Clinical Laboratory Evaluation Checklist
(ISO 15189:2012)

QUALITY ASSURANCE & STANDARDIZATION DIVISION

MINISTRY OF HEALTH, THIMPHU: BHUTAN

1. **Name of the healthcare centre:** Phuentsholing Hospital
2. **Name of the laboratory:** Phuentsholing Hospital laboratory
3. **Chief Medical Officer/ Medical Superintendent:** Dr Thinley Pelzang
4. **District Health Officer:**
5. **Lead evaluator:** Kuenzang Dorji, QASD, MoH
6. **Evaluating members:** Nil
7. **Evaluation for the year:** 2022

QMS section	QMS requirements	Yes	No	Partial	NA	Remarks
4. MANAGEMENT REQUIREMENTS						
4.1. Organization and management responsibility						
4.1.1.1	Is the QMS of the laboratory as per the ISO 15189:2012 requirement and cover the activities performed in all the sections of the laboratory?					
4.1.1.2	Does the laboratory take legal responsibility for its activities?					
4.1.1.3	Does the laboratory management ensure the following? i. staff do not involve themselves in any activity which will affect their competence, impartiality, judgment, and operational integrity;					
	ii. management and personnel are free from any undue internal and external, commercial, financial, and other pressures and influences that may adversely affect the quality of work;					
	iii. where potential conflicts of interests exist, they are openly and appropriately declared;					
	iv. confidentiality of patient's or client's information.					
4.1.2.1	Does Laboratory Quality Management System (LQMS) include policies and procedures for the pre-examination, examination, and post-examination processes of laboratory testing?					
	Does the laboratory ensure compliance to the same through the following? i. laboratory management communicate with laboratory personnel regarding the importance of meeting the needs and requirements of user as well as regulatory and accreditation requirements;					
	ii. the laboratory has an established quality policy;					
	iii. the quality policy understood by all the staff;					
	iv. the laboratory has an established quality objective and planning;					
	v. the job description, responsibilities, authorization matrices and interrelationships for all staff defined;					
	vi. there is an appropriate communication process established;					
	vii. the laboratory has a Quality Manager (QM) appointed;					

	viii. laboratory review of the progress of the LQMS once a year and whenever required;					
	ix. the laboratory evaluates the competence of each staff in assigned activities at a regular interval;					
	x. the laboratory has a centralised store to ensure optimal functioning of the pre-examination, examination, and post-examination process.					
4.1.2.2	Is there a mechanism to ensure whether the laboratory services (inclusive of advisory and interpretative services) meet the need of the users?					
4.1.2.3	Does the laboratory provide state of the art diagnostic services?					
	Do the current services fulfil the healthcare needs of the clients?					
	Are the testing methodologies appropriate and cost-effective?					
	Is there a quality assurance and resource management programme to achieve the desired outcome?					
4.1.2.4	Does the laboratory have defined quality objectives based on the quality policy?					
	Does the quality objectives? i. focus on reviews and continual improvement?					
	i. comply with the ISO 15189:2012 standards?					
	ii. ensure state of the art services?					
	iii. comply with the regulatory requirements?					
	iv. focus on ensuring staff competency, resource adequacy and service reliability?					
	v. focus on the test TAT?					
	vi. focus on our clients' healthcare needs and quality expectations?					
4.1.2.5	Does the laboratory have a defined organogram or management structure, responsibilities, key managerial and technical personnel appointments, and deputy appointments?					
4.2 Quality management system (QMS)						
4.2.1	Has the laboratory established, documented, implemented, and maintained a quality management system as per the ISO 15189:2012?					
	Do the quality policy address processes need for the LQMS and assurance of their application?					

	Has the laboratory determined the processes needed for the quality management system and are the processes applied throughout the laboratory?					
	Has the laboratory determined the sequence and interaction of these processes?					
	Are there determined criteria and methods needed to ensure that these processes' operation and control are effective?					
	Does the laboratory ensure the availability of resources and information necessary to support the operation and monitoring of these processes?					
	Does the laboratory monitor and evaluate these processes?					
	Has the laboratory implemented actions necessary to achieve planned results and continual improvement of these processes?					
4.2.2.1	Does the LQMS documentation include a quality policy statement and quality objectives?					
	Does the LQMS documentation include Laboratory Quality Manual?					
	Does the LQMS documentation include procedures and records required by the ISO15189:2012?					
	Does the LQMS documentation include documents and records determined by the laboratory to ensure the effective planning, operation, and control of its processes?					
	Does the LQMS documentation include copies of applicable regulations, standards, and other normative documents?					
4.2.2.2	Is the quality manual prepared as per the IS015189:2012 and other relevant standards requirements?					
	Does the laboratory quality manual address the following? i. quality policy;					
	ii. scope of application of the LQMS;					
	iii. overview of the organizational and management structure and its place in the parent organization;					
	iv. responsibilities of the laboratory director, LM, QM, teaching co-ordinator, laboratory safety officer and unit I/C;					
	v. the document control system;					
	vi. master lists of QSPs, SoPs, forms, and formats**.**					

