise Quality Improvement Checklist for Federal Tertiary Hospitals

LABORATORY MEDICINE

An Assessment Tool to Strengthen the Operations, Service Delivery, Safety, Continuous Quality and Management of Laboratory Medicine

Department of Hospital Services
Federal Ministry of Health

Tertiary Hospitals Laboratory Medicine

Medical laboratory services aid in diagnosis and treatment of patients and is as essential part of continuous quality improvement. As health care accelerates from empirical to precision medicine, the quality of laboratory medicine is becoming a very critical element at every level of the care delivery value chain and the foundation of care plans

Poor quality medical laboratory services leads to mis-diagnosis, wrong treatment, wastage and even litigation in the wake of the patients' bill of rights.

Objectives of this Checklist

This quality assessment checklist will provide **direction**, **support,** and **accountability framework** while focussing on individuals, systems, management of resources and self-governance. It will build corporate accountability for clinical performance into the medical laboratory services and develop a corporate culture in which quality improvement becomes a shared enterprise through shared learning and information. It will also provide strategic opportunities to diagnose and repair broken processes.

Frequent and accurate assessment and timely feedback will support action plans to implement systems that are lacking and revive those that are not functioning effectively.

This checklist therefore represents a clinical governance assessment tool to determine:

- *The level and quality of the medical laboratory services and resources*
- *The capacity of the laboratory department to provide safe and quality services*
- *The level of process capabilities*
- *Key drivers of quality and patients' satisfaction in a strategic plan.*
- *The competency level of clinical and non –clinical support staff in the laboratory department.*
- *Areas for improvement.*

Assessment Scoring

The contents of this checklist have been awarded point values based on their relative importance. Responses to all questions must be either **"Yes" or "No" or "Not Applicable" (NA).**

The checklist has considerable overlap and expanded to include important continuous quality tools.

NOTE:

- *Only responses marked yes should be given the allotted points. All the required answers to a particular question must be present before you can indicate a "yes" for any given checklist question and then award the corresponding allotted points.*
- *It is often not necessary to ask all the checklist questions verbatim. An experienced auditor can often learn to answer multiple checklist questions through open-ended questions with the key or designated staff contact.*

This checklist is divided into different aspects of Quality Management System that the laboratory department is required to develop and implement regularly as listed below;

Assessment Score Sheet			
Section		**Total Allotted Scores**	**Assessed Scores**
5.1	**Facility and Safety**	16	
5.2	**Organization and Management**	20	
5.3	**Equipment**	11	
5.4	**Inventory Management**	9	
5.5	**Process Control** - *internal and external Quality Assessments.*	21	
5.6	**Documents and Records**	12	
5.7	**Information Management**	6	
5.8	**Occurrence/Incidence Management**	17	
5.9	**Client Management**	7	
5.10	**Infection Control**	4	
5.11	**Waste Management**	5	
	Total Scores	***128***	

Assessment Score Sheet					
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5.8	**Occurrence/Incidence Management**	17			
5.9	**Client Management**	7			
5.10	**Infection Control**	4			
5.11	**Waste Management**	5			
	Total Scores	***128***			

General Information

Date of Assessment:	
Name(s) and Affiliation(s) of Assessor(s):	
Name of Federal Tertiary Hospital:	
Address:	
State:	
Name of CMD/MD:	Telephone/E-mail (CMD/MD):
Type of Laboratory:	
Laboratory Telephone:	Email:
Head of Pathologists:	Telephone (Head of Pathologists):
Head of Medical Laboratory Scientists:	Telephone (Head of Medical Laboratory SCientists):
Number of test requested monthly:	Number of test requested annually:
Number of test completed:	Number of test repeated:
Number of test referred:	
Referral Network Is a back-up laboratory formally designated for specimen referral in the event of instrument breakdown or power outage? If so, list the names of the back-up laboratory.	List the names and types of laboratories to which the laboratory refers specimens.

