



Chapter XXI

Laboratory (LB)



Introduction

This is a sensitive and important area that needs strict rules and standards to make sure that the results are accurate and produced in a timely manner. So many aspects of the lab are vital, especially the measures which need to be closely monitored and enforced. The Blood Bank also needs to enforce rigid criteria on how to collect, screen, store, and issuing a unit of blood. There should be zero tolerance to any flexibility in applying the rules in this unit.

Laboratory (LB)

Scoring:



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
PHYSICAL FACILITIES						
LB.1.	The space available does not compromise the quality and the flow of work, safety of personnel, or limit quality control activities (according to College of American Pathologists Standards - CAP, Joint Commission International - JCI Standards, and Clinical & Laboratory Standards Institute - CLSI) and this includes:					
	LB.1.1 Adequate water taps, sinks and drains.					
	LB.1.2 Adequate emergency power.					
	LB.1.3 Adequate electrical outlets.					
	LB.1.4 Adequate ventilation.					
	LB.1.5 Adequate lighting.					
	LB.1.6 Adequate temperature /humidity control adequate.					
	LB.1.7 Conveniently located telephones and calls easily transferred.					
SCOPE OF SERVICES						
LB.2.	The lab services and capacities match the patient needs and includes:					
	LB.2.1 Emergency lab service available 24 hours/day.					
	LB.2.2 Basic lab work (e.g. Hematology, Blood Bank and Biochemistry) available 24 hrs/day.					
LB.3.	All lab services are known and available to all medical staff.					
	LB.3.1 A list of all available lab services should be distributed to all departments.					
	LB.3.2 Turn-around times are included.					
	LB.3.3 Collection methods and collection medium is included for the various laboratory tests.					
ORGANIZATION AND STRUCTURE						
LB.4.	The lab organization structure is defined and available.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.4.1	The director in-charge of the laboratory is a qualified pathologist or a qualified clinical scientist.					
LB.4.2	All lab sections are identified and they are under the directors' supervision.					
LB.4.3	All staff categories are included.					
LB.4.4	Chain of command is clear.					
HUMAN RESOURCES						
LB.5.	All staff have clear documented information on what is expected from them towards their work which includes:					
LB.5.1	Job descriptions					
LB.5.2	Orientation and training programs.					
LB.6.	The lab has a staff competency program that ensures the staff awareness of the Internal Policies & Procedures (IPPs) and the work essentials:					
LB.6.1	Written evaluation and documented direct observation of test procedures should be done at least once a year.					
LB.7.	The lab staff are qualified to do the tests and includes:					
LB.7.1	Identification of staff who can perform the tests.					
LB.7.2	Identification of staff who supervises the tests.					
LB.7.3	Identification of staff who interpret the tests results.					
INSTRUMENTS AND EQUIPMENT						
LB.8.	The lab has a documented procedure defining how pipets are checked for accuracy of calibration using certified balance and this includes the following:					
LB.8.1	Pipets are checked for accuracy before being placed in service initially, and results are documented.					
LB.8.2	Pipets are checked every six months and results are documented.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.8.3 Pipets are checked for reproducibility and the results are recorded.					
LB.9.	Thermometers in use are checked against an appropriate thermometric standard device before being placed in service.					
LB.10.	Temperatures are checked and recorded, and acceptable ranges are defined for all temperature dependant equipment (water baths, dry baths, heating blocks, incubators and ovens, refrigerators and freezers).					
LB.11.	The lab has evidence of corrective action taken if temperature exceeds the acceptable ranges for temperature dependant equipment, including evaluation of contents for adverse effects.					
	LB. 11.1 An IPP in place for corrective action.					
	LB. 11.2 Evidence of corrective action.					
LB.12.	All balances are properly maintained by:					
	LB.12.1 Periodically checking against a certified standard weight.					
	LB.12.2 Cleaning, servicing and mounting them such that vibrations do not interfere with readings.					
INSTRUMENT MAINTENANCE						
LB.13.	The lab has a schedule or system for the regular checking of all instruments including periodically checking the operating speeds of all centrifuges or as needed for the intended use, in a safe manner.					
LB.14.	The lab has a system for unscheduled maintenance that includes:					
	LB.14.1 Utilizing the QC run charts to detect trends or malfunctions.					
	LB.14.2 Documenting the linearity limits for specific instruments.					
	LB.14.3 Providing instructions for minor troubleshooting and repairs of instruments (such as manufacturer's service manual).					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.14.4 Maintaining records AT or NEAR each instrument to document all repairs and service procedures.					
REAGENTS						
LB.15.	Reagents and solutions are properly labeled, as applicable and appropriate, with the following elements:					
	LB.15.1 Content, quantity, concentration and / or titer.					
	LB.15.2 Storage requirements.					
	LB.15.3 Date prepared or reconstituted by laboratory.					
	LB.15.4 Expiration date.					
	LB.15.5 All reagents are used and stored as recommended by the manufacturer.					
	LB.15.6 All reagents used must be within their indicated expiration date.					
	LB.15.7 If there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.					
	LB.15.8 New reagent lots are checked against old reagent lots or with suitable QC material before or concurrently with being placed in service.					
RESULTS REPORTING						
LB.16.	The lab has an accepted system and clear method for results reporting:					
	LB.16.1 Age and sex specific reference intervals (normal values) are verified or established by the laboratory. If a formal reference interval study is not possible or practical, then the laboratory carefully evaluates the use of published data for use as the formal reference.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.16.2 Defining upper and lower limits of the analytical measurement range (AMR) for all analyses (results that fall outside these limits must be appropriately reviewed and re-assayed if necessary before reporting).					
LB.17.	The lab has an established Turn Around Time (TAT) to report results for all different kinds of tests and:					
	LB.17.1 All STAT tests are be defined and reported within 1 hour.					
	LB.17.2 The lab has a policy for Turn Around Time (TAT) for routine test in agreement with medical staff.					
COLLECTION MANUAL						
LB.18.	The lab has a specimen collection manual that covers:					
	LB.18.1 Methods for patient identification (2 unique patients' identifier).					
	LB.18.2 Methods for patient preparation.					
	LB.18.3 Specimen collection and labeling.					
	LB.18.4 Specimen preservation.					
	LB.18.5 Specimen storage.					
	LB.18.6 Condition for transportation.					
LB.19.	Specimen identifications and labeling are checked periodically to prevent errors in mixing the specimens or labeling them.					
LB.20.	There are clear instructions to be distributed to the physicians and paramedical personnel for proper collection, handling, transportation, and preparation for all samples including cytology and histology specimens.					
LB.21.	Services not available are out sourced to an accredited lab and:					
	LB.21.1 There is documentation of selection process and certificates of accreditation are available.					
	LB.21.2 A list of tests to be sent out is available.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.21.3 There is an IPP for specimen transportation and result reporting.					
MANUAL PROCEDURE						
LB.22.	The lab procedure manual that includes policy & procedure is available and approved by the lab director. This manual includes:					
	LB.22.1 A sectional policies and procedure that is readily available for all staff.					
	LB.22.2 A documented review every 2 years by the lab section head and / or designee.					
	LB.22.3 It is mandatory that all lab personnel are knowledgeable with the relevant policies and procedure.					
LB.23.	The lab has a policy that defines the test to be reported as "panic values".					
	LB.23.1 Name of the person providing the results.					
	LB.23.2 Name of the person receiving the results.					
	LB.23.3 Time of the call.					
BLOOD BANK						
LB.24.	Policies and procedures are written and enforced for all aspects of work related to blood and blood products and:					
	LB.24.1 Blood and blood products are maintained and available according to the size of the Hospital and its scope of service.					
LB.25.	There are policies on how to collect, handle, and store blood which includes:					
	LB.25.1 Donor selection criteria for blood collection.					
	LB.25.2 Donor consent shall be obtained before donation.					
	LB.25.3 Aseptic collection method shall be clearly written and strictly followed by staff.					
LB.26.	Care of donor is addressed in the policies and procedures and includes:					



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Standard	FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.26.1 Treating donor adverse reactions.					
LB.26.2 The necessary equipment and supplies for immediate assistance and care.					
LB.26.3 Donor selection criteria is done in private and confidentiality is maintained.					
LB.27. The following blood bank procedures are available, performed and documented according to blood bank policy:					
LB.27.1 Blood type/ Rh.					
LB.27.2 Cross matches.					
LB.27.3 Antibody screening and identification.					
LB.28. A tracing record for all blood units is available and includes:					
LB.28.1 Following strict policy and procedure for screen donated blood.					
LB.28.2 Following strict policy and procedure for donor notification of abnormal test results.					
LB.28.3 Keeping a record to ensure easy tracing of a unit of blood from drawing until final disposition.					
LB.29. There is a clear hospital policy when blood is ordered.					
LB.29.1 A positive identification for blood and blood products according to policy and procedure.					
LB.29.2 A policy on how to handle a blood shortage.					
LB.30. Blood is ordered only by authorized physician.					
LB.31. The hospital has a policy for reporting all adverse transfusion reactions. The report is reviewed by the lab director and submitted to Blood Utilization Committee.					
LB.32. There is an IPP for reporting blood utilization and blood product wastage.					
LB.33. All equipment, refrigerators, and freezers are monitored and:					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.33.1	Equipment used to regulate the temperature of blood, blood components and reagents have the required thermometers, recorders, alarms and other monitoring devices. (This includes heating blocks, water baths, and devices of blood components).					
LB.33.2	An approved blood-warming device is used appropriately as indicated, and monitored so that blood is not warmed above 42°C.					
LB.33.3	Donor's blood not intended for preparation of platelets is refrigerated at a temperature of 1° - 6°C. If platelets are to be harvested, donated blood are kept at 22-24 °C.					
LB.33.4	Refrigerators and freezers for blood storage have central electronic monitors or twenty-four (24) hour chart recorders to ensure all blood and components are continuously stored at acceptable temperatures.					
LB.33.5	If there is no continuous automated recording; temperatures are manually recorded at least every four (4) hours. The recorded temperature on all systems is checked at least once daily.					
LB.33.6	The temperature recording sensor is stored in a volume of liquid, equal to a unit of blood, (e.g. water).					
LB.34.	The alarm system has a separate power source in order to ensure proper monitoring of power and:					
LB.34.1	The alarm system is maintained periodically.					
HISTOPATHOLOGY & CYTOPATHOLOGY (ANATOMIC PATHOLOGY)						
LB.35.	A complete procedure manual for Histopathology and Cytopathology is available with approved policies and procedures signed by the lab director. All lab personnel are knowledgeable about the contents of the procedure manual.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.36.	All specimens removed from patients should be sent to the pathology. Any specimen that is not submitted to pathology or exempted from microscopic examination is approved by the lab director in agreement with the medical staff.					
LB.37.	The pertinent previous cytological and /or histological material from the patient are reviewed with current material being examined.					
LB.38.	When significant disparities exist between frozen section, cytology, or gross evaluation and final pathology diagnosis, this is reconciled and documented either in the pathology report or in the departmental quality management file.					
LB.39.	All gross specimens are examined by a pathologist. The specimens must be retained at least 1 month after the final pathology reports are signed and results reported to referring physicians.					
LB.40.	The pathologist has direct supervision on all stages of specimen processing and staining. There also documented evidence of daily review of the technical quality of histological preparations by the pathologist. All special stains and immunohistochemistry stains have negative and positive controls.					
LB.41.	The pathology report includes all the relevant information for proper patient management, and is signed by a qualified histopathologist and / or cytopathologist. (Presence of IPPs in pathology reporting is highly recommended to provide consistency in reporting).					
LB.42.	The pathology reports Turn Around Time for frozen section and routine specimen (Histology & Cytology Specimen) is defined and monitored.					
LB.43.	All intra-departmental and extra-departmental cases submitted for consultation are documented and sent to be included with the original pathology report.					
LB.44.	Pathology records and materials are retained at least for an appropriate period:					
	LB44.1 Accession log records 2 years.					
	LB44.2 Paraffin blocks 10 years.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB44.3 Glass slides and reports 10 years.					
	LB44.4 Cytopathology and Histopathology Reports 10 years.					
	LB44.5 Gynecologic and non-gynecologic glass slides 5 years.					
	LB44.6 Fine needle aspiration glass slides 10 years.					
LB.45.	There is a documented criterion for categorizing a gynecologic specimen as unsatisfactory. The unsatisfactory rate is monitored by lab director. Also, the statistical records are maintained of the number of cases of the following Cytopathology results:					
	LB45.1 Diagnostic category (including unsatisfactory cases).					
	LB45.2 Significant cytologic / histologic discrepancies (as defined by laboratory policy).					
	LB45.3 Where re-screen resulted in re-classification of a result as pre-malignant or high malignant.					
	LB45.4 Where histopathology results are available to compare with malignant or high-grade squamous intra-epithelial lesion (HSIL) cytopathology results.					
SAFETY						
LB.46.	For lab safety, there is evidence that the chief of the lab cooperates with the safety officer of the hospital and is following the general safety guidelines of the hospital and includes:					
	LB.46.1 A lab safety officer appointed.					
	LB.46.2 A written job description for the Safety Officer.					
	LB.46.3 The safety officer is a member of the safety committee (preferred).					
LB.47.	The lab safety officer ensures the lab compliance with the FMS standards.					
LB.48.	The lab has a safety manual that is approved by the laboratory director and available to all laboratory staff that includes the following:					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.48.1 Handling chemical spills and how to use the spill kits, with posted instructions.					
	LB.48.2 How to handle chemical hazards, and reduce their risk.					
	LB.48.3 A list of all the chemical hazards, and their manufacturers, (e.g. mercury and ethylene oxide).					
	LB.48.4 The documentation of all laboratory accidents resulting in property damage or involving spillage of hazardous substances.					
	LB.48.5 The reporting of all occupational injuries or illness that require medical treatment (more than first aid).					
	LB.48.6 Fire prevention and control.					
	LB.48.7 The safe handling of electrical equipment.					
	LB.48.8 Hazardous waste handling, storage, and disposal.					
LB.49.	Fire safety is implemented according to the Facility Management Safety (FMS) chapter and includes but is not limited to:					
	LB.49.1 Training all staffs how to use fire extinguishers.					
	LB.49.2 Being able to state what action to take in the event of fire.					
	LB.49.3 Posting maps to show the evacuation routes.					
	LB.49.4 Fire alarms, fire extinguishers are checked periodically by the hospital safety officer.					
LB.50.	Annual electrical checks are conducted which include:					
	LB.50.1 Grounding checks conducted on all outlets.					
	LB.50.2 Electrical equipment grounded or doubly insulated.					
LB.51.	All compressed gas cylinders are marked and clearly identified the type of gas contained and they are:					



Laboratory (LB)

Standard	FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.51.1 Marked (full not in use/full in use/empty).					
LB.51.2 Placed in an upright position and mounted against the wall or a stand.					
LB.52. The following safety signs and phone numbers are posted:					
LB.52.1 All doors leading to the lab are marked to indicate hazard.					
LB.52.2 No smoking signs.					
LB.52.3 Caution signs of potential hazards.					
LB.52.4 Emergency telephone numbers.					
LB.52.5 Danger signs in areas where special precautions are required.					
LB.53. All sharp wastes (needle, syringes, blades, lancets) are discarded in a puncture proof rigid labeled container and all containers are:					
LB.53.1 Discarded when 2/3 full.					
LB.53.2 Discarded in a safe and sanitary manner.					
LB.54. Eye wash stations and emergency showers are located within 30 meters where acids, caustics, corrosives and oxidizers are located.					
LB.55. There are no obstructions to exits, fire extinguishers, fire alarm boxes, emergency blankets, safety showers and eye wash stations, and:					
LB.55.1 Emergency lighting is adequate for safe evacuation of the laboratory.					
LB.55.2 All exits are maintained free of obstructions. All exits are free of locks or fastening devices that could prevent free escape.					
LB.55.3 All rooms in the laboratory have direct and unimpeded access to the outside corridor or a second exit.					
LB.55.4 All doors leading to laboratories are marked to indicate the fire hazards of materials used within this area					
LB.56. All liquid materials are stored in a way to secure them against spills.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.57.	Formaldehyde and Xylene vapor concentrations are monitored at least once a year.					
LB.58.	Special containers are available for broken glass.					
LB.59.	All containers of hazardous materials are labeled with precautionary labels e.g. flammables, corrosives, oxidizers etc.					
LB.60.	Flammable gas (acetylene, hydrogen, hydrocarbons, propane) cylinders are stored in a separate room or enclosure reserved exclusively for that purpose and with a fire-resistance classification. The area must be well ventilated and:					
	LB.60.1 Flammable gases are not stored within 6 meters (20 feet) of oxidizing gases unless separated by a firewall.					
	LB.60.2 Flammable liquid storage cabinets are labeled and vented.					
	LB.60.3 Highly flammable and toxic procedures are performed in a fume hood.					
	LB.60.4 A specially constructed storage room is provided for large amounts of flammable or combustible liquids. This includes a floor seal across the door to contain liquids, explosion-proof fixtures and venting of vapors to the outside.					
	LB.60.5 Refrigerators and freezers approved for storage of flammable liquids are identified with a sign or label.					
LB.61.	The section of the lab dealing with Radioactive material is marked with a Radiation sign, and staff training in handling and disposing of RA material is documented.					
LB.62.	If the mercury is used in the lab, a written plan is in place to reduce or eliminate the usage of mercury.					
LB.63.	Exhaust air from biological safety cabinets is filtered through high efficiency particulate air (HEPA) filters.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.63.1 Inspection for condition and fit of the HEPA filters for air flow velocity and smoke patterns, and for output of UV lights.					
LB.64.	Fume hoods are inspected and certified at least once a year and this includes:					
	LB.64.1 Inspection for air flow velocity and smoke patterns, and for output of UV lights.					
QUALITY MANAGEMENT PROGRAM						
LB.65.	The lab must have quality management program. This is approved by the lab director and available for all lab personnel.					
LB.66.	The lab director designates a qualified person to coordinate the quality management program with other medical departments. Also, this person is in-charge of implementing the quality management program in the department.					
LB.67.	The lab develops the quality indicators to evaluate and detect problems. These following quality indicators are monitored:					
	LB.67.1. Incident reports.					
	LB.67.2. Turn around time for lab test.					
	LB.67.3 Specimen identification errors.					
	LB.67.4 Corrected Pathology and lab result reports.					
LB.68.	The incident and accident reports are incorporated into the laboratory's quality improvement program and include:					
	LB.68.1 An evaluation of the incident and accident reports to avoid re-occurrence.					
LB.69.	There is a system for proficiency testing in the laboratory. This can be either by participating in external PT or performing split sample analysis. The split sample can be with a reference lab, national or international accredited lab or established in house method.					
	LB.69.1 All the problems identified by PT have been recognized and corrected.					



**Laboratory
(LB)**

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.70.	Documented quality control program is available to clarify the following:					
	LB.70.1 Results of the control.					
	LB.70.2 Instruments function.					
	LB.70.3 Temperature limits for procedures.					
	LB.70.4 Expiration date on reagents.					
	LB.70.5 Periodic maintenance program for equipment.					
	LB.70.6 Checking of tolerance limits.					
	LB.70.7 Checking pipettes and dilutors for accuracy.					
	LB.70.8 Checking media for quality.					
	LB.70.9 The results of QC assays are reviewed before reporting the results.					
	LB.70.10 The lab has a system to detect and correct analytic errors or uncertainty from each test and instrument.					
INFECTION CONTROL						
LB.71.	For Infection Control: there is evidence that the lab is following and cooperating with the Infection Control Department of the hospital and implementing all the rules and guidelines and:					
	LB.71.1 Gloves, masks, and eye, face shield, gowns, and aprons and lab coats are available and are worn as appropriate on lab sections.					
	LB.71.2 Eating and drinking is prohibited.					
LB.72.	Employees receive information on the potential risk of infections from materials that they work with and they are:					
	LB.72.1 Trained on how to clean up the leaks or the spills according to policy.					
	LB.72.2 Trained on how to dispose of infectious material according to policy.					
	LB.72.3 Trained on how to clean and disinfect work surface areas and equipment according to policy.					



Laboratory (LB)

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
	LB.72.4 Trained on how to handle infections specimens e.g. T.B and how to dispose them according to policy.					
LB.73.	Universal precautions are implemented to protect lab employees from exposure to pathogens by:					
	LB.73.1 Implementing universal precautions for handling blood and body fluids.					
LB.74.	All specimens of blood and body fluids are transported in leak-proof containers.					
LB.75.	Clean and contaminated working areas are marked and:					
	LB.75.1 There is evidence of proper cleaning by housekeeping.					
LB.76.	All employees are vaccinated with (HBV) Hepatitis B Vaccine.					
LB.77.	The lab has a policy for safely handling of reagents.					
LB.78.	A Class II safety cabinet is required when working with high infectious material and:					
	LB.78.1 Hoods used in the lab are tested periodically.					
LB.79.	Negative pressure is maintained in laboratory dealing with high infectious material.					
LB.80.	The lab has a policy on how to deal with suspected TB specimens, and:					
	LB.80.1 Samples for TB testing are dealt with as high risk specimens.					
	LB.80.2 Staff handling TB samples receives special training and this is documented.					
	LB.80.3 The TB room is separate from the main lab and negative pressure monitored.					
	LB.80.4 Gowns, aprons, gloves and face shield are used when handling TB specimens.					
	LB.80.5 Hoods and safety cabinets are monitored for efficiency and work is stopped when hoods or safety cabinets are not properly working.					
THE POINT OF CARE TESTING (POCT)						



**Laboratory
(LB)**

Standard		FM (3)	PM (2)	MM (1)	NM (0)	NA
LB.81.	There is documented evidence of ongoing evaluation by the laboratory director or designee of point of care testing and ;					
	LB.81.1 A point of care testing has a written QC/QM program.					
	LB.81.2 A list of all point of care testing equipment in the hospital is available in the laboratory.					
	LB.81.3 A documented procedure manual for POCT available in the lab and in the areas where POCT is performed.					
LB.82.	A documented policy is in operation to detect and correct significant clerical and analytical errors and unusual or unexpected test results.					
	LB.82.1 The lab has an appropriate person available on all shifts to assist with trouble shooting or other unusual POCT situations					
	LB.82.2 There is a documented orientation, training, and competency for POCT users.					