	Does laboratory staff have access to and have been instructed to use and apply the quality manual and the referenced documents?					
	Is the quality manual revised as per the pre-defined interval or whenever major changes are needed?					
	4.3 Document Control					
4.3	Do the laboratory control documents required by the LQMS prevent the use of obsolete documents?					
	Does the laboratory archive the copy of documents (internally and externally generated) used for later reference as per the pre-defined period?					
	Is the laboratory document control defined concerning the following features and implemented?					
	i. need for appropriate revisions of the necessary documents at workplaces;					
	ii. all documents issued to laboratory personnel as part of the LQMS are reviewed and approved by authorized personnel before issue;					
	iii. documents uniquely identified: title, document number, issue number, issue date, amendment number and date, page number and number of pages, signatures of authority for preparation, approval, issue, and source identification where needed;					
	iv. a master list identifying the current valid revisions and their distribution;					
	v. only current and authorized editions of applicable documents are available at points of use;					
	vi. where the laboratory document control system allows for the amendment of documents by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are marked, initialled and dated and a revised document is issued within a specified period;					
	vii. documents remain legible;					
	viii. documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose;					
	ix. obsolete controlled documents are dated and marked as obsolete;					

	x. copy of an obsolete controlled document is retained for 3 years or per applicable local regulatory requirements and accreditation body requirements.					
	4.4 Service agreement					
4.4.1	Does the laboratory have documented procedures for establishing and reviewing agreements for providing clinical laboratory services to out-patients, corporate executive health check-ups, health insurance companies, etc.?					
	Are the test methods to be used adequately defined, documented, and understood by both parties?					
	Does the laboratory have the capability and resources to meet the requirements?					
	Does the laboratory personnel have the skills and expertise necessary for the performance of the agreed examinations?					
	Are the pre-analytical, analytical, and post-analytical procedures selected appropriately to meet the customer's needs?					
	Are the customers and users informed of any deviations from the agreement which may impact examination results?					
	Does the laboratory participate in Inter-lab comparisons as well as EQAS to determine uncertainties of measurement, limits of detection etc.?					
	Does the laboratory make reference to any work referred to a referral laboratory or consultant?					
4.4.2	Does the laboratory maintain records of service agreement reviews, including any significant changes and pertinent discussions?					
	Does the service agreement review record include any significant changes in the agreement and pertinent discussions?					
	Does the service agreement review cover any work to be subcontracted/ referred by the laboratory?					
	For amended agreements, does the laboratory follow the same agreement review process and demonstrated that they have communicated these to all affected parties?					

4.5 Examination by referral laboratories						
4.5.1	Does the laboratory have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline?					
	Does the examination by referral laboratory procedure ensure the following? i. monitor the quality of performance of the referral laboratories or consultants to perform the requested examinations;					
	ii. test parameters are referred to as the appropriate laboratory only;					
	iii. quality manager periodically reviews that the relevant parts of ISO15189:2012 are met;					
	iv. the quality manager maintains records of such periodic reviews;					
	v. register of all referral laboratories and consultants from whom opinions are sought are maintained;					
	vi. requests and results of all samples referred are kept as per the SoP.					
4.5.2	Does the laboratory keep a copy of the report (hard or soft) received from the referral laboratory for five years or as per the national or international regulatory requirement?					
	Does the referring laboratory ensure the examination results of the referral laboratory are provided to the person making the request?					
4.6 External service and supplies						
4.6	Does the laboratory have an appropriate and documented procedure for the selection and purchasing of external services, equipment, reagents, and consumable supplies that affect the quality of its service?					
	Does the laboratory develop a clear specification of the equipment and reagents required?					
	Does the laboratory ensure that the purchased items consistently meet the laboratory's quality requirements?					
	Does the laboratory ensure that supplies like equipment, consumables, reagents and other materials are used only after necessary verification or inspection to ensure compliance with the specified requirements?					
	Does the laboratory properly maintain the record of such verification or inspection?					

	Does the laboratory have a suitable inventory control system adopted for all supplies purchased to facilitate their monitoring?					
	Does the laboratory evaluate the supplier's suitability to supply the critical reagents, supplies and services that affect the quality of testing and maintain the records of such evaluation and a list of approved suppliers?					
	4.7 Advisory services					
4.7	Does the laboratory have established arrangements for communicating with users on the following? i. advising on a choice of laboratory test and use of the services including the required type of sample, clinical indications, limitations of examination procedures and the frequency of requesting the examination;					
	ii. advising on individual clinical cases;					
	iii. professional judgments on the interpretation of the results of examinations;					
	iv. promoting the effective utilization of clinical laboratory services;					
	v. consulting on scientific and logistic matters such as instances of failure of asample(s) to meet acceptance criteria.					
	4.8 Resolution of complaints					
4.8	Does the laboratory have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties?					
	Does the laboratory maintain a record of all the complaints, investigations and corrective or preventive action taken?					
	4.9 Identification and control of non-conformities					
4.9	Does the laboratory have a documented procedure to promptly detect nonconformities in all phases of laboratory analysis (pre-analytical, analytical, and post-analytical) and prevent reporting of incorrect results?					
	Does the laboratory appropriately define all the non-conformities?					