5.0 Staffing Summary

Profession	Number of Full Time Equivalents (FTEs)	Adequate for Facility Operations		
Pathologist		Yes	No	Insufficient Data
Medical Laboratory Scientist		Yes	No	Insufficient Data
Resident Doctor		Yes	No	Insufficient Data
Medical Laboratory Science Trainee		Yes	No	Insufficient Data
Laboratory Technician		Yes	No	Insufficient Data
Laboratory Assistant		Yes	No	Insufficient Data
Data Clerk		Yes	No	Insufficient Data
Phlebotomist		Yes	No	Insufficient Data
Cleaner(s) dedicated to laboratory:		Yes	No	Insufficient Data
Driver dedicated to laboratory:		Yes	No	Insufficient Data
Other		Yes	No	Insufficient Data
If the laboratory has IT specialists, accountants or non-laboratory-trained management staff this can be listed below:				
Does the laboratory provide on-call services?		Yes	No	Insufficient Data

Available Laboratory Investigations *(respond as applicable)*

Test Type	Sample Type	Instrument Used	Average No. of Test per Month	Instrument currently functioning? (Y/N/NA)	Regular maintenance service in place? (Y/N)	Last date of service
HEMATOLOGY						
Pathologist In-Charge:						
Medical Laboratory Scientist In-Charge:						
CBC: HB, WBC, and Platelet						
Differential Count						
Peripheral blood smear examinations						
Cd4 Count / CD4%						
Malaria, thick and thin blood film examinations						
Blood grouping & cross matching						
Coagulation Test						
Sedimentation rate						

CHEMISTRY						
Pathologist In-Charge:						
Medical Laboratory Scientist In-Charge:						
Routine chemistry (blood): *urea, electrolytes, creatinine, glucose, liver function and renal tests, muscle enzymes, lipid profile*						
Urinalysis: *urine chemistry, microscope examination*						
Pregnancy test: *urine and blood*						
CSF Chemistry -*total protein, glucose, LDH*						
Whole blood lacate						

Available Lab Tests *(tick as applicable)*

Test Type	Sample Type	Instrument Used	Average No of Test/month	Instrument currently functioning? (Y/N/NA)	Regular maintenance service in place? (Y/N)	Last date of service
INFECTIOUS DISEASE SEROLOGY, including HIV						
Pathologist In-Charge:						
Medical Laboratory Scientist In-Charge:						
HIV Serology: Rapid test						
HIV Serology: *ELISA, EIA, Western Blot, P24 Antigen ELISA*						
Hepatitis B & C Test: *antiHBS mAb, HBS Ag, Anti Hbc AB, Anti Hbe Ab*						
Syphilis Serology: *Rapid Test*						
Syphilis Serology: *VDRL, RPR, TPHA*						
Rubella Serology						
Toxoplasmosis Serology						
Cytomegalovirus Serology						
Herpes Simplex Serology						
Malaria ICT						
Pap Smear						

MICROBIOLOGY						
Pathologist In-Charge:						
Medical Laboratory Scientist In-Charge:						
Microscopy: *sputum, urine, stool, CSF*						
TB AFB: *stain, gram stain, india ink stain*						
Bacterial culture and susceptibility testing						
Fungal culture						
Body Fluid Cell Count						
Cryptococcal Antigen						

REFERRAL TESTING (if applicable)	
List the types of tests that are referred from this laboratory to another facility for testing	
Test	Laboratory Referred to

