



Directorate General of Health Services
Hospitals & Clinics Section
www.hospitaldghs.gov.bd

**Monitoring Tools
for Medical Laboratory**

Name of Hospital / Diagnostics Services:

Name.....

Title.....

Date:

Quality system	Evaluation				Remark
	Y	P	N	NA	
1. Structural Areas					
1. Patient Reception , siting facilities , Toilet facilities					
2. Necessary equipment according to category of services					
3. Waste Management according to the guideline					
4. Contract for Outhouse management					
5. Working / Existing of Pathologist & Radiologist					
6. Fulltime of Laboratory Technicians (MT lab & MT Radiology)					
2. Organization and Management					
1. Appointment of a quality manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system.					
2. A quality manual shall describe the quality management system and the structure of the documentation used and shall include or make reference procedures.					
3. Adequate training, specified responsibility, authority, and interrelationships of all personnel.					
3. Laboratory Equipment					
4. Laboratory shall be furnished with all items of equipment required for the provision of services.					
5. Laboratory shall have a manual for used and maintenance of equipment.					
6. Laboratory shall have identified of the equipment, reference materials and reagents which affect to the results.					
7. Laboratory shall have a labeled or otherwise coded to indicate the status of calibration or verification ant the date when calibration or verification.					
4. External Services and Supplies					
8. The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safely of personnel or patient care services.					
9. The laboratory shall be controlled temperature of refrigerator for reagents, blood sample, calibrator, control materials which affect the analytical results.					

10. Work areas shall be clean and well maintained. Measure shall be taken to ensure good housekeeping.					
5. Assuring quality of examination procedure					
11. Laboratory shall design internal quality control systems that verify the attainment of the intended quality results.					
6. Pre – analytical process					
12. Specific instructions for the proper collection and handling of primary sample shall be documented and implemented by laboratory management and made available to those responsible for primary sample collection.					
13. Laboratory shall monitor the transportation of samples to the laboratory such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual and in a manner that ensures safety for carrier.					
14. Criteria shall be developed for acceptance or rejection of primary sample.					
7. Analytical					
15. If in – house procedures are used, they shall be appropriately validated (SOP should be available)					
8. Post – analytical Procedures					
16. Authorized personnel shall systematically review the results of examinations, and signature.					
9. Reporting					
17. The laboratory shall have a procedure for reporting of results including date time. Procedure, and receiver and reported by telephone and facsimile.					
10. Amendment of Reports					
18. The laboratory shall have written policies and procedures regarding the alteration reports. When altered, the record must show the time , date and name of the person responsible for the change.					
11. Document control					
19. All documents relevant to the quality management system shall be uniquely identified.					
12. Control of Nonconformities					
20. Laboratory shall have a policy and procedure to be implemented when it defects that any aspect of its examination does not conform to its own procedures					
13. Internal Audits					
21. The Laboratory. shall be conducted an internal audit for quality management system.					
14. Continual Improvement					
22. The Laboratory shall be reviewed quality management system every year and planed for next year.					
15. Client Management					
23. The laboratory shall establish and maintain procedures for review of contracts. The review of capability should establish that the laboratory possesses the necessary physical, Personnel and information resources and the laboratory's personnel have skills and expertise for lab.					

Remark

Y=Yes P= Partial N=No NA = not applicable