	Does the procedure cover the following? i. Defined responsibility and authority for management of nonconformities?					
	ii. Actions to be taken for the nonconformities defined.					
	iii. The medical significance of nonconformities is determined and informed to the patient/clinician where appropriate?					
	iv. Halting of examinations and withholding of reports, as necessary?					
	v. The medical significance of any nonconforming examinations is considered and where appropriate, the requesting clinician or authorized individual responsible for using the results is informed?					
	vi. Recalling or identification of the results of non-conforming examination already released?					
	vii. Defined responsibility and authority for the resumption of examination?					
	viii. Review of each episode of documented nonconformity at regular intervals by laboratory management to detect trends and initiate corrective actions.					
	Does the laboratory perform root cause analysis and place necessary corrective and preventive actions when evaluation indicates that nonconforming work could recur or there is a doubt on the effectiveness of the LQMS, including operating procedures and policies?					
	4.10 Corrective action					
4.10	Does the laboratory take corrective actions to eliminate the cause(s) of nonconformities and is it appropriate to the effects of the nonconformities encountered?					
	Does the laboratory have a documented procedure for the following? i. Reviewing nonconformities?					
	ii. Determining the root causes of nonconformities?					
	iii. Evaluating the need for corrective action to ensure that nonconformities do not recur?					

	iv. Determining and implementing corrective action needed?					
	v. Recording the results of corrective action taken?					
	vi. reviewing the effectiveness of the corrective action taken?					
	4.11 Preventive action					
	Do the laboratory place preventive actions to prevent future occurrence of nonconformities? Are the preventive actions appropriate to the effects of the potential problems?					
	Does the laboratory have the following procedures documented? i. reviewing laboratory data and information to determine where potential nonconformities exist,					
	ii. determining the root cause(s) of potential nonconformities,					
	iii. evaluating the identified areas and drawing up action plans for the implementation of the preventive actions and record the same in the Corrective & Preventive Action Report					
	iv. determining and implementing preventive action needed,					
	v. recording the results of preventive action taken,					
	vi. reviewing the effectiveness of the preventive action taken.					
	4.12 Continual improvement					
4.12	Does the laboratory management systematically review all the operational procedures to explore opportunities for continuous quality improvement in both technical and management categories?					
	Does the laboratory develop the action plan and implement and document the same?					
	Does the laboratory ensure improvement activities are directed at areas of highest priority based on risk assessment?					
	Does the laboratory management communicate with staff regarding improvement plans and related goals?					
	Does the laboratory systematically review or audit the effectiveness of the action plan implemented?					

	4.13 Control of records					
4.13	Does the laboratory have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment, and safe disposal of records?					
	Are the records created concurrently with the performance of each activity that affects the quality of the examination?					
	In case of record amendment, does the laboratory capture the date, time and reason for an amendment of records along with the identity of the person making the amendments?					
	Does the laboratory have a defined period of retaining various records about the QMS including pre-examination, examination, and post-examination processes?					
	Are the reported results appropriately stored and retrievable as required by the national or international regulations?					
	Does the laboratory have a suitable environment for the storage of records to prevent damage, deterioration, loss and unauthorized access?					
	Does the laboratory have the following records? i. supplier selection and performance, and changes to the approved supplier list;					
	ii. staff qualifications, training, and competency records;					
	iii. request for examination wherever applicable;					
	iv. records of receipt of samples in the laboratory;					
	v. information on reagents and materials used for examinations (e.g., lot documentation, certificates of supplies, package inserts);					
	vi. laboratory workbooks or worksheets;					
	vii. instrument printouts and retained data and information;					
	viii. examination results and reports;					
	ix. instrument maintenance records, including internal and external calibration records;					
	x. calibration functions and conversion factors;					
	xi. quality control records;					
	xii. incident records and action taken;					

	xiii.	accident records and action taken;					
	xiv.	risk management records;					
	xv.	nonconformities identified and corrective action taken;					
	xvi.	preventive action is taken;					
	xvii.	complaints and action were taken;					
	xviii.	records of internal and external audits;					
	xix.	inter-laboratory comparisons of examination results;					
	xx.	record of EQAS participation;					
	xxi.	records of quality improvement activities;					
	xxii.	minutes of meetings that record decisions made about the laboratory's QMS;					
	Does the laboratory ensure that all these records are available for management reviews?						
	4.14 Evaluation and audits						
4.14.1	Has the laboratory established a system of periodic internal evaluations and audits?						
	Does the established evaluation and audits conform to the ISO15189:2012 and LQMS of the laboratory?						
	Does the established audit effectively examine the pre-examination, examination, and post-examination processes?						
	Does the management review evaluate and monitor the effectiveness of preventive actions, corrective actions and subsequent improvements resulting from these audits?						
4.14.2	Doe the Quality Manager periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received?						
	Does the laboratory periodically review its sample volume, collection device and preservative requirements for the blood samples to ensure that neither insufficient nor excessive amounts of samples are collected?						
4.14.3	Does the laboratory seek information relating to user perception as to whether the service has met the needs and requirements of patients and clinicians?						
	Does the laboratory maintain the documents of such user feedback assessment?						