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.1 FACILITY & SAFETY						
Is the layout of the laboratory workstations appropriate for optimal workflow?	YES	NO	N/A		3	
Standard: *The laboratory floor plan should be configured to promote high quality work, personnel safety, and efficient operations*						
Are the client area and the testing areas of the laboratory distinctly seperate?	YES	NO	N/A		1	
Is the physical work environment appropriate for testing?	YES	NO	N/A		3	
Is the workplace:	Tick Items Present					
Free of clutter?						
Adequately ventilated?						
Free of excess moisture?						
Adequately lit?						
Are wires and cables properly located and protected from traffic?						
Is there a functioning back-up power supply?						
Are critical equipment supported by uninterrupted power source (UPS) systems?						
Are equipment placed appropriately, i.e. away from water hazards, out of traffic areas, etc.						
Is a contingency plan in place for continuous testing in the event of prolonged electricity disruption?						
Are appropriate provisions made for adequate water supply?						
Is clerical work completed outside the testing area?						
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 procedures and documentation. The laboratory should be clean and well organised, free of clutter, well ventilated, adequately lit, and within acceptable temperature ranges. Emergency power should be available to 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.*						
Is the laboratory properly secured from unauthorised access with appropriate signage?	YES	NO	N/A		1	
Standard: *The access of unauthorised 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*						
Is major safety signage posted and enforced in the laboratory, prohibiting eating, drinking, and storing food/drink in laboratory refrigerators, etc.?	YES	NO	N/A		1	
Standard: *Laboratories should post specific warning and hazard signage to ensure the safety of laboratory staff and visitors (e.g., posting biohazard warning on laboratory door). Eating, drinking and smoking are prohibited in the laboratory.*						
Are patients samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?	YES	NO	N/A		1	
Standard: *Laboratory reagents and blood products should be stored separately when refrigerated or frozen.*						

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
Is the work area clean, free of leakage & spills, and properly disinfected daily?	YES	NO	N/A		1	
Standard: *The work area should be regularly inspected for cleanliness and leakage. Spills should be contaminated immediately and the surfaces disinfected with an appropriate disinfectant. All benchtops and working surfaces should be disinfected at least once a day or once a shift and immediately following every spill.*						
Is an appropriate fire extinguisher available, in working condition, and routinely inspected?	YES	NO	N/A		1	
Standard: *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 assigned place, not 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.*						
Is an operational fire alarm system in place in the laboratory?	YES	NO	N/A		1	
Standard: *A fire alarm should be installed in the laboratory and tested regularly for readiness and all staff should participate in periodic fire drills.*						
Are safety inspections or audits conducted regularly and documented?	YES	NO	N/A		1	
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.*						
Is standard safety equipment available and in use in the laboratory	YES	NO	N/A		2	
	Tick Items Present					
Biosafety cabinet(s)						
Covers on centrifuge(s)						
Hand-washing station						
Eyewash station						
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.*						
Subtotal					***16***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.2 ORGANIZATION & MANAGEMENT						
Does the department have in place a long and short-term strategic plan for quality improvement?	YES	NO	N/A		3	
Is the scope of service clearly defined?	YES	NO	N/A		1	
Is a work plan and budget in place for the laboratory?	YES	NO	N/A		1	
Does the laboratory supervisor perform a documented review of quality records routinely?	YES	NO	N/A		2	
Standard: *There must be documentation that the head of laboratory or a designee review the programme regularly. The review must ensure that recurrent problems have been addressed, and that new or redesigned activities have been evaluated. These documents include: internal audit reports, surveillance reports, quality index results, laboratory services, evaluation reports, and complaint records for management planning.*						
Does the laboratory management identify and undertake quality improvement projects?	YES	NO	N/A		2	
Standard: *Management should regularly review internal audit reports and use results to implement quality improvement projects.*						
Does the laboratory management have developed policies, procedures and manuals in place?	YES	NO	N/A		1	
Does the management ensure that these documents are implemented by the laboratory staff?	YES	NO	N/A		1	
Are drivers/couriers involved in sample transport trained in the appropriate and safe transportation of specimens?	YES	NO	N/A		1	
Is a safety officer designated to implement and monitor the safety programme in the laboratory?	YES	NO	N/A		1	
Standard: *A safety officer should be designated to work with the laboratory manager to implement the safety programme, monitor the ongoing safety conditions and needs of the laboratory, coordinate safety training, and serve as a resource for other staff.*						
Are daily routine work tasks established, assigned, and monitored?	YES	NO	N/A		1	
Standard: *Daily routines should be prioritized, organized, and coordinated to achieve optimal service delivery for patients.*						
Are lines of authority and responsibility clearly defined for all laboratory staff, including the designation of a supervisor?	YES	NO	N/A		1	
Standard: *An up to date organisational chart and/or narrative description should be available detailing the external and internal reporting relationships for laboratory personnel.*						
Is there a system for competency and performance assessment of staff and does it include planning and documentation of retraining and reassessment?	YES	NO	N/A		2	
Standard: *Work performance evaluation shall be regularly monitored for designing the training plan.*						

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
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	YES	NO	N/A		1	
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*						
Are staff meetings held regularly?	YES	NO	N/A		2	
Do meetings include the following items:	Tick Items Present					
Are problems and complaints discussed?						
Are SOPs routinely reviewed?						
Are systemic and/or recurrent problems and issues addressed, including actions to prevent recurrence?						
Are improvement topics/projects discussed & evaluated?						
Are meeting notes recorded and monitored for progress on issues?						
Standard: *There should be regular meetings to ensure communication within the laboratory. Meetings should have recorded notes to facilitate review of progress over time.*						
Subtotal					***20***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.3 EQUIPMENT						
Is equipment installed and placed as specified in operators' manuals?	YES	NO	N/A		1	
Standard: *The analytical and logistics technology has to be available on a level which fulfil the minimal requirement for quality diagnostic services*						
Is current equipment inventory data available on all equipment in the laboratory?	YES	NO	N/A		1	
	Tick Items Present					
Name of equipment						
Manufacturer						
Serial number						
Date of purchase						
Is relevant equipment service information readily available in the laboratory?	YES	NO	N/A		2	
	Tick Items Present					
Service contract information						
Contact details for service provider						
Last date of service						
Next date of service						
Is non-functioning equipment removed from the laboratory and storage area?	YES	NO	N/A		1	
Is routine calibration of laboratory equipment - including pipettes, centrifuges, balances, and thermometers - scheduled and verified?	YES	NO	N/A		2	
Is equipment routinely serviced according to schedule and documented in appropriate logs?	YES	NO	N/A		1	
Are there back-up procedures for equipment failure?	YES	NO	N/A		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 different testing method, the referral of samples to another laboratory, or the freezing of samples until testing is reestablished.*						
Are the equipment manufacturer's operator manuals readily available to bench staff?	YES	NO	N/A		1	
Subtotal					***11***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.4 INVENTORY MANAGEMENT						
Is an inventory control managemnt system in place?	YES	NO	N/A		2	
Are supply & reagent specifications periodically reviewed?	YES	NO	N/A		1	
Are storage areas set up and monitored appropriately?	YES	NO	N/A		3	
	Tick Items Present					
Is the storage area well organised and free of clutter?						
Are there set places labelled for all inventory items?						
Are hazardous chemicals stored appropriately?						
Is adequate cold storage available?						
Is temperature monitoring conducted according to MSDS instruction?						
Is storage in direct sunlight avoided						
Is storage area adequately ventilated?						
Is the storage area clean and free of dust and pest						
Are expiry products disposed off properly?	YES	NO	N/A		1	
Has the laboratory provided uninterupted testing services with no disruptions due to stock outs in the last year (or since the last assessment)	YES	NO	N/A		2	
Subtotal					***9***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.5 PROCESS CONTROL (Internal and External Quality Assessment)						
Are SOPs for specific testing present and easily accessible at the workbench?	YES	NO	N/A		2	
	Tick Items Present					
Does the SOP include procedures that ensure specimen integrity and prevent mixing of samples?						
Is internal quality control (IQC) performed, documented, and reviewed prior to release of patient results?	YES	NO	N/A		2	
Are QC results monitored for biases, shifts and trends?	YES	NO	N/A		2	
Are test requests crosschecked with test results thereby assuring completion of all tests?	YES	NO	N/A		1	
Is there a procedure for result reporting including use of standardized abbreviations and standard report form?	YES	NO	N/A		1	
Are corrective actions taken on results violations?	YES	NO	N/A		1	
Are guidelines for patient identification specimen collection, labelling, and transport readily available to persons responsible for primary sample collection?	YES	NO	N/A		2	
Are adequate specimen collection, receiving and storage procedures in place?	YES	NO	N/A		2	
	Tick Items Present					
Are specimens labelled with time, date, patient ID, and collector's initials?						
Are all test requests accompanied by an approved test requisition form?						
Are specimens logged appropriately upon receipt in the laboratory?						
Is a two-identifier system in use and is each sample assigned a unique identifying number?						
Are specimens delivered to the correct work stations in a timely manner?						
Are specimens stored appropriately?	YES	NO	N/A		1	
Standard: *Specimens should be stored under the appropriate conditions to maintain the stability of the specimen.*						
Are specimens packaged appropriately for shipment to referral laboratory?	YES	NO	N/A		1	
Are referred specimens tracked properly, using a logbook or tracking form?	YES	NO	N/A		1	

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?	YES	NO	N/A		1	
Are environment checks/temperature logs complete, accurate, and regularly reviewed?	YES	NO	N/A		1	
Are the following environmental checks performed daily?	Tick Items Present				2	
Room temperature						
Humidity						
Freezers						
Refrigerator						
Incubators						
Water Bath						
Have acceptable ranges been defined for all temperature dependent equipment with procedures that detail what to do when temperatures are out of range?	YES	NO	N/A		1	
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.*						
Subtotal					***21***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.6 DOCUMENTS & RECORDS						
Is there a system or procedure for document & record control?	YES	NO	N/A		1	
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.*						
Are documents and records properly maintained and easily accessible by the authorized personnel?	YES	NO	N/A		2	
Standard: *Records, policies and procedures should be readily accessible, either in paper copy or electronic form. If documents and records are maintained in electronic form, they should be backed-up on CD or other media, and only authorised personnel should have access to them.*						
Are these Standard Operating Procedures (SOPs) current and available for laboratory functions?	YES	NO	N/A		2	
SOPs for:	Tick Items Present					
Writing SOPs for laboratory procedures						
Each testing procedure performed						
Laboratory safety						
Equipment maintenance						
Document and record control						
Specimen Collection and Procurement						
Quality Assurance						
Employee communication of concerns about test quality and laboratory safety						
Are SOPs reviewed and updated at least once a year?	YES	NO	N/A		1	
Are SOPs changes documented, approved and communicated to staff immediately?	YES	NO	N/A		1	
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.*						
Are SOPs easily accessible/available to all staff?	YES	NO	N/A		1	
Is there a laboratory quality manual containing quality assurance policies and procedures?	YES	NO	N/A		2	
Standard: *A quality manual should be avilable that summarizes the laboratory's quality programme, includes policies that address all areas of the laboratory service, and identifies the goals and objectives of the quality programme. The quality manual include policies (processes and procedures) for all areas of the laboratory service and should address all of the quality system essentials (QSE).*						

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
Is a laboratory safety manual available, accessible and up-to-date?	YES	NO	N/A		2	
Does the safety manual include guidelines on the following topics?	Tick Items Present					
Blood and Body Fluid Precautions						
Hazardous Waste Disposal						
Hazardous Chemicals/Materials						
MSDS Sheets						
Personal, protective equipment						
Fire Safety						
Electricity Safety						
Subtotal					***12***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.7 INFORMATION MANAGEMENT						
Are test results legible, technically verified, and confirmed against patient identity?	YES	NO	N/A		1	
Are testing personnel identified on the requisition and record?	YES	NO	N/A		1	
Are test results recorded in a logbook or electronic record in a timely fashion	YES	NO	N/A		1	
Is there a system for reviewing clerical errors?	YES	NO	N/A		1	
Are archived results stored in a secure location accessible only to authorised personnel?	YES	NO	N/A		1	
Are there documented procedures for the preservation of essential laboratory data in the event of hardware/software failure, theft, or an unexpected destructive event (e.g., fire, flood).	YES	NO	N/A		1	
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 back-up and storing of information, and off-site storage of back-up data.*						
Subtotal					***6***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.8 OCCURRENCE/INCIDENCE MANAGEMENT						
Is there any designated incidence reporting book in the laboratory?	YES	NO	N/A		3	
Are laboratory occurrence reports completed and is corrective and preventive action taken on all reports to avoid recurrence?	YES	NO	N/A		3	
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.*						
Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly?	YES	NO	N/A		2	
Standard: *Key indicators of quality must be monitored regularly and evaluated for opportunities to improve testing services. Indicators should be drawn from pre-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.*						
Does the laboratory management review all operational procedures periodically in order to identify any form of non-conformance or opportunities for process quality improvements?	YES	NO	N/A		2	
Are action plans for relevant areas for continuous improvement developed and implemented regularly?	YES	NO	N/A		2	
Is there a criteria and procedure for handling out of control or non-conformable test runs?	YES	NO	N/A		2	
Are corrective actions taken on out of control test runs?	YES	NO	N/A		2	
Standard: *Results reported during non-conformance test runs should be recalled when the violation level is critical to patient care.*						
Are occupational injuries or illnesses documented in the safety/occurrence log?	YES	NO	N/A		1	
Standard: *All occupational injuries/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.*						
Subtotal					***17***	

For each item, please circle either Yes, No, or Not Applicable (N/A). All elements of the question must be satisfactorily present to indicate "yes" and award credit. Provide explanation or further comments for each "no" or "n/a" response.

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.9 CLIENT MANAGEMENT						
Is there any developed process or tool for monitoring clients' satisfaction and complaint?	YES	NO	N/A		3	
Is there any procedure developed and documented for receiving clients feedback, suggestions, and reporting to laboratory and top management?	YES	NO	N/A		2	
Do the laboratory management develop an implementation plan to address all complaints?	YES	NO	N/A		2	
Subtotal					***7***	

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.10 INFECTION CONTROL						
Is a personal protective equipment (PPE) easily accessible at the workstation and utilised appropriately and consitentently?	YES	NO	N/A		1	
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 wash for reuse.*						
Are laboratory personnel offered appropriate vaccination(s)?	YES	NO	N/A		1	
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.*						
Are post-exposure prophylaxis policies and procedures posted and implemented?	YES	NO	N/A		1	
Standard: *The laboratory must have a procedure 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.*						
Are staff supported to have annual medical check-ups and appropriate vaccinations?	YES	NO	N/A		1	
Standard: *Annual medical check-ups and vaccinations should be supported*						
Subtotal					***4***	

	YES	NO	N/A	Comments	Allotted Scores	Scores Assessed
5.11 WASTE MANAGEMENT						
Is a certified and maintained biosafety cabinet used for all specimens or organisms considered to be highly contagious by airborne routes? *(Biosafety cabinet should be recertified according to national protocol).*	YES	NO	N/A		3	
Standard: *A biosafety cabinet should be used to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, biosafety cabinets require periodic maintenance and should be serviced regularly.*						
Is waste disposal separated into infectious & non-infectious waste, autoclaved, incinerated or buried?	YES	NO	N/A		1	
Standard: *Waste should be separated according to biohazard risk, with infectious and non-infectious waste disposed off in separate containers. Infectious waste should 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.*						
Are 'sharps' handled & disposed of properly in 'sharps' containers that are appropriately utilized?	YES	NO	N/A		1	
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.*						
Subtotal					***5***	

SUMMARY

Noted Challenges:

Noted Recommendations: