PATHOLOGICAL LABORATORY ACCREDITATION DRAFT DOCUMENT

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Introduction:

Health care delivery is no longer a simple process of examining the patient and giving him a prescription. Over the years there has been rapid expansion in the various branches of health care services. As part of this expansion process and explosion of scientific medical knowledge, laboratory diagnosis has gained tremendous importance in today's practice. Through the use of quality control (QC) the laboratory can ensure that the results being issued by it are reliable enough to allow decisions to be taken with confidence. Incorrect laboratory results may lead to wrong management decisions with possible fatal results. The reliability of laboratory results is therefore most important. It is not sufficient to ‘think’ that ‘my’ results are satisfactory. This has to be proved with scientific evidence. Towards achieving quality, accreditation program need to introduce for the pathological laboratories in public and private sector. In general accreditation may be defined as **“*Accreditation is a formal process by which a recognized body usually an independent body assesses and recognizes that a health care organization meets applicable predetermined and published standards.”*** The accreditation also can be defined as a process on system under which an organization / institution on achieving or reaching a definite level of excellence or adequacy and or meeting the criteria/ standard set down by an authority gets certification.

Therefore, Laboratory Accreditation is a process which gives formal recognition to the technical competence of a laboratory to perform specific tests, types of tests or calibrations. The process requires the maintenance of a documented quality management system and identification of personnel qualified and authorized to perform tasks related to the scope of accreditation.

In Bangladesh there is no system of pathological laboratory accreditation for the public and private sector by an independent organization. The regulatory framework for the licensing of private sector pathological laboratory exists as 1982 clinic ordinance. The process of licensing and renewal of pathological laboratory in the private sector can invite the quality aspect of laboratory. This is an initiative for addressing the accreditation issue with the support of World health organization and mostly focused the outlines, not very much comprehensive. One working group formed with the relevant expert and they prepared this document. Detailed and comprehensive document is needed to materialize the accreditation concept for the pathological laboratories in the public and private sector.

Accreditation concept:

Some times confusion arises among the definitions like certification, licensure and accreditation. For the clarity the definitions are:

- ***Accreditation:*** *Public recognition by a national healthcare accreditation body of the achievement of accreditation a standard by a healthcare organization's, demonstrated through an independent external peer assessment of that organization's level of performance in relation to the standards.*
- ***Certification:*** *Formal recognition of compliance with set standards (e.g. ISO 9000 series for quality systems) validated by external evaluation by an authorized auditor.*
- ***Licensure:*** *Process by which a government authority grants permission, usually following inspection against minimal statutory standards, to an individual practitioner or healthcare organization to operate or to engage in an occupation or profession.*

Definition of Pathological / Medical laboratory

Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

Purpose of pathological laboratory accreditation

The accreditation program provides an effective means whereby a laboratory can assess their level of performance against national standard. The accreditation standards offer a means whereby organization/pathological laboratory can monitor and improve their performance on an ongoing basis.

The following things can be achieved by laboratory accreditation

- *Standard service delivery*
- *Protect service quality*
- *Assesses capacity / strength of the lab/organization*
- *Encourages continuous improvement in respect of quality service delivery*
- *Promote development to provide better care*
- *Detect deficiencies with an aim to improve the services*
- *Gives opportunity to rectify for future*
- *Safe guard to the public*

- *Ensures reliability of quality and services.*

Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation.

Objectives of pathological laboratory accreditation

- To assess quality and safety of care;
- To assess a health care organization's/laboratory ability to ensure continuous improvement in providing quality service;
- To formulate explicit recommendations for the improvement;
- To involve professionals at all stages of the quality initiative;
- To provide external recognition of the quality of care;
- To improve public confidence
- To assess quality and safety of care;

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Benefits of the providers

- A useful management tool.
- A cost effective means to review current practices.
- A program of continuous organizational developments.
- Motivates staff and develops greater team spirit.
- Develops higher standards.
- Improves patient care.

Benefits of the purchaser

- Tested performance standards focused on patient care.
- Achievement of quality standard demonstrated by an independent organization.
- Encourages continuous organizational development.
- Improve delivery of patient care.
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The benefits of accredited pathological laboratories are:

- *It can be used as a marketing tool;*
- *It supports policies to keep abreast of new technological developments;*
- *It promotes continuous improvement of the services offered;*
- *Effective management of the quality system enhances staff discipline and development;*
- *Users have confidence in the technical capability of the accredited lab;*

- *Users of calibration services have confidence in the accuracy of their measurements;*
- *Reliable test data aid the decision making process for tenders and contracts;*
- *Test results from accredited labs provide confidence that supplies comply with specifications, and*
- Test data contribute to consistently high quality products.

The following elements as intrinsic to an accreditation program success (Donahue & O' Leary)

Mission & Philosophy

Infrastructure & authority

Published performance standards

Management of field operation

A framework for accreditation decision making

Accreditation data base

Accreditation program sustainability

Quality aspect of pathological lab

Definition of Quality:
Quality means meeting the predetermined requirements of the users for a particular substance or service.
Benefits of Quality assurance:

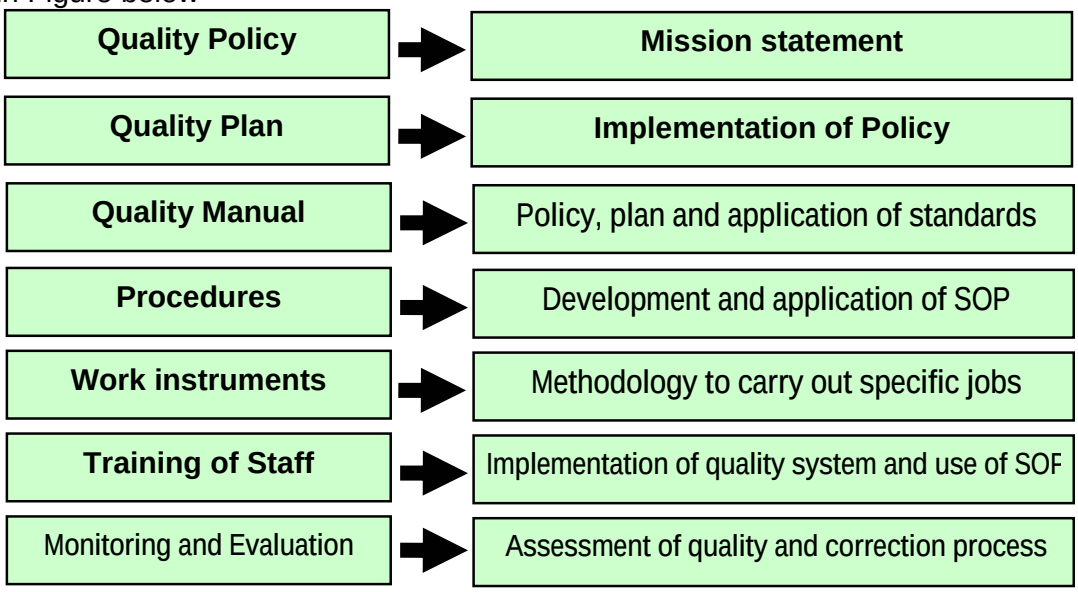
- Production of a quality product or generation of a reliable service
- Helping the physician in establishing proper diagnosis rapidly, thus generating confidence and better health care for the patient
- Creation of a good reputation for the laboratory
- Motivation factor for staff to work better
- Mandatory requirement for accreditation
- Prevention of legal suits and associated complication

Good laboratories practices:

- Proper collection of samples
- Appropriate identification of specimen with special level of hazardous specimens
- Proper transportation to laboratory at appropriate temperature
- Collection and storage under conditions which prevent deterioration of the sample before the performance of test
- Accurate performance of test
- Release of reports to the correct destination in the shortest possible time
- Cordial relationship with the users
- Development of a quality system

Development of a quality system:

The development of a quality system can be done in a step-wise approach as shown in Figure below



- The quality manual of a laboratory is a document or a set of documents describing the organizational structure, responsibilities, procedures and processes by which the laboratory achieves its objectives and gains confidence in its work. The manual is indispensable for achieving and maintaining good overall quality. Furthermore, the preparation of a quality manual may induce the laboratory to improve quality.
- The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice. The hospital management shall ensure that these policies and objectives are documented in the quality manual and communicated to, understood by, and implemented by all laboratory personnel concerned. The quality manual contents are as follows

Contents of quality

These are:

- Quality Policy and Quality System
- Organization
- Quality Control
- Personnel
- Accommodation and Environment
- Equipment
- Reference Materials
- Test Procedures
- Handling of Reagents
- Sample Collection, Storage and Disposal
- Maintenance of Records
- Laboratory Reports and Dispatch of Reports

Quality policy

- The aim of the laboratory is to provide clinically useful information through laboratory measurement of samples from patients, taking into account the allocated resources. The quality policy is implemented by the following means:

1. Proper sample collection, stabilization, transport, sample preparation and identification.
2. Reliable analytical work so that systematic and random errors do not exceed specified limits.
3. Turn-around time within specified limits for routine and emergency measurements, and for rare routine measurements.
4. Data reported in a clear form and supplemented with relevant information, including reference intervals to allow reliable clinical interpretation.
5. Appropriate communication to the clinicians so that the results will be interpreted correctly and logically integrated into further (clinical and laboratory) evaluation of the patients, and that the clinicians become aware of unexpected problems and errors.

Standard operating procedures

The preparation of test procedures comes under the broad heading of Standard Operating Procedures (SOPs). SOP is a clear, concise and comprehensive written instruction of a method or procedure which has been agreed upon and authorized as the operating policy of the department.

In general, SOPs, which mainly contain detailed descriptions of each analytical method, are essential for maintaining the same analytical quality over a long period of time. The procedures are a prerequisite to correct transfer of methods from one laboratory to another. The contents of SOP are as follows:

- Principle of method
- Specimen types, collection and storage
- Reagents, standards and control - preparation and storage
- Equipment, glassware and other accessories
- Detailed procedure
- Calculations, calibration curve
- Analytical reliabilities – (QC and Statistical assessment)
- Hazardous reagents
- Reference range and clinical interpretation
- Limitations of method (e.g. interfering substances and troubleshooting)
- References
- Date and signature of authorization
- (Effective date + Schedule for review)

Stages of Pathological laboratories accreditation process:

The Pathological laboratory wants to be accredited, By the NAB must observe the following steps/phases:

1. ***Preparatory Phase.***
2. ***Onsite assessment***
3. ***Desktop review.***
4. ***Certification of the laboratory***
5. ***Re-accreditation***

1.Preparatory Phase:

Submission of application for an Initial Laboratory Survey

Organizations that wish to be accredited must submit an application to the National accreditation body in a prescribed proforma formulated and approved by NAB. The application for initial Laboratory Accreditation is valid for six months from the date submission, which means after submission of the application, the authority of the laboratory still have time to finish the preparatory work before the on-site survey takes place. It is best to submit the application when the authority of laboratory is confident that **Laboratory Accreditation Overview be** able to demonstrate a four month track record of compliance at the time of the on-site survey. On submission of the application for initial Laboratory Accreditation, the lab authority may specify time periods when they would like the survey to take place, and/or specific time periods when the survey *not* to take place. The National accreditation body will make every effort to accommodate the request.

Other preparatory work for accreditation

Once the application for Accreditation is received, the identified persons of National accreditation body office will answer the relevant query about survey preparation, and also will help the applicant through each step of the accreditation process. The authority of applicant pathological laboratory will do the following preparatory work for accreditation

• updating of the necessary information including demographic information, address, contact name(s), etc., are needed for accreditation survey.
• To know the areas, issue and other related things in relation to accreditation as a part of preparatory work by the applicant authority will ask necessary help from the accreditation authority.
• Performance review trail with the help of published standard and measurement tool formulated by the NAB.

The laboratory on-site survey is scheduled as an announced survey based on information provided in the application for Laboratory Accreditation. With the information provided, the national accreditation body will fix the number of days

required for a survey, the composition of the survey team, the fees, and the services to be reviewed. Approximately four weeks before the survey, the NAB will notify the date of the survey and also the documents and records will need to gather for the survey. The NAB will select the assessors before initial survey. The NAB will send letter to the applicant laboratory authority and the assessors two week before for necessary action to complete the preparation of survey.

Changes in the Organization during the application Process

The laboratory/ organization must notify the NAB immediately if it undergoes a change that modifies the information reported in the application for Accreditation. Information that must be reported includes:

- a change in organization name and/or ownership;
- a change in Medical Director;
- a significant increase or decrease in the volume of services;
- a change in the number of specialties or subspecialties;
- the addition of a specialty, subspecialty, or new category of testing;
- change in instrumentation and /or methodology;
- a significantly altered building/physical plant.

The NAB may schedule an additional survey for a later date if its survey team arrives at the organization and discovers that a change was not reported. The NAB may also review any unreported services addressed by its standards. The NAB will make the final accreditation decision for the organization only after reviewing all services provided by the organization according to the formulated standard by NAB.

Definition of Postponements and Delays

After fixation of date by the NAB for initial survey, the applicant authority may send request for the delay or postponements of the visit by showing the valid reason. The NAB may accept the request after reviewing the reason or may reject the request**.** The request for delay or postponements must reach the NAB in writing at least four weeks before the fixed date of conducting survey. The NAB reserves the right, however, to deny any request for a postponement or delay, regardless of the organization's willingness to pay the special fees.

Accepted Reasons for Postponement

An organization may postpone initial scheduled surveys when one or more of the following events happen:

- a natural disaster or another major unforeseen event occurs that totally or substantially disrupts operations;
- the organization is involved in a major strike, has ceased accepting patients, and is transferring patients to other facilities; or
- patients, the organization, or both are being moved to another building during the scheduled survey or any other valid reason.

Length of Postponement or Delay

An initial survey ordinarily may be postponed or delayed for no more than six months.

Accreditation Participation Requirements

The registration as a pathological laboratories in favor of the applicant organization from the Directorate general of health services, Dhaka i.e license of pathological laboratories.

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Documentation Checklist required for accreditation

The following materials are generally required to be available to the surveyors at some point during the laboratory survey:

- Completed test volume and specialty report
- Administrative policies and procedures
- Technical procedure manuals for all areas
- Specimen collection procedure manuals
- Quality control policies and procedures
- Safety and infection control procedures (including the chemical hygiene plan)
- Evidence of medical direction or consultation (as applicable)
- Transfusion services policies and procedures
- If applicable, policies and procedures governing cell savers
- Tissue storage policies and procedures (bone, tendons, skin, other tissue)
- Track records of performance improvement or quality assessment and improvement activities
- Departmental records for inpatients (if applicable) and outpatients
- Staffing information
- Applicable laboratory and personnel licenses
- Job descriptions and performance appraisals, including annual competency assessment
- Personnel information showing qualifications
- Education programs and records of participation
- Preventive maintenance reports for all equipment
- Instrument function, calibration, maintenance, and repair records
- Temperature records for all temperature compensated spaces

Compliance Requirements

The Standards Manual

The NAB Comprehensive Accreditation Manual will be formulated by a working group from different discipline. The manual will contain different standard set by the NAB for compliance. The manual can be used for the self appraisal of the pathological laboratory authority and also for the assessor recruited by the national accreditation body. The standards manual will be divided into following section.

- Performance Improvement
- Leadership
- Environment of Care
- Management of Human Resources
- Management of Information
- Infection Control
- Quality Control
- Waived Testing

2. Onsite assessment by the surveyors

Duration of survey:

All surveys are at least two days in duration. However, depending on the size and the scope of the laboratory services provided, a survey may last five days or more. One to two weeks before survey, the assigned coordinator of surveyors or NAB authority will contact the laboratory to discuss the survey schedule.

Key components of a survey

a) Opening Conference

This conference, which will be held on the first day of the survey, is a meeting between key laboratory staff and the surveyor(s). The meetings will lasts approximately one hour. The purpose of the meeting will be

- To introduce the surveyor(s), laboratory leaders, and other key organization staff.
- Make any last-minute adjustments to the survey agenda.
- Address any support or logistical details concerning the survey.

After introductions have been made, the surveyor (or survey team leader) will give a brief description of how the survey is structured (the use of Priority Focus Process output, tracers and system tracers, meetings, and so on).

b) Briefing session by the laboratory authority

During this session, organization and laboratory leaders will explain the organization's purpose and structure to the surveyor(s). The meeting should continue at lasts for an hour. The following personnel from the organization will participate in the briefing session.

- The laboratory director and/or laboratory manager/laboratory in charge
- The survey coordinator from the respective pathological laboratory
- Other senior leaders and staff as designated by the organization

In the briefing session the organization will have the opportunity to describe its basic structure, mission, and vision, scope of care, patient population, and strategic planning approach to the Laboratory Accreditation Overview. The team leader of the organization will ask staff members to talk about how the organization provides

required laboratory testing services, focusing on management, oversight, and important processes and functions.

C) **Filling the prescribed and approved checklist (Area wise) by the surveyors**

The coordinator of the Surveyor will be responsible for allocating responsibilities among the surveyors and this allocation will be on the basis of individual experty of surveyors

The surveyors will visit all areas of the organization that affect the delivery of a laboratory service, including areas where orders are written or received, specimens are collected and processed, testing is performed, and results are documented and communicated. The surveyor will follow the entire testing process of the patient. Tracers will be selected on the basis of the mechanism by which samples are collected and should include at least one of each of the following, as applicable:

- Outpatient sample collected by laboratory personnel and transported to the laboratory
- Inpatient sample collected by laboratory personnel
- Inpatient sample collected by patient care personnel
- Sample sent to a reference laboratory
- Specimen from an Emergency Department patient

The surveyor will require the medical record, test requisition, lab equipment records, quality control records, laboratory test reports, and staff competency and the surveyor will tour the main laboratory, assessing the space and evaluating for environmental issues. This is an interactive tour between the surveyor and supervisory and other staff. Any staff may be interviewed about safety or other environmental issues.

- Give the surveyor an opportunity to observe the following:
  - Adequacy of space and resources for services provided
  - Implementation of infection control processes
  - Implementation of laboratory environment safety processes as defined in policies
  - Methods of inter-laboratory and organization-wide communication
  - Enforcement of a nonsmoking policy
  - Adequacy of the number of staff members

. A comparison will be made between the types of services provided and those listed on the survey application to ensure all have been included on the survey agenda. During the walk-through, the surveyor will also make observations regarding such functions as laboratory safety and infection control, laboratory security, safety equipment, laboratory space and configuration, storage of chemicals, management of information, and leadership. The surveyor may interview staff about safety and infection control practices, equipment use, hazardous materials use and waste disposal, and security of information.

Surveyor Report Preparation

The surveyor(s) will use this time to compile, analyze, and organize the data he or she has collected throughout the survey into a report reflecting the laboratory’s compliance with standards. The surveyor(s) meets with the laboratory and organization leaders, and other staff as appropriate, to present the survey findings and address questions and comments from staff. This meeting should last no longer than one hour.

- Review standards compliance issues that were identified during the survey.
- Allow staff a final opportunity to question the survey findings or present or have surveyors review evidence of compliance while the surveyors are on site.
- Reach agreement between the surveyor(s) and staff regarding the survey findings,

when possible.
• Review any follow-up actions that will be required.

3) Desktop review by the National accreditation body

- The National accreditation body for pathological laboratory will do the desktop review on the basis of assessment findings. The committee will fix-up the accreditation status:
- Denial of accreditation
- Provisional accreditation with some condition to fulfill within 6 months of time period.
- Conditional accreditation for one year
- Full accreditation for 2 years.

The accreditation status of the hospital will be based on the rating system.

a) Denial of Accreditation, when the pathological laboratory fails to demonstrate the compliance of standard approved by the National accreditation body during the onsite visit.
b) Provisional accreditation with some condition to fulfill within 6 months of time period. After six month of time period, if the lab authority again fails to demonstrate the compliance of NAB standard during the second visit then the accreditation will be denied.

c) Conditional Accreditation

This decision indicates that substantial compliance deficiencies exist in an organization. Correction of deficiencies, which serve as the basis for further consideration or awarding full accreditation, must be demonstrated through a follow-up survey. An organization is conditionally accredited when:

(a) The survey results in the assignment of follow-up monitoring in many areas, indicating that the organization's overall performance is marginal.

(b) One specific issue is serious enough to require closer monitoring; or

(c) An organization with this accreditation status is required to demonstrate sufficient improvement in a follow-up survey after one year.

(d) Full accreditation for two years. This decision indicates that an organization is in compliance with applicable standards at the time of the on-site survey or has successfully addressed the survey requirements.

4) Certification of the accredited pathological laboratories:

The National accreditation council after desk top review will determine the accreditation status on the basis of survey findings and will recommend certification. The NAB will forward the decision to DGHS for certification.

5) Re-accreditation

- The status of the accredited pathological laboratory will be re-ascertained immediately before completion of two years of receipt of accreditation. The same methodology will apply for re-accreditation process. The status of the pathological laboratory accreditation will be on the basis of rating system.
- If the institution failed to secure the standard of accreditation, the accreditation status will be canceled.

Assessment team:

The assessment team will comprise of eleven members:

Sl. No.	Type of discipline
1.	Specialist from Clinical Pathology
2.	Specialist from Microbiology
3.	Specialist from Biochemistry
4.	Specialist from Histopathology
5.	Specialist from Hematology
6.	Specialist from Virology
7.	Specialist from Blood transfusion medicine
8.	Specialist from Immunology
9.	Representative from Director Hospital, DGHS
10	Representative from NIPSOM
11	Representative from MOH&FW

Composition of the National Accreditation Body

Sl. No.	Composition	Position
1.	President, Pathological society	Chairman
2.	President, Society of Hematology	Member
3.	Director (Hospitals & Clinics), DGHS	Member
4.	Director -	Member
5.	Head	
6.	Head of the department of Microbiology, BSSMU	Member
7.	President, Society of Blood Transfusion Medicine	Member
8.	President, Bangladesh Society of Medicine	Member
9.	President, OGSB	Member
10.		Member
11.		Member
12.	Deputy Secretary, Hospital, MOHFW	Member
13.	Representative from WHO	Member
14.	Assistant Director (MBPC) Hospital, DGHS	Member
15.	Secretary General, Pathological society	Member Secretary

Terms of reference of national accreditation body

The specific terms of reference (TOR) of the National Accreditation Body are as follows:

- ***Set standard and norms for accreditation***
- ***Finalize assessment tools, assessment process and methods for the accreditation***
- ***Review the assessment report submitted by the assessment team.***
- ***Review technical issues and feasibility of the assessment report to see that the underlying principles of the accreditation standard***
- ***Recommend certification of accredited pathological laboratories to Director General, DGHS***

- ***Refer back to the assessor's/facilities with recommendations for resubmission after necessary alterations (according to specific recommendations) if not found technically competent.***
- ***The National Accreditation Body can co-opt any person in the committee from any discipline to foster their activities.***

Modus operandi of national accreditation body

- ***The term of the National Accreditation Body will be for five years and will be formed through official notification of MOHFW.***
- ***The body will work as an independent body.***
- ***The body will preserve the authority of making final decisions on the accreditation status of any Pathological laboratories or any discipline of the laboratory***
- ***Any interpretation of the body on standards will be treated as final.***
- ***The body will do the preliminary selection of the assessors and forward this to the DGHS for notification.***
- ***The body will be responsible for orienting the assessors on the overall process.***
- ***The National Accreditation Body will forward their decision to Director General, DGHS for awarding certification to the respective facilities as accredited pathological laboratories.***

- ***The NAB will be responsible for the development of accreditation manual, setting standard for different discipline under the broad area of pathology***
- ***For any decision making process agreement of majority member's of NAB will be considered necessary.***
- ***The National Accreditation Body can invite any member of the assessment team to facilitate the decision making process.***
- ***The secretarial support for the committee will be provided by Society of Pathology, Bangladesh.***

Rating:

The rating will be the summation of point scoring method and the total score of the rating system will be hundred. The use scale will be on a three-point scale of "0= No/insufficient compliance," "1=partial compliance," and "2=satisfactory compliance." The rating will be done on the basis of developed checklist by National accreditation body for service delivery area and also discipline wise.

- ***Five star rating system:***
  - ***One star: 50-60 -- Two star: 61-70***
  - ***Three star: 71-80 -- Four star : 81-90***
  - ***Five star : 91-100***
- ***To certify as an accredited pathological laboratories, the requisite minimum score will be 50.***

Some Important areas of pathological laboratories accreditation

Laboratory management shall be responsible for:

a) Setting quality objectives and undertaking quality planning
b) Preparing a quality manual
c) Appointing a quality manager
d) Establishing a procedure for document control
e) Establishing a procedure for control of process and quality records
f) Establishing a procedure for control of clinical material
g) Conducting management reviews

Quality objectives and plans

Implementation of a quality policy requires the establishment of quality objectives and plans. Laboratory management shall establish written quality objectives that are measurable and consistent with the quality policy and regularly reviewed. Laboratory management shall have plans to achieve and maintain its quality objectives.

Quality manual

A quality manual describes the quality management system of a laboratory and includes the quality policy and arrangements for its implementation.

Laboratory management shall be responsible for the preparation of a quality manual. The quality manual shall include:

a) a quality policy
b) a description of the quality management system
c) a presentation of the organizational structure
d) an outline of the structure of the documentation used in the quality management system

Personnel shall be familiar with and work to current versions of the quality manual and all referenced documentation. The quality manual shall be reviewed regularly, updated as required and any changes communicated to all personnel concerned.

Quality manager

The quality manager is the individual who ensures, on behalf of laboratory management, that the quality management system functions correctly. Laboratory management or management of the parent organization shall appoint a quality manager. The quality manager shall report to the level of laboratory management at which decisions are made
on policy and resources.

The quality manager, irrespective of other responsibilities shall have defined authority for:

a) Ensuring the quality management system is implemented and maintained
b) Reporting to laboratory management on the functioning and effectiveness of the quality management system
c) Coordinating awareness of the needs and requirements of users.

Laboratory management shall determine which process and quality records are to be retained and for how long. Notice shall be taken of current legislation, regulations and guidelines. Quality records shall be readily available to demonstrate compliance with the requirements and operation of the quality management system.

Management review

A management review of the quality management system serves to identify any changes required, to meet the needs and requirements of users, and any action needed to ensure the continuation of the service. Laboratory management shall conduct an annual review of the laboratory's quality management system and all its services. The review shall include:
a) Reports from managerial and supervisory personnel
b) Assessment of user satisfaction and complaints
c) Internal audit of quality management system
d) Internal audit of examination processes
e) External quality assessment reports
f) Reports of assessments by outside bodies
g) Status of preventive, corrective and improvement actions
h) Major changes in organization and management, resource (including staffing) or process.
i) Follow-up of previous management reviews

Personnel management

Laboratory management shall ensure that procedure(s) for personnel management which include:
a) Staff recruitment and selection
b) Staff orientation
c) Job descriptions and contracts
d) Staff records
e) Staff annual joint review
f) Staff meetings and communication
g) Staff training and education
h) Grievance procedures and staff disciplinary action.

Staff records shall include:

a) Personal details
b) Employment details
c) Job description
d) Terms and conditions of employment
e) A record of staff induction and orientation
f) A record of attendance at appropriate health and safety lectures and fire drills
g) A record of education and training including continuing professional development
h) Relevant educational and professional qualifications
i) Certificate of registration or license, if relevant
j) Reference from previous employment
k) Absence record
l) Accident record
m) Record of staff annual joint reviews

n) Record of competency evaluations, if appropriate
o) Occupational health record
p) Record of disciplinary action.

Staff training and education

There shall be a training and education programme for all members of staff governed by the following criteria:
a) Training and education shall be in accordance with guidelines from the relevant professional and registration bodies
b) All staff shall be given the opportunity for further education and training in relation to the needs of the service and their professional development.

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Premises and environment

A department requires sufficient space to ensure that work is performed safely and efficiently. The premises shall provide a working environment in which staff can perform required functions in accordance with current national legislation and regulations.
The premises shall have space for the following:
a) The functioning and use of all equipment
b) Specimen reception
c) Separation of incompatible activities
d) Facilities for staff
e) Facilities for patients
f) Facilities for storage.

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Facilities for staff

All staff needs facilities, within the department, to ensure personal safety, comfort and hygiene.
The premises shall have staff facilities that are readily accessible and include:
a) Safe and secure working arrangements
b) Adequate bathroom facilities
c) Access to a supply of drinking water
e) A changing area and secure storage for personal effects
f) Storage for protective clothing

Facilities for patient

The facilities available for patients should provide for privacy during reception and sampling and be suitable for the examination being performed.

Facilities for specimen collection and examination of patients shall include:
a) A waiting/reception area with suitable facilities and access for disabled persons
b) A phlebotomy area which offers privacy and recovery facilities
c) Toilet facilities for patients separate from those provided for staff.

Facilities for storage

The provision of sufficient storage space, under the correct conditions, is important in maintaining the integrity of samples, reagents and records.
There shall be separate storage facilities, as required, for:
a) Process and quality records
b) Clinical material

c) Blood and blood products
d) Hazardous substances
e) Drugs, vaccines and other therapeutics
f) Reagents
g) Waste material for disposal

Health and safety

A health and safety statement, and procedures to implement it, are required to ensure a safe environment in the laboratory for staff, patients and visitors. Laboratory management shall be responsible for:
a) Defining and implementing health and safety procedures
b) Ensuring that there is a safe working environment in accordance with current safety guidelines and legislation
c) Providing personal protective equipment
d) Delegating day to day management of health and safety to a designated individual
e) Providing model rules for staff and visitors to the laboratory
f) Where applicable, nominating a consultant microbiologist responsible for infection control and regular reporting to the Communicable Disease Surveillance Centre.
All staff shall be aware of their responsibilities relating to health and safety.

Laboratory management shall establish a health and safety procedure(s) that includes:
a) Action in the event of fire
b) Action in the event of a major spillage of dangerous chemicals or clinical material
c) Action in the event of inoculation accident
d) Reporting and monitoring of accidents and incidents
e) Risk assessments
f) Disinfection processes
g) Decontamination of equipment
h) Chemical handling
i) Storage and disposal of waste
j) Specimen collection and handling, transportation, reception and referral to other laboratories

Procurement and management of equipment

Laboratory management shall establish a procedure(s) for the procurement and management of equipment that includes:
a) Assessment and justification of need
b) Selection
c) Acceptance
d) Training
e) Maintenance, service and repair
f) Decontamination
g) Record of instrument failure and subsequent corrective action
h) Planned replacement and disposal
i) Adverse incident and vigilance reporting

There shall be an inventory of equipment that includes:
a) Name of manufacturer, contact person & telephone number
b) Serial number & condition when received
c) Date of purchase or acquisition
d) Record of contracted maintenance and calibration services
e) Record of equipment performance

Management of data and information

.
Laboratory management shall establish a procedure(s) for the management of data and information that includes:
a) Security
b) Access
c) Confidentiality and data protection
d) Backup systems
e) Storage, archive and retrieval
f) Secure disposal.

Information for users and patients

The information for users shall include:
a) Contact details of key members of staff
b) The location of the laboratory
c) Services offered by the laboratory
d) Times of opening of the laboratory
e) Details of any out of hours service or shift system
f) Instructions for completion of the request form
g) Instructions for transportation of samples, including any special handling needs
h) Availability of clinical advice and interpretation

Specimen collection and handling

Proper preparation of the patient, specimen collection and handling are essential for the production of valid results by a laboratory. Laboratory management shall establish a procedure(s) for the specimen collection and handling that includes:
a) Checking the completion of the request form and confirming the identity of the patient
b) Checking that the specimen container is labeled correctly
c) Checking that the patient is appropriately prepared
d) Ensuring that the specimen is collected correctly
e) Minimizing the risk of interchange of samples and sub samples
f) Ensuring that environmental and storage conditions are fulfilled
g) Ensuring the safe disposal of all materials used in specimen collection
h) Ensuring that high risk specimens are identified and processed correctly
i) Ensuring that all spillages and breakages are dealt with correctly
j) Minimizing the risk to ensure the safety of the specimen collector, carrier, the general public and the receiving laboratory.

Specimen transportation

Specimen transportation systems need to ensure the timely arrival of specimens at the correct destination at minimum risk to both laboratory and non laboratory personnel.
Laboratory management shall establish a procedure(s) for the transportation of specimens that includes:
a) Ensuring the safety of the courier, the general public and receiving laboratory
b) Packaging, labeling and dispatch
c) Protection of the specimens from deterioration
d) Reporting incidents during transportation that may affect the quality of the specimen or the safety of personnel.

Specimen reception

.
Laboratory management shall establish a procedure(s) for specimen reception that includes:
a) Accurate identification of the request and specimen
b) Recording of request form and specimen information
c) Recording the date and time of receipt of specimens
d) Handling urgent specimens
e) Ensuring staff safety.

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Selection and validation of examination procedures

The selection of examination procedures needs to be clear, appropriate and subject to regular evaluation. Examination procedures, including those for sampling, shall meet the needs and requirements of users and be appropriate for investigation(s) being undertaken. Examination procedures shall be validated for their intended use prior to introduction, and the methods used and results obtained, recorded. When examination procedures are changed so that results or their interpretation may be significantly different, the implications shall be explained to users, prior to the introduction of the change.

Examination procedures

Adherence to examination procedures is essential to ensure a quality diagnostic laboratory service. There shall be procedures for the conduct of all examinations that include and/or refer to, as applicable, the following:

a) Clinical relevance / purpose of examination
b) Principle of examination
c) Specimen requirements and means of identification
d) Equipment and special supplies
e) Reagents, standards or calibrants and internal quality control materials
f) Instructions for the performance of the examination
g) Limitations of the examination
h) Recording and calculation of results
i) Internal quality control procedures and criteria against which examination processes (measurement and observation) are judged
j) Reporting reference limits
k) Responsibilities of personnel in authorizing, reporting, and monitoring reports
l) Hazards and safety precautions

Recommendation:

1. Development of a comprehensive document on Pathological laboratory accreditation is an important aspect for the introduction and practice of laboratory accreditation in Bangladesh
2. National working group with relevant expert needs to form for the development of accreditation document
3. World health organization should provide financial and technical support for the development of a comprehensive document on Pathological laboratory accreditation
4. Professional organizations opinion needs to reflect in the document
5. Pathological society of Bangladesh should play major role for the introduction of lab. accreditation
6. The proposed accreditation system should be in accordance with the existing regulatory framework
7. The practice of pathological lab. accreditation of developed and neighboring countries needs to consult during the development of the draft document
8. Accreditation system need to introduce both for the public and private sector pathological laboratories
9. Financial support is needed for the continuation of proposed national accreditation body activities

Laboratory Accreditation: Assessment area for Histopathology Laboratory- Public and Private Sectors

INTRODUCTION:

The histopathology laboratory prepares tissue sections for establishing a histopathologic diagnosis. Histotechnology provides convincing physical evidence of disease by studying changes in tissues and has proved to be one of the most effective tools in diagnosing tissue abnormalities and cancerous condition. The specimens submitted to the laboratory come mostly from surgical operation theatre in the form of small pieces of tissues (biopsies) or whole organ. These tissues are submitted either fresh or immersed in a fluid fixative (e.g. 10% formalin). The result of the test mostly depends on subjective interpretation of the pathologist and relies on the skill and experience of the latter. However, optimum handling and preparation of the specimens by the histotechnologist and other stuffs greatly facilitate their gross and microscopic examination by histopathologist. In laboratories with large volumes of work, automation (e.g. automatic tissue processor) greatly reduces time of processing. Incorporation of immunohistochemistry is increasingly demanded particularly in difficult situation where morphological examination alone is not conclusive.

This document describes the specific requirements to be complied by histopathology section before they can be accredited.

ASSESSMENT AREA OF ACCREDITATION:

1. Infrastructure facility:

SPACE

The space area should be preferably 3000 sq feet in public and 2000 sq feet in private sector.The following areas should have sufficient space and are located so there is no hindrance to the work.

1. Laboratory director
2. Staff pathologists and residents
3. Clerical staff
4. Chief technologist
5. Laboratory
6. Report section
7. Waiting and Reception etc.
8. Lavatories
9. Library, conference and meeting room
10. Personnel lounge and lockers

It preferably should be centrally air-cooled and housed in the department of pathology in public institutions e.g. Medical college, postgraduate institutes, district hospitals etc.

ENVIRONMENT

1. Ambient or room temperature and humidity must be controlled to minimize evaporation of specimens and reagents, and not to interfere with performance of electronic instruments. Personnel comfort is also important.
2. Passageways should be unobstructed.
3. Floors, walls and ceilings should be clean and well maintained.
4. Bench tops, cupboards, drawers and sinks should be cleaned and well-maintained

2. Basic / general facilities:

Good water supply and electrical supply with generator facility/ IPS, and sewerage facility, waste disposal, adequate wash rooms, and lavatory.

3. Manpower with qualification:

The laboratory should have an organizational chart, personnel policies, and job description that define qualifications and duties for all positions. Personnel files should contain qualifications, references, performance evaluations, health records and continuing education records for each employee. Ideally these files should be located in the laboratory.

Following is a proposed organizational framework both for public and private laboratories.

SL	Name of the post	Qualification
1.	Laboratory director	MBBS, Postgraduate degree in anatomic pathology/ Laboratory Medicine
2.	Technical supervisor(s)	MBBS, Postgraduate degree in anatomic pathology
3.	Senior lab technologist	BSc/Diploma in health technology (lab) from a recognized paramedical institute with at least 3 years experience
4.	Junior lab technologist	Diploma in health technology (lab)
5.	Accountant cum store keeper	Bachelor degree in accounting
6.	Computer operator	H.S.C. with computer experience
7.	Desk clerk	H.S.C.
8.	Cleaner	S.S.C.

The technical personnel records should include the following:

1. Summary of training and experience
2. Formal certification or license
3. Description of current duties
4. Records of continuing education
5. Work related incident and /or accident records.

4. Job description

1. Laboratory director: He/she is responsible for overall supervision of the laboratory. He/she is also responsible for administration, budget preparation, planning, policy making, implementing quality assurance programs etc.
2. Technical supervisor (s): Within the laboratory's organizational structure, the actual position title may be different e.g. Senior and Junior consultant histopathologist.
a. Senior Histopathologist (technical supervisor): He/she is responsible for gross and microscopic examination of the tissue and reporting.
b. Junior Histopathologist (technical supervisor): He/she is responsible for grossing and helping senior histopathologist in reporting.
3. Senior lab technologist: He/she is responsible supervision of bench-work, preparation of stains and reagents, tissue processing after grossing of the specimen, record keeping, quality control. In appropriate cases he/she may be required to perform high-tech procedures in processing sample for immunohistochemistry and molecular pathology.
5. Junior lab technologist: Tissue processing and slide preparation, report checking, helping senior histotechnologist in his work.
6. Accountant cum store keeper: Maintain accounts and store keeping.
7. Computer operator: Report typing, Record keeping
8. Desk clerk: Receive samples and report delivery
9. Cleaner: Cleaning and waste disposal

5. Capacity development

1. There should be annual reviews of the performance of existing employees and an initial review of new employees within the first six months.
2. Competency of each person to perform his/her assigned duties has to be assessed following training, and at least annually thereafter.
3. Competency assessment for each individual must include the following elements as are applicable to individual's duties:

i) Direct observations of specimen handling, tissue processing, and section cutting on microtome, staining and slide preparation.

ii) Monitoring the recording and reporting of test results

iii) Direct observation of performance of instrument maintenance and function checks.

iv) Evaluation of problem-solving skills.

4. Retraining and reassessment of employee competency must occur when problems are identified with employees performance. If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and re-assessed in that particular area. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which include, supervisory review of the work, reassignment of duties, or other actions deemed appropriate by the laboratory director.
5. Documentation should be made of retraining and reassessment for employees who initially fail to demonstrate satisfactory performance on competency assessment.
6. There should be functional continuing laboratory educational program adequate to meet the needs of all personnel.

6. Specimen handling and identification:

The laboratory should develop its own way of specimen identification, giving the tissue a unique accession number. This may include the year and month the specimen was received, e.g. 01-05-08 could represent a specimen that was the first case received in

May 2008; the laboratory computer usually generates this number. If multiple specimens are received on the same patient from the same operation/procedure, then specimens may be given the same number followed by a numerical or alphabetical designation.
The specimen container label and accompanying request form should arrive in the laboratory already completed and should include patient's name, age or birth date, sex, address, referring surgeon, provisional diagnosis and brief clinical history, name of specimen, investigation required etc.
The label should be firmly attached to the body of the (not to the lid) container so that it cannot be separated.
The correct identification of the specimen(s) with its unique number is the link between specimen and the patient. Incorrect identification of any specimen results in the wrong diagnoses and incorrect treatment to potentially two patients.

The unique identification number given to the tissue sample should accompany the specimens throughout the entire laboratory process, including documentation in the pathology report.

There should be procedure manual containing collection/handling instructions of laboratory specimens. This specimen collection manual should be distributed to all specimen collecting areas and areas outside the main laboratory.

6. Equipment, instrument and other logistic support:

For surgical pathology gross room

The room should be large enough to permit the simultaneous of work of all the pathologists assigned to gross activities; it should be well illuminated and properly ventilated.
Each dissection area should contain the following:

1. A cutting board placed inside a metal box designed in such a fashion that all the fluids will flow directly into the sink.
2. Shelves for specimen container
3. Ready access to a sink with hot and cold water
4. Ready access to formalin
5. Dictation equipment
6. Computer terminal
7. Box of instruments- containing heavy and small scissors, different sized smooth and toothed forceps, a malleable probe, a scalpel handle, disposable blades, a long knife
8. Box of cassettes and labels

In addition, gross room should also contain the following equipment:

1. A large formalin container with formalin pumped into it by a mechanical pump and the fixative delivered to the individual dissection area by tubing system ending in faucets (tap).
2. Containers with other fixatives, with instructions on how to mix them at the time of use.
3. Photographic facilities for black and white and digital colour photography.
4. Large refrigerator
5. Band saw
6. Balances- one large for regular specimens and one delicate for small specimens.

For tissue processing

This may be automated or manual.

a. Automated tissue processing-

   Equipments-

   1. Tissue processor-

   i) Carousel-type (tissue transfer) processor: This type of processor carries tissue contained in baskets mechanically through a series of reagents housed in stationary containers.

   ii) Vacuum tissue processor: In this type of processor, tissues are loaded into a retort chamber where they remain throughout the process. Reagents and melted paraffin are moved sequentially into and out of the retort chamber using vacuum and pressure.

   Use of automated tissue processing is labor saving and allows overnight processing thereby reduce interval of time between sample reception and report delivery.

b. Manual tissue processing- Here tissue blocks are transported manually through a series of reagents housed in stationary containers.

   Equipments-

   1. Paraffin oven

   2. Containers of reagent made either of glass or stainless steel.

For tissue sectioning and staining

MICROTOMY: PARAFFIN

Microtomy is the means by which tissue can be sectioned and attached to a surface (slide) for further microscopic examination.

Equipments-

1. Microtome:

i) Rotary microtome- This may be manual, semi automated or fully automated. Advantages of rotary microtome include: ability to cut thin 2-3 mm sections and easy adaptation to all types of tissue (hard, fragile or fatty) sectioning.

ii) Base sledge microtome: With the sledge microtome, the specimen is held stationary and the knife slides across the top of the specimen during section cutting. It is used primarily for large blocks, hard tissues, or whole mounts, it is especially useful for neuropathology and ophthalmic pathology. Thin sections (3 micron) are difficult to produce.

2. Microtome knives- there are many shapes and sizes, and materials for microtome knives. Most steel knives have been replaced by disposable blades.

3. Disposable blades- They provide a sharp cutting edge that can produce flawless 2-4 mm sections. Introduction of disposable blades has revolutionized microtomy in the laboratory. Reliability of constant sharp edge, ease of use, low maintenance cost relative to steel knife sharpening make these blades a mainstay in most laboratories.

PARAFFIN SECTION CUTTING

Equipments-

1. Floatation (water) bath.
2. Slide drying oven or hot plate.
3. Fine pointed or curved forceps.
4. Sable or camel haired brush.
5. Scalpel.
6. Slide rack.
7. Clean slides.
8. Teasing needle.
9. Ice tray.

MICROTOMY: FROZEN

Frozen sections have many applications in routine histology laboratories:

- Rapid production of sections for intraoperative diagnosis.
- Diagnostic and research enzyme histochemistry: enzymes are labile
- Immunofluorescent method.

- Immunohistochemistry method: heat and fixation may destroy many antigen
- Diagnostic and research non-enzyme histochemistry: e.g. lipid and some carbohydrates
- Silver methods particularly in neuropathology

Equipment:

1. Cryostat: This is a special type of microtome housed in a refrigerated cabinet. All the controls of microtome are operated outside the cabinet. Tissue is hardened by first freezing in the cabinet and then sections are cut by the microtome inside.

STAINING & MOUNTING

Staining procedure can be either automated or manual.

Equipments-

Manual:

1. Staining dishes or coplin jar with lid.
2. Slide baskets holding up to 60 slides.

Automated:

1. Automatic slide stainer:

7. Quality assurance:

In conjunction with 'quality assurance', 'quality control (QC)' is an integral component of a required 'quality system'. A good QC system provides information for quality assurance activities.

QUALITY CONTROL (QC)

This system checks that the work process is functioning properly. This system helps to eliminate errors. Errors and deviations from the expected result must be documented that should also include corrective actions taken. An experienced histotechnologist has the responsibility to carry out routine quality checks before the release of slides for diagnosis. This QC evaluation will include:

i) accurate patient identification,

ii) fixation,

iii) adequate processing,

iv) appropriate embedding techniques,

v) acceptable microtomy,

vi) unacceptable artifacts,

vii) Inspection of controls to determine correctness of special staining and immunohistochemical methods.

In addition pathologists with a higher level of experience perform the final QC examination as they 'read' the slides. It is their responsibility to determine that the section/slide is adequate for diagnostic interpretation. Errors/problems reported by pathologists and others should be included as part of the laboratory QC data collection.

QUALITY ASSURANCE (QA): Internal and external

This is a shift from a focus on the end product or service to a focus on the process. Subsequent analysis of good QC documentation provides the data for quality assurance activities. Reviewing the data allows identification of declining quality and should trigger appropriate corrective action.

Apart from these internal quality assurance activities, participation in external programs/schemes also contributes valuable information for a quality assurance program.

A quality assurance scheme may be based on peer review of the stained sections submitted by the participating laboratories. Twice each year, participating laboratories may submit one stained and cover slipped glass slide from five different cases (two H&E, two special, and one Immunohistochemistry stain). Submitted slides are evaluated for histological technique by an expert panel of histotechnologists, biomedical scientists and pathologists using uniform grading criteria. The following areas may be evaluated- fixation, tissue processing and embedding, microtomy, staining and cover slipping.

The result of evaluation is communicated to participating laboratory with educational notes and suggestions for improvement.

8. Service delivery modalities:

Histopathological laboratories receive tissue samples from different operation theatres and hospitals for histopathological evaluation and diagnosis.

Following measures are essential-

All the sample containers should be appropriately labeled and accompanied by request forms signed by a authorized medical personnel.

Unless specified otherwise routinely tissues are received in 10% formalin fixative which prevents autolytic processes in tissue that starts immediately after removing the tissue from the body.

An unique excision number is given to the tissue sample which is essential for proper identification of sample.

Tissue is processed in the laboratory, sections are made and slides are prepared.

Finally slides are evaluated by the pathologist and report issued.

The whole process should take 3 to 6 days.

9. Record keeping

Computerized record of reports issued should be kept in the laboratory for considerable period of time, as determined by the requirements of patient's wellbeing. A period of 2 years may be proved sufficient. The data must be retrieved when necessary within this period.

Tissue samples with the container and added fixative should be kept for at least three months.

Processed tissue blocks are to be stored in boxes marked by accession number so that they can be retrieved easily and kept for at least one year.

Slides are also kept in slide drawers for at least one year. However it is to be noted that slides tend to fade with time.

Working Paper on Accreditation of Laboratories

Assessment area of accreditation (Microbiology area)

1.Infrastructural development

- Space distribution

Name	Area	Toilet	Remarks
Microbiologist's Chamber	12 feet × 15 feet	Attached bath with tiles 5 × 4	Within the laboratory separated by glass
Medical officer	8 feet ×8 feet	Attached bath with tiles 5 × 4	Within the laboratory
Patients'waiting room	20 feet ×10 feet	2 separate bath rooms with tiles for male & female (5 × 4)	Outside and in front of the laboratory
Registration & Sample collection	8 feet × 6 feet	No bathroom needed	Outside and in front of the laboratory
Laboratory Proper	50 feet × 15 feet	2 separate bath rooms, wall plastic paint, floor mosaic	Good quality door and window
Cleaning Room	8 feet × 8 feet	Floor tiles, wall half tiles	Good quality fittings
Store room	12 feet× 15 feet	Floor tiles, wall plastic paint	Good quality fittings
Waste disposal	12 feet × 15 feet	Floor tiles, wall tiles	Common for the hospital

- Water supply
- Electric supply
- Waste disposal
    - Normal-disinfectant
    - Biohazardous-autoclaving/underground
- Sputum collection area

2. General Facilities

- Location
    - Separate building
    - 40% free space around

3. Manpower with qualification:

- For public laboratory

Name of the post	Qualification	Number
Junior Consultant, Laboratory Medicine	Postgraduate, Lab Medicine	1
Medical officer, Microbiology	MBBS	2
Senior Lab Technologist	Diploma in Health Technology(Lab) with 3 yrs experience	1
Junior Lab Technologist	Diploma in Health Technology(Lab)	2 (one must be female)
Computer Operator cum office Assistant	HSC with Computer experience	1
Phlebotomist	HSC with Science background	2
Cleaner	Class VIII	1

- For Private Lab:

Name of the post	Qualification	Number
Lab Manager	Masters in management with experience	1
Junior Consultant, Laboratory Medicine	Postgraduate, Lab Medicine	1
Medical officer, Microbiology	MBBS	2
Senior Lab Technologist	Diploma in Health Technology(Lab) with 3 yrs experience	1
Junior Lab Technologist	Diploma in Health Technology(Lab)	2 (one must be female)
Accountant		1
Computer Operator cum office Assistant	HSC with Computer experience	1
Phlebotomist	HSC with Science background	2
Cleaner	Class VIII	1
Guard	Class VIII	1

4. Job description

Name of the Post	Responsibilities
Laboratory Manager	Over all supervision of the laboratory
	Control of subordinate staff
	Budget preparation
Junior Consultant Lab medicine	Over all supervision of the laboratory
	Reporting of routine and referral specimen
	Forwarding application of subordinate staff
	Budget preparation
	Quality control
Medical officer, Microbiology	Reporting
	Supervision of Lab Technologist
	Help in quality control
	Store keeping
Senior Lab Technologist	Supervision of table works
	Assist the microbiologist
	Report checking
	Help in quality control
	Sample distribution
Jr. Lab Technologist	Procedures for blood (desk work)
	Procedures for urine (desk work)
	Procedures for stool (desk work)
Computer Operator	Registration
	Record keeping
	Report typing
	Report delivery
	All other official works
Phlebotomist	Patient motivation
	Sample collection
	Sample labeling
	Sample submission to the lab
Cleaner	Cleaning of total lab premises
	Disposal of waste products

5. Capacity development

- Training for lab improvement and regulation
- Policy development
- Emergency response

6. Equipment, Instrument and other logistic support

- Furniture
- InstrumentChemicals
- Glass wear
- Office equipments
- Electric devices
- Sanitary fittings
- IPS/Generator

7. Quality assurance:

Parameters:

- Follow updated procedure manual like SOP(Standard operative procedure)-Ref: Guideline &Standard operating procedure for Government and Public Laboratories-Directorate General of Health Services(DGHS), Ministry of Health and Family Welfare(MoHFW)
- Follow checklists
- Specimen collection and transport
- Skilled personnel according to need
- Quality control records
- Patient reports
- Referral specimens
- Quality assurance skill
- Equipment performance
- Culture media
- Staining reagents
- Serum quality
- Commercial diagnostic kits
- Safe disposal

8. Service delivery modalities

- Courteous personnel
- Consistent Tests results
- Sample mix-ups prevention
- Quick report delivery
- Emergency response with due service
- Needs of the users is understood and met
- Complaints and problems of user and server are solved immediately and not repeated

9. Record Keeping

- For documentation
- For proper lab management

10.Checklists for performance appraisal-A simple step by step details:

- Identify the right person
- Ordering of relevant test
- Collecting appropriate specimen of adequate quality and quantity
- Labeling the specimen
- Rapidly transport specimen to the lab
- Proper and timely documentation and reporting
- Proper interpretation
- Timely action on right patient

11. Scoring for accreditation-

Each assessment / selection area can be categorized as below:

- Criteria fulfilled 100% will be categorized as score-5
- Criteria fulfilled 80-90% will be categorized as score-4
- Criteria fulfilled 60-70% will be categorized as score-3
- Criteria fulfilled 40-50% will be categorized as score-2
- Criteria fulfilled 20-30% will be categorized as score-1
- Criteria fulfilled 0-10% will be categorized as score-0

A standard score will be decided by Accreditation body for accreditation.

12. Accreditation body with TOR(Terms of reference)

- Updated procedure manual like SOP(Standard operative procedure)-Ref: Guideline &Standard operating procedure for Government and Public Laboratories-Directorate General of Health Services(DGHS), Ministry of Health and Family Welfare(MoHFW)

13. Accreditation process

- Preparation of accreditation document and approval

Approved documentation for accreditation should be available at the laboratory identifying the sector and service facility where underlying parameters are to be included

  - Administrative
    - Manpower-quality and quantity
    - Instrument maintenance
    - Standard Reagent supply
    - Store management
  - Patient dealing

        - Valid and reliable Test procedure
        - Standard Reporting
        - Rapid user friendly turnover of patient
- Selection of Assessor
    - Consists of multidisciplinary personnel- Members may include Medical Microbiologist, Medical Biochemist, Pathologist, Public health specialist, Transfusion medicine specialist, Environment specialist and a DG health personnel
- Capacity development of the assessor
    - Structural
        - Office with necessary logistic supply & manpower
    - Functional
        - Visit and Training of Assessor in different countries can be arranged to gather knowledge about technical problems and to take necessary action and supervision.
- Visit of the Assessment team-biannually/yearly
- Desktop review of assessment findings
    - Data of the checklist
    - Score
- Accreditation decision-Assessed by Assessor body after total scoring. Final decision will be taken by the opinion of maximum number of assessors.