4.14.4	Does the laboratory encourage staff to make suggestions for the improvement of any aspect of the laboratory services? Does the laboratory evaluate staff suggestions and make appropriate changes if required?					
	Does the laboratory provide feedback to the staff regarding their suggestions?					
	Does the laboratory maintain the records of staff suggestions and actions that were taken?					
4.14.5	Is the internal audit conducted by trained and qualified personnel, independent of the activity being audited, to the extent possible?					
4.14.6	Does the laboratory evaluate the impact of the work process to assess the potential to cause pre-analytical, analytical, and post-analytical errors?					
	Whenever the risk is identified, does the laboratory modify the process to eliminate the identified risks and document the decisions and actions taken?					
4.14.7	Has the laboratory established quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post-examination processes?					
	Are the indicators periodically reviewed, to ensure their continued appropriateness?					
4.14.8	Does the laboratory management consciously choose to subject itself to the voluntary process of accreditation?					
	Does the laboratory subject its system and processes to unbiased third-party reviews or audits?					
	Does the laboratory promptly act on any nonconformity, opportunity for improvement, or observations identified during such external reviews within the stipulated period?					
	Do the laboratory document all the actions that are taken as a result of the review by the external organization and submit the same to the external agencies?					
	Does the laboratory present the external agency's review findings to the laboratory management review meetings?					

	4.15 Management review					
4.15.1	Does the laboratory carry out periodic management reviews to ensure continuous quality improvement?					
	Are the results of the review incorporated into a plan that includes goals, objectives, and action plans?					
4.15.2	Does the laboratory management review at least cover the following? i. internal audits;					
	ii. staff suggestions;					
	iii. risk management;					
	iv. assessment of user feedback;					
	v. reviews by external organizations;					
	vi. performance of suppliers and supplies;					
	vii. monitoring and resolution of complaints;					
	viii. follow-up actions from previous management reviews;					
	ix. periodic review of requests and suitability of procedures and sample requirements;					
	x. results of participation in inter-laboratory comparison programmes including IEQAS and NEQAS performance;					
	xi. results of continual improvement including the current status of corrective actions and preventative actions;					
	xii. changes in the volume and scope of work, personnel and premises that could affect the quality management system;					
	xiii. use of quality indicators and the appropriateness of these in terms of assessing the laboratory's contribution to patient care;					
	xiv. identification and control of nonconformities including the causes of nonconformities and patterns or trends which highlight potential process problems;					
	xv. recommendations for improvement to the QMS, including the impact on the quality policy, quality objectives and technical requirements.					
4.15.3	Does the review analyze the input information for causes of nonconformities, trends and patterns that indicate process problems?					

	Does the review include assessing the opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives?					
4.15.4	Does the review output include the following? i. potential areas of improvement in customer services,					
	ii. plans to improve the LQMS and its application for processes,					
	iii. infrastructural and other resources that the management proposes to improve operational productivity and quality.					
	Does the laboratory management allocate a time frame to close the actions arising from the management review and complete it within a defined time?					
5. TECHNICAL REQUIREMENTS						
5.1 Personnel						
5.1.1	Does the laboratory have a documented procedure for personnel management?					
5.1.2	Does LM maintain an authorization matrix for individual departments where the specific responsibilities of individuals working within the laboratory are specified, accepted, and approved?					
5.1.3	There is a job description for every position in addition to the RCSC Job description.					
5.1.4	Does the laboratory: i. subject new staff to induction training to familiarize the laboratory's activities and structure.					
	ii. induction training cover both management and technical familiarisation and the same are documented by the LM in the individual personal file?					
5.1.5	Does the lab provide training to staff concerning? i. ethics,					
	ii. quality management system,					
	iii. confidentiality of patient information,					
	iv. assigned work processes and procedures,					
	v. applicable laboratory information system,					
	vi. health and safety including the prevention or containment of the effects of adverse incidents.					

	Does the laboratory management review the effectiveness of the training?					
5.1.6	Is the competency of laboratory professionals evaluated yearly and documented?					
	Does the competency assessment include the following? i. review of work records;					
	ii. assessment of problem-solving skills;					
	iii. monitoring the recording and reporting of examination results;					
	iv. direct observation of equipment maintenance and function checks;					
	v. direct observation of routine work processes and procedures including all applicable safety practices;					
	vi. examination of specially provided samples such as previously examined samples, inter-laboratory comparison materials or split samples.					
5.1.7	Is the performance of the staff reviewed to improve the quality of services and to fulfil the need of the staff and department or unit?					
5.1.8	Does the laboratory management propose and facilitate Continuous Medical Education (CME) and professional development initiatives for all staff?					
	Does the intended or carried out CME satisfy the BMHC credit requirements?					
5.1.9	Is the personal record maintained and regularly updated by the LM or in charge?					
	Do job descriptions, competence assessments, CME and other training records, employee performance review records, accident and hazardous exposure reports, and vaccination status appear in the personal record?					
5.2 Accommodations and environmental conditions						
5.2.1	Is the designated laboratory space sufficient to guarantee proper test execution, quality control processes, and worker safety?					
5.2.2	Is the laboratory environment and facilities conducive to cross-functionality and easy communication among laboratory employees and across departments?					
	Is there a dedicated and appropriate office for the laboratory director, LM, QM, laboratory medicine specialist, and unit I/Cs to monitor and support effective operation?					
	Are the access to areas that impact examination quality controlled and the movement of a person into and out of the laboratory recorded?					

	Are the laboratory resources, patient samples and medical or laboratory information of patients accessible only to the authorised personnel?					
	Are the laboratory premises well-lit with artificial and natural light, and do they have enough water supply and waste disposal facilities?					
	Is there an effective communication system in place?					
	Is the laboratory attempting to reduce occupational hazards, and are there a fire alarm system and fire extinguishers in place?					
5.2.3	Is there adequate and suitable storage space to maintain the continued integrity of sample materials, documents, equipment, reagents, consumables, records, results, and any other objects that may impact the quality of examination results?					
	Are the hazardous material storage and disposal facilities appropriate for the hazard level of the materials?					
5.2.4	The following staff facilities are available: i. conference Room,					
	ii. staff lounge/duty room,					
	iii. separate changing room,					
	iv. locker facilities for staff,					
	v. dining and refreshment area,					
	vi. hygienic drinking water facility,					
	vii. separate washroom for males and females.					
5.2.5	Is there a separate reception or waiting room, collecting spaces, and conveniently situated toilets for phlebotomy and other sample collection facilities?					
	Are there first aid and spill kits available in the phlebotomy station, as well as a good communication connection to the emergency department?					
	Are the patient's privacy, comfort, and needs provided (for example, a wheelchair accessible phlebotomy station for the disabled)?					
	Are suitable Personal Protective Equipment (PPE) and handwashing facilities available to sample collection employees?					
5.2.6	Is the work environment kept nice, clean, and well-maintained following the 5s-CQI guidelines?					

	Are the environmental conditions (e.g., temperature, humidity) as required by the specifications monitored, controlled, and recorded?					
	5.3 Laboratory equipment, reagent, and consumables					
5.3.1.1	Is the Laboratory selecting or procuring laboratory equipment and consumables following the general procurement rules and regulations (https://www.mof.gov.bt/publications/rules/)?					
	Is the Laboratory linked to any Biomedical Engineering Division (BMED) for equipment maintenance?					
	Is the laboratory fully equipped to provide services in accordance with the Ministry of Health's healthcare or clinical laboratory service standards?					
5.3.1.2	Does a competent individual from the laboratory check the equipment's performance and compliance with the specifications to ensure a quality result after the vendor instals it?					
	Is the installed equipment counter verified by the BMED?					
	Is the successful installation and commissioning of the equipment endorsed by the LM and QM?					
	Is the equipment uniquely labelled for identification?					
5.3.1.3	Is the equipment always operated by trained and authorised staff?					
	Is the concerned individual ensuring that authorised laboratory personnel have access to up-to-date instructions on the use and maintenance of the equipment, including SOPs, manuals, and work instructions?					
	Does the laboratory have processes in place to ensure that equipment is handled, transported, stored, and used safely to avoid contamination or deterioration?					
5.3.1.4	Is there a defined procedure for the calibration of equipment that affects examination results directly or indirectly?					
	Does the calibration procedure include? i. conditions of use and the manufacturer's instructions;					
	ii. recording of the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;					

	iii. verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;						
	iv. recording the calibration status and date of re-calibration;						
	v. ensuring that, where correction factors are applied as a result of calibration, any previous calibration factors are suitably updated;						
	vi. ensuring that staff is aware that subsequent tampering or adjustment may invalidate any examination results achieved.						
5.3.1.5	Is there a documented programme for equipment preventive maintenance and does it follow the manufacturer's instructions and BMED's procedure/guidelines/policies?						
	Is the equipment kept in safe operating order, including a review of electrical safety, emergency stop mechanisms, and the safe handling and disposal of chemical, radioactive, and biological material by authorised personnel only?						
	Is the equipment labelled with the calibration status and next calibration due date?						
	Does the laboratory ensure that equipment which has been removed from direct control of the laboratory for repairs or service is checked and found to be functioning satisfactorily before being taken for laboratory use?						
5.3.1.6	Are the adverse incidents and accidents attributed directly to specific equipment investigated and reported to the BMED/MSPD/concerned authority?						
5.3.1.7	Are records of examination-related equipment kept within specific departments?						
	Does the record include: i. the identity of the equipment;						
	ii. manufacturer's instructions;						
	iii. contact information of the equipment supplier;						
	iv. details of where the equipment is located within the laboratory;						
	v. records that confirm the equipment's initial acceptability for use;						
	vi. equipment condition when received, i.e., new, used, or reconditioned;						
	vii. maintenance record including any preventative maintenance performed;						
	viii. manufacturer's name, model and serial number or other unique						

	identifiers;					
	ix. date of receipt into the laboratory and the date the equipment entered into use;					
	x. performance records that confirm the equipment's ongoing acceptability for use (adjustments made, acceptance criteria, copies of calibration reports/certificates, date of next calibration and/or verification, verification data including dates, times, and results).					
	xi. record of any damage, malfunction, modification, or repair.					
5.3.2.1	Is there a documented procedure for receiving, storing, quality testing, and managing reagents and consumables?					
5.3.2.2	Are the laboratory items received in the central store checked for quality before use and stored at the manufacturers' recommended specifications?					
5.3.2.3	Are the purchased equipment and consumables that affect or can potentially affect the quality of laboratory services verified for quality before use?					
	Is the performance and usability of new lot number reagents or rapid test kits evaluated?					
5.3.2.4	Are all the laboratory reagents and consumables indented and selected as per the annual procurement system?					
	Are the selected products' acceptability checked as per the quality inspection guideline of MSPD or EMTD?					
	In case, a particular product is rejected or found to be in unacceptable condition even in subsequent supply, does the central store immediately return the product with due notification to the concerning department and the supplier/manufacturer?					
	Does the laboratory indent the reagent and consumables from the central store based on its requirement?					
5.3.2.5	Are instructions for the use of reagents and consumables, including those provided by the manufacturers, controlled and readily available?					
5.3.2.6	Are adverse incidents and accidents that can be attributed directly to specific reagents or consumables investigated and reported to the QM as well as the vendor/supplier?					

5.3.2.7	Are the records of reagents and consumables that contribute to the performance of examinations kept within the individual laboratory unit?					
	Does the record include: i. contact details of the item supplier,					
	ii. name of the reagent or consumable,					
	iii. manufacturer's instructions (if applicable),					
	iv. total quantity indented for the financial year,					
	v. records of confirmation of acceptance for use,					
	vi. manufacturer's name and batch code or lot number,					
	vii. a condition when received (e.g., acceptable, or damaged),					
	viii. performance records that confirm the reagents or consumables' ongoing acceptance for use.					
	5.4 Pre-examination process					
5.4.1	Does the laboratory have documented procedures and information for pre-examination activities that ensure the validity of the analytical results?					
5.4.2	Doe the laboratory provides information for patients and users of the laboratory services?					
	Doe the information includes: i. location of the laboratory;					
	ii. opening hours of the laboratory;					
	iii. Laboratory's complaint procedure;					
	iv. instructions for patient-collected samples;					
	v. instructions for transportation of samples;					
	vi. instruction for the preparation of the patient;					
	vii. instructions for completion of the request form;					
	viii. policy on the protection of personal information;					
	ix. Laboratory's criteria for accepting and rejecting samples;					
	x. types of clinical services offered by the laboratory including examinations referred to other laboratories;					

	xi. list of factors known to significantly affect the performance of the examination or the interpretation of the results;					
	xii. availability of clinical advice on the ordering of examinations and the interpretation of examination results;					
	xiii. any requirements for patient consent (e.g., consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);					
	xiv. examinations offered by the laboratory including information concerning samples required, primary sample volumes, special precautions, turnaround time, biological reference intervals and clinical decision values.					
5.4.3	Is there a test request form or an electronic equivalent?					
	Does the test request form or electronic equivalent have space for the following discussion? i. examinations requested;					
	ii. time of primary sample collection;					
	iii. time, date, and year on the request form;					
	iv. type of primary sample and where relevant, the anatomic site of origin;					
	v. patient identification including gender, age, and a unique identifier number;					
	vi. clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;					
	vii. name or other unique identifiers of the clinician, healthcare provider or other people legally authorized to request examinations or use medical information, together with the destination for the report and contact details.					
5.4.4.1	Does the laboratory have documented procedures for the collection and handling of primary samples and is readily available to the responsible primary sample collection staff?					
	Are the in-house phlebotomy staff trained on phlebotomy procedures and biohazard waste management procedures?					

	Is there a classified list of laboratory procedures that requires informed consent (written/oral)?					
	Is written consent obtained for special or invasive procedures, as well as those with a higher risk of complication?					
	Is there a mechanism for obtaining informed consent when the patient is unable to give consent?					
5.4.4.2	Are there pre-collection activities instructions?					
	Does the pre-collection activity instruction include the following? i. special timing of collection where needed;					
	ii. completion of request form or electronic request;					
	iii. preparation of the patient (e.g., instructions to caregivers, phlebotomists, sample collectors and patients);					
	iv. type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;					
	v. clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g., history of administration of drugs).					
5.4.4.3	Do the laboratory Instructions for collection activities include the following instructions to ensure appropriate specimen collection? i. determination of the identity of the patient from whom a primary sample is collected;					
	ii. verification of patient's pre-examination requirements [e.g., fasting status, medication status (time of last dose, cessation), sample collection at a pre-determined time or intervals etc.];					
	iii. instructions for the collection of primary blood and non-blood samples with descriptions of the primary sample containers and any necessary additives;					
	iv. in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and					

	sample transport conditions shall be determined and communicated to the appropriate clinical staff;					
	v. instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;					
	vi. recording of the identity of the person collecting the primary sample and the collection date and when needed, recording of the collection time;					
	vii. instructions for proper storage conditions before collected samples are delivered to the laboratory;					
	viii. safe disposal of materials used in the collection.					
5.4.5	Does the laboratory have a documented procedure for monitoring the transportation of samples to ensure that they are transported as follows? i. within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;					
	ii. within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;					
	iii. in a manner that ensures the integrity of the sample and the safety of the carrier, the public and the receiving laboratory, in compliance with established requirements.					
5.4.6	Do the primary sample collection procedures ensure that the following conditions are met? i. samples shall be unequivocally traceable by request and labelling to an identified patient or site;					
	ii. laboratory-developed and documented criteria for acceptance or rejection of samples shall be applied;					
	iii. Where there are problems with a patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and caution where applicable;					

	iv. all samples received shall be recorded in a logbook, worksheet, computer or other comparable systems;					
	v. date and time of receipt and/or registration of samples shall be recorded, whenever possible, and the identity of the person receiving the sample shall be also recorded;					
	vi. authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s);					
	vii. where relevant, there shall be instructions for the receipt, labelling, processing, and reporting of samples specifically marked as urgent: the instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed.					
5.4.7	Does the laboratory process sample immediately upon receipt? Where the samples cannot be directly processed for analysis, are they stored in refrigerators/deep freezers/room temperature as relevant?					
	Does the laboratory staff obtain verbal requests within a specified time limit for the following? i. adding tests to already registered orders,					
	ii. deletion of tests if the test has not been initiated.					
	5.5 Examination processes					
5.5.1.1	Does the laboratory select examination procedures (principle of analysis) and verify them for the intended use?					
	Is the identity of persons performing activities in examination processes recorded?					
5.5.1.2	Are validated examination procedures used without modification subjected to the independent verification by the laboratory before being introduced into routine use?					
	Does the laboratory obtain information from the manufacturer for confirming the performance characteristic of the procedure?					

	Does the laboratory document the procedure used for the verification and record the results obtained?					
5.5.1.3	Are the laboratory test results generated from the validated procedures validated in terms of quality by the staff performing the procedure?					
	Are the laboratory test results generated further validated by the specialist in laboratory medicine of the respective unit if needed?					
5.5.1.4	Does the laboratory determine the CV% for each quantitative test result in all relevant and possible scenarios?					
5.5.2	Does the laboratory use biological reference intervals published based on local or national research?					
	In case of non-availability of such reference intervals, does the laboratory use the most relevant reference interval published or the manufacturer's recommended reference interval after validating as per the CLIA process?					
	Does the laboratory reflect the information of the reference interval source at the end of every result?					
	Are the biological reference intervals periodically reviewed (by the unit I/C/LM/QM/SPLM) concerning? i. appropriateness to the population served, ii. changes in pre-examination procedures, iii. changes in examination procedures.					
5.5.3	Are all examination procedures documented in the form of SOPs and work instructions or authorised kit inserts written in English and made available at the workstation for relevant staff?					
	Are all SOPs, working instructions and kit-based procedures part of the document control system?					
	Does the laboratory explain and inform any changes to existing examination procedures which could potentially influence the test results or their interpretations to users of the laboratory services after validating the procedure via written official correspondence?					
	Does the laboratory provide training on individual procedures?					
	Are the SoPs classified into?					

	i. General SOPs					
	ii. Unit specific SOPs					
	Does each test specific SOPs documented as the following? i. purpose of the examination;					
	ii. principle and method of the procedure used for examinations;					
	iii. performance characteristics;					
	iv. type of sample (e.g., plasma, serum, urine);					
	v. patient preparation;					
	vi. type of container and additives;					
	vii. required equipment and reagents;					
	viii. environmental and safety controls;					
	ix. calibration procedures (metrological traceability);					
	x. procedural steps;					
	xi. quality control procedures;					
	xii. interferences (e.g., lipaemia, haemolysis, bilirubinaemia, drugs) and cross-reactions;					
	xiii. principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values;					
	xiv. biological reference intervals or clinical decision values;					
	xv. the reportable interval of examination results;					
	xvi. instructions for determining quantitative results when a result is not within the measurement interval;					
	xvii. alert/critical values, where appropriate;					
	xviii. laboratory clinical interpretation;					
	xix. potential sources of variation;					
	xx. references.					
	Are the approved SOPs/working instructions available in the form of hard copies, released as **'CONTROLLED COPY'** from the QM?					
	5.6. Ensuring quality of examination results					
5.6.1	Is the laboratory committed to the quality of its pre-examination, examination, and post-examination procedures?					

	Does the laboratory adhere to ethical practice?					
5.6.2.1	Does the laboratory have established procedures for IQC, to verify the quality of test results before they are released?					
	Is the frequency of performing IQC (e.g., daily) defined and based on the stability of the procedure and the risk of harm to the patient from an erroneous result?					
5.6.2.2	Does the laboratory use certified reference material (controls) to verify the performance at relevant decision points?					
	Are the control data electronically plotted on the Levy-Jennings chart and Westgard Multi-rules applied for acceptance or rejection of the run?					
	Does the laboratory use the following IQC materials? i. in-house QC material in surgical pathology, ii. lyophilized/liquid QC material in biochemistry, iii. commercial or partially stabilised QC material in haematology.					
5.6.2.3	Does the laboratory have procedures to indicate actions to prevent the release of patient results following a QC failure?					
	Does the procedure detail the re-examination of the appropriate sample after the error has been corrected?					
	Are the QC data reviewed periodically to identify trends that may suggest deterioration in examination procedure performance and, if necessary, appropriate CAPA implemented?					
5.6.3.1	Does the laboratory participate in interlaboratory comparison and External Quality Assessment Scheme (EQAS)?					
	Does the laboratory rigorously monitor EQAS or NEQAS and put CAPA in place if acceptable standards are not met?					
	Is there a documented system in place for inter-laboratory comparison involvement that includes specified duties and participation instructions?					
5.6.3.2	In the absence of inter-laboratory comparison schemes, does the laboratory strive to provide objective evidence for the acceptability of examination results through a variety of means such as the use of certified reference material, re-assessment of previously examined samples, exchange of samples with other laboratories, and correlation within the laboratory findings in all possible					

	scenarios?					
5.6.3.3	Does the laboratory integrate inter-laboratory comparison samples into the routine workflow to ensure that these samples are analysed as much as possible in a routine manner?					
5.6.3.4	Does the laboratory review performance in Inter-laboratory comparisons and discuss it with the relevant staff?					
	When non-conformities are identified, does the staff participate in the implementation and recording of CAPA?					
5.6.4	If the laboratory uses different procedures or equipment or methods for the same test, do they assure comparability of the results at clinically appropriate intervals?					
	Does the laboratory document such activities and undertake CAPA if required?					
	5.7. Post-examination process					
5.7.1	Do the authorized personnel review the results of examinations before release and evaluate them against IQC and if appropriate or possible with the available clinical information and previous examination results?					
5.7.2	Does the laboratory have documented procedures as per the national or international guidelines for appropriate identification, archival and storage of analysed specimens?					
5.8.1	Are the test results of each examination reported accurately, clearly, in the SI unit where applicable, unambiguously and in accordance with specific instructions in the examination procedures?					
	Is there a defined format and medium (electronic/paper) for the report?					
	Is there a provision in the Laboratory Information System (LIS) for inserting necessary interpretational remarks within laboratory reports, wherever needful?					
	Is there a documented procedure to ensure that information about anticipated delays is sent to respective clients and patients through telephone and e-mails or another appropriate medium?					
5.8.2	Does the lab report effectively communicate the following? i. critical results, where applicable;					
	ii. interpretive comments on results, where applicable;					

	iii.	comments on sample quality that might compromise examination results;					
	iv.	comments regarding sample suitability concerning acceptance/rejection criteria.					
5.8.3	Does the laboratory report contain the following information?						
	i.	a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;					
	ii.	identification of the laboratory that issued the report;					
	iii.	identification of all examinations that have been performed by a referral laboratory;					
	iv.	patient identification and patient location on each page;					
	v.	name or other unique identifiers of the requester and the requester's contact details;					
	vi.	date of primary sample collection (and time, when available and relevant to patient care);					
	vii.	type of primary sample;					
	viii.	measurement procedure, where appropriate;					
	ix.	examination results reported in SI units, units traceable to SI units, or other applicable units;					
	x.	biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable;					
	xi.	interpretation of results, where appropriate;					
	xii.	other comments such as cautionary or explanatory notes (e.g., quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);					
	xiii.	identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;					

	xiv. identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);					
	xv. date of the report, and time of release (if not contained in the report, readily available when needed);					
	xvi. page number to a total number of pages.					
5.9.1	Is there a defined procedure for the Release of Laboratory Results?					
	Does the reporting procedure or policies define the following? i. mention of compromised specimen status in the laboratory reports in relevant scenarios					
	ii. process for communicating “alert” or “critical” laboratory results and appropriate documentation for the same (SOP on reporting of critical values of test results),					
	iii. that laboratory reports are generated in an appropriate font and that they are checked for transcription errors,					
	iv. process for the generation of interim laboratory reports,					
	v. process for documentation of verbally released laboratory results.					
5.9.2	In all possible scenarios, is the reports generated electronically transferred to the LIS and concerned laboratory personnel release the result?					
5.9.3	Is there a defined procedure for the amendment of laboratory reports?					
	When the amendment is required, is there a documented procedure to ensure the following? i. the revised report is clearly identified as a revision and includes a reference to the date and patient’s identity in the original report,					
	ii. the user is made aware of the revision,					
	iii. the revised record shows the time and date of the change and the name of the person responsible for the change,					
	iv. the original report entries remain in the record when revisions are made.					
5.10.1	Does the laboratory ensure that Patient and test-related data management are seamlessly communicated from being captured in the Test Request Form (TRF)					

	to being registered in the LIS and finally being authorized in the form of the laboratory report?					
	Does the laboratory have procedures in place to always protect the confidentiality of patient information?					
	Is the access to LIS guarded by a unique login ID and password, while access to individual laboratory equipment is also secured?					
5.10.2	Does the laboratory have defined authorities and responsibilities for all staff who use the system, in particular, those who: i. access patient data and information,					
	ii. enter patient data and examination results,					
	iii. change patient data or examination results,					
	iv. authorize the release of examination results and reports.					
5.10.3	Does the laboratory ensure that the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data are? i. validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented, and verified before implementation;					
	ii. documented, and the documentation, including that for the day-to-day functioning of the system, is readily available to authorized users;					
	iii. protected from unauthorized access;					
	iv. safeguarded against tampering or loss;					
	v. operated in an environment that complies with supplier specifications or, in the case of non-computerized Systems, provides conditions which safeguard the accuracy of manual recording and transcription;					
	vi. maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;					
	vii. in compliance with national or international requirements regarding data protection.					

	Does the laboratory have documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service?					

Summary: