Medical Laboratory Science Council of Nigeria

Laboratory Accreditation Checklist Guidance Document

For Public Health Laboratories

Table of Content (To be completed after review)

INTRODUCTION

Laboratories play a critical role in the diagnosis, management and control of diseases. Available literature demonstrates that diagnoses contribute 60-70% to clinical decisions. It is therefore imperative that accurate and reliable laboratory results are generated from medical laboratories. This can only be ensured if laboratories are deemed competent to offer quality and timely laboratory services.

The International Organization for Standardization (ISO) has developed ISO 15189 as the standard for medical laboratories. This document defines the standards for quality and competence. Because of its comprehensive approach to issues of laboratory quality and competence, accreditation of laboratories using this standard has been accepted internationally when recognition is granted by an authoritative body such as Medical Laboratory Science Council of Nigeria (MLSCN).

This guidance document to MLSCN accreditation checklist was developed for standardization of the assessment by MLSCN certified assessors and use by laboratories preparing for accreditation.

	ISO 15189:2012 Clause No.	Standard	Requirements
1	**4 Management requirements**		
2	**4.1 Organization and management responsibility**		
3	**4.1.1 Organization**		
4	**4.1.1.1 General**	The medical laboratory (hereinafter referred to as 'the laboratory') shall meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities.	Quality manual based on current ISO 15189 Adherence to contents of quality manual
5	**4.1.1.2 Legal entity**	The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.	Enabling Law or Edict, CAC registration as applicable.
6	**4.1.1.3 Ethical conduct**	Does your laboratory management have arrangements to ensure the following:	
7	a	No involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity	Policy and procedure on conflict of interest, Operational integrity, competence, confidentiality. Procedure may be guideline, SOP or any documented arrangement
8	b	Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work	Policy and procedure on conflict of interest that address each of these criteria
9	c	Potential conflicts in competing interests may exist, they shall be openly and appropriately declared	A procedure for declaration of conflict of interest. Signed declaration of potential conflict of interest
10	d	There are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements	Policy, SOP, Guidelines, manual, references are available to relevant legal requirements.
	e	Confidentiality of information is maintained	Signed confidentiality forms and /or oath of secrecy, code of conduct.
	4.1.1.4 Laboratory director	Does the laboratory have a competent person(s) with medical, scientific and technical background to direct the laboratory services?	Personnel file; current professional license, certificates, trainings,

			letter of appointment and Job description, competency assessment report.
		The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.	Job description
		The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.	Evidence of delegation of duty.
		The duties and responsibilities of the laboratory director shall be documented.	Job description
		The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfill the requirements of this International Standard.	Personnel file: license, letter of appointment, job description, qualifications and trainings, list of staff, equipment and consumables.
		The laboratory director (or designate/s) shall:	
	a	provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities	Minute of meetings eg. staff and top management meetings for efficient laboratory services. Approved work plan, budget and forecast for staff, equipment and consumables.
	b	relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required	Documented evidence of communication and meetings with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required
	c	ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users	Personnel budget and training, education budget, administration and utilization of competency assessment.
	d	ensure the implementation of the quality policy	Signed quality manual and SOPs by all staff. Appointment of quality manager.

			Annual quality management review meeting
	e	implement a safe laboratory environment in compliance with good practice and applicable requirements	Evidence of safety practices and environmental monitoring eg. equipment placement according to manufacturers specification, decontamination procedure, PPE, monitoring of ambient, fridge, freezer, temperatures etc, serviced fire safety equipment, training and alert. Ergonomics and safety audit.
	f	serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate	Minute of meetings, Service agreement, appointment letters if applicable and appropriate.
	g	ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results	Advisory services to clients and patients as contained in the quality manual and patients' handbook.
	h	select and monitor laboratory suppliers	Policy and criteria for selecting suppliers. List of approved suppliers. Supplier's performance review
	i	select referral laboratories and monitor the quality of their service (see also 4.5);	Policy and SOP on selection of referral labs, List of selected referral lab. Periodic performance review
	j	provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations	Training policy, training forecast/ budget and records of trainings attended, attendance at step down training conducted.
	k	define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services	Quality Manual that defines standard of performance, technical reviews,records management quality improvement activities, audits.
	i	monitor all work performed in the laboratory to	Customer survey and

		determine that clinically relevant information is being generated	lab users feedback. Review of technical records.
	m	address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4)	Records of resolution of complaints and utilization of suggestions by staff/users.
	n	design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable	Back-up plans; equipment back-up onsite or off site. Referral service agreement with referral laboratories.
	o	plan and direct research and development, where appropriate.	Research Plans and Publication where appropriate.
	4.1.2 Management responsibility		
	4.1.2.1 Management commitment	Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:	
	a	communicating to laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements	Minutes of meetings with agenda that address needs and requirements of users as well as regulatory and accreditation requirements.
	b	establishing the quality policy (see 4.1.2.3)	Quality policy stated in quality manual.
	c	ensuring that quality objectives and planning are established (see 4.1.2.4)	Quality planning and objectives that is measurable and consistent with quality policy.
	d	defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5)	Organogram Appointment letter Job description
	e	establishing communication processes (see 4.1.2.6)	Minute of meetings, internal memo, e-mails, notice board announcement.
	f	appointing a quality manager, however named (see 4.1.2.7)	Letter of appointment and job description
	g	conducting management reviews (see 4.15)	Evidence of review of quality and technical records; controls, results, equipment maintenance,

			temperature chart, etc
	h	ensuring that all personnel are competent to perform their assigned activities (see 5.1.6)	Evidence of competency assessment tests conducted on all aspects of laboratory tasks.
	i	ensuring availability of adequate resources (see 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5,5, and 5.7).	Availability of necessarypersonnel,required equipment,consumables and infrastructure to sustain its activities. Note should be taken of adequacy of space, work load in relation to personnel, meeting set turnaround time (TAT) and management response to laboratory requests.
	4.1.2.2 Needs of users	Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. (see also 4.4 and 4.14.3).	Customer survey Client feedback
	4.1.2.3 Quality policy	Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy:	Quality statement that defines the intent of the QMS: (a) –(e)
	a	is appropriate to the purpose of the organization	
	b	includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services	
	c	provides a framework for establishing and reviewing quality objectives	
	d	is communicated and understood within the organization	
	e	is reviewed for continuing suitability	
	4.1.2.4 Quality objectives and planning	Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	Quality objectives that are Specific, Measurable, Achievable, Realistic, Time Bound and reflects the quality policy.
		Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives.	Work-plan with budget.
		Laboratory management shall ensure that the integrity of the quality management system is	QMS reviews by management and the

		maintained when changes to the quality management system are planned and implemented.	necessary corrective actions eg. internal audit, safety audit etc.
	4.1.2.5 Responsibility, authority and interrelationships	Laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization. This shall include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel.	Appointment letters, organogram, job description.
	4.1.2.6 Communication	Laboratory management shall have an effective means for communicating with staff (see also 4.14.4). Records shall be kept of items discussed in communications and meetings.	Minutes of meetings, e-mails, call logs, file copies of communications with staff
		Laboratory management shall ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.	Policy and SOP for communication with stake holders. Evidence of compliance with SOP
	4.1.2.7 Quality manager	Laboratory management shall appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:	Letter of appointment, job description detailing (a) – (c)
	a	ensuring that processes needed for the quality management system are established, implemented, and maintained	
	b	reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement	
	c	ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization	
	4.2 Quality management system		
	4.2.1 General requirements	The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.	
		The quality management system shall provide for	

		the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users. The laboratory shall:	
	a	determine the processes needed for the quality management system and ensure their application throughout the laboratory	Quality Manual SOPs Evidence that they have been read and understood
	b	determine the sequence and interaction of these processes	Evidence In the Quality Manual of the sequence of interacton of all processes.
	c	determine criteria and methods needed to ensure that both the operation and control of these processes are effective	Quality Manual SOP on criteria and methods Evidence of Laboratory managers review.
	d	ensure the availability of resources and information necessary to support the operation and monitoring of these processes	Evidence of work plan and budget
	e	monitor and evaluate these processes	Evidence of documented Audits and management reviews.
	f	implement actions necessary to achieve planned results and continual improvement of these processes.	Selected quality indicators,documented improvement projects and management review reports.
	4.2.2 Documentation requirements		
	4.2.2.1 General	The quality management system documentation shall include:	
	a	statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4)	Endorsed Quality policy and objectives by management
	b	a quality manual (see 4.2.2.2)	A Quality manual that consist of the following; quality policy, scope of the QMS, Organization and its structure and inter-relationships where applicable.Document structure.
	c	procedures and records required by this International Standard	Master list of documents, Records and SOPs
	d	documents, and records (see 4.13), determined by the laboratory to ensure the effective planning, operation and control of its processes	Master list of documents, Records and SOPs
	e	copies of applicable regulations, standards and other normative documents.	Copies of applicable regulations (eg. MLSCN

			regulatorydocuments); standards (eg. ISO 15189) and other normative documents (eg. reference materials, books and documents)
	4.2.2.2 Quality manual	The laboratory shall establish and maintain a quality manual that includes:	Quality manual that contains (a) – (f)
	a	the quality policy (4.1.2.3) or makes reference to it;	
	b	a description of the scope of the quality management system;	
	c	a presentation of the organization and management structure of the laboratory and its place in any parent organization;	
	d	a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard;	
	e	a description of the structure and relationships of the documentation used in the quality management system;	
	f	the documented policies established for the quality management system and reference to the managerial and technical activities that support them.	
		All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.	Evidence of accessibility and communication of the Quality Manual to all staff.
	4.3 Document control	The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented. The laboratory shall have a documented procedure to ensure that the following conditions are met.	Document control SOP for internal and external documents.
	a	All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.	A documented process for document review and approval by authorized personnel and evidence that it has been reviewed
	b	All documents are identified to include: — a title; — a unique identifier on each page; — the date of the current edition and/or edition number; — page number to total number of pages (e.g. “Page 1 of 5,” “Page 2 of 5,”); — authority for issue.	Document identification specifications(documen t control procedure) to speak to listed items
	c	Current authorized editions and their distribution are identified by means of a list (e.g. document	Document master list of current editions and

		register, log or master index).	distribution log.
	d	Only current, authorized editions of applicable documents are available at points of use.	Evidence of current and authorized editions at the point of use.
	e	Where a laboratory's 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 clearly marked, initialed and dated, and a revised document is issued within a specified time period.	A documented procedure for amending documents with stated timeframe for release of revised document where applicable. Evidence: Amended documents according to stated procedure
	f	Changes to documents are identified.	SOP for document amendment Evidence of changes made
	g	Documents remain legible.	Legibility of document
	h	Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.	Document review SOP that stipulates the time frame for reviews. Evidence: a document reviewed according to the SOP
	i	Obsolete controlled documents are dated and marked as obsolete.	Policy on retrieval and archiving of obsolete documents. Clearly designated and marked as obsolete
	j	At least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.	Document retention policy. At least a copy of obsolete controlled document should be kept in the archive and be marked as obsolete.
	4.4 Service agreements		
	4.4.1 Establishment of service agreements	**4.4.1 Establishment of service agreements** The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services.	Documented procedures for the establishment of service agreements and review of agreements for providing medical laboratory services. (i) – (ii)
	i	Each request accepted by the laboratory for examination(s) shall be considered an agreement.	Availability of Laboratory request forms.
	ii	Agreements to provide medical laboratory services shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result	A completed laboratory report ready for dispatch.

		interpretation.	
		The following conditions shall be met when the laboratory enters into an agreement to provide medical laboratory services.	
	a	The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood (see 5.4.2 and 5.5).	Availability of a laboratory handbook.
	b	The laboratory shall have the capability and resources to meet the requirements.	Qualified personnel, Space, Adequate equipment and evidence of management support
	c	Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.	Qualified and skilled personnel. Evidence: Personnel files (the C.V, license and competency assessment)
	d	Examination procedures selected shall be appropriate and able to meet the customers' needs (see 5.5.1).	Selected, verified and validated procedures (methods) for intended use
	e	Customers and users shall be informed of deviations from the agreement that impact upon the examination results.	Documented evidence of communication about deviation from original service agreements e.g call logs,memos,letters,notices,emails.Etc
	f	Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.	Reference to the referral lab in the referring labs report.
	4.4.2 Review of service agreements	Reviews of agreements to provide medical laboratory services shall include all aspects of the agreement. Records of these reviews shall include any changes to the agreement and any pertinent discussions.	Documented review of agreements and changes agreed upon.
		When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.	Evidence of communication of any amendment made after laboratory services have commenced.
	4.5 Examination by referral laboratories		
	4.5.1 Selecting and evaluating referral laboratories and consultants	The laboratory shall 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.	Availability of documented procedure for selection and evaluation of referral laboratories.

		The procedure shall ensure that the following conditions are met.	The procedure should address sub parts (a - e)
	a	The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.	Evidence of criteria used in selecting referral labs and/or consultants.
	b	Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met.	Evidence of performance review eg. checklist
	c	Records of such periodic reviews are maintained.	Record of periodic review of all referral labs and/or consultants.
	d	A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.	Register of all referral laboratories and/or consultants.
	e	Requests and results of all samples referred are kept for a pre-defined period.	Evidence that retained referral request, results and samples are kept for a period defined in the SOP.
	4.5.2 Provision of examination results	Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.	Evidence of a well coordinated tracking system for referred requests and proper documentation in the appropriate laboratory reports to reflect the identity of the referral laboratory.
		The author of any additional remarks shall be clearly identified.	Retained copy of sent out reports with name and/or signature
		Laboratories shall adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, this process shall not be hindered by commercial or financial considerations.	A reviewed referral laboratory report addressing all the requirements of this sub clause
	4.6 External services and supplies	The laboratory shall have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service (see also 5.3).	Documented procedure for selection and purchase of external services,equipment,reagents and supplies.

		The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfill this requirement. Criteria for selection shall be established.	Criteria for selection of suppliers and list of approved suppliers
		A list of selected and approved suppliers of equipment, reagents and consumables shall be maintained.	List of selected and approved suppliers
		Purchasing information shall describe the requirements for the product or service to be purchased.	Specification for products and services.
		The laboratory shall monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria.	Records of suppliers performance review
	4.7 Advisory services	The laboratory shall establish arrangements for communicating with users on the following:	Evidence supporting the following sub parts
	a	advising on choice of examinations and use of the services, including required type of sample (see also 5.4), clinical indications and limitations of examination procedures and the frequency of requesting the examination;	- Clients' handbook - Relevant SOPs - Minutes of meetings with clinical service providers - Notices
	b	advising on individual clinical cases;	Report forms with interpretation, comments, reference ranges, critical values etc.
	c	professional judgments on the interpretation of the results of examinations (see 5.1.2 and 5.1.6);	List of qualified personnel identified to provide professional judgments
	d	promoting the effective utilization of laboratory services;	Records of communication with stake holders on lab. services
	e	consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.	- Acceptance and rejection criteria - Communication log with affected clients
	4.8 Resolution of complaints	The laboratory shall have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken (see also 4.14.3).	- Documented procedure for managing complaints and feedback - Record of complaints and feedback - Investigation carried out (e.g: corrective and preventive actions taken)
	4.9 Identification	The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality	SOPs for identification and control of nonconformities

	and control of nonconformities	management system, including pre-examination, examination or post-examination processes. The procedure shall ensure that:	addressing sub parts (a - h)
	a	the responsibilities and authorities for handling nonconformities are designated;	Evidence that non conformities are handled by designated personnel
	b	the immediate actions to be taken are defined;	Records of immediate action taken
	c	the extent of the nonconformity is determined;	Classification of non-conformities
	d	examinations are halted and reports withheld as necessary;	Sample of results withheld as a result of non-conformity
	e	the medical significance of any nonconforming examinations is considered and, where appropriate, therequesting clinician or authorized individual responsible for using the results is informed;	Evidence of communication of non-conformities to clinical service providers
	f	The results of any nonconforming or potentially nonconforming examinations already released are recalledor appropriately identified, as necessary;	Records of recalled results
	g	the responsibility for authorization of the resumption of examinations is defined;	Records of implementation by authorized personnel
	h	each episode of nonconformity is documented and recorded, with these records being reviewed at regularspecified intervals to detect trends and initiate corrective action.	Record of non-conformities Evidence of review
	4.10 Corrective action	The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shallbe appropriate to the effects of the nonconformities encountered. The laboratory shall have a documented procedure for:	Availability of SOP on corrective action addressing sub parts (a - f) Occurrence or non-conformity /Corrective action log
	a	reviewing nonconformities;	Evidence of review of identified non-conformities
	b	determining the root causes of nonconformities;	Record of root causes identified
	c	evaluating the need for corrective action to ensure that nonconformities do not recur;	Records of reviewed root causes to determine the appropriate corrective action
	d	determining and implementing corrective action needed;	Record of corrective actions implemented
	e	recording the results of corrective action taken (see 4.13);	Record of the outcome of the corrective action taken
	f	reviewing the effectiveness of the corrective action taken (see 4.14.5).	Record of follow-up action
	4.11 Preventive	The laboratory shall determine action to eliminate the causes of potential nonconformities	Availability of SOP on preventive action

	action	in order to preventtheir occurrence. Preventive actions shall be appropriate to the effects of the potential problems. The laboratory shall have a documented procedure for:	addressing sub parts (a - f) - Occurrence or non-conformity /preventive action log
	a	reviewing laboratory data and information to determine where potential nonconformities exist;	Evidence of review of laboratory data information to identify potential non-conformities
	b	determining the root cause(s) of potential nonconformities;	Record of possible root causes ofpotential non-conformities
	c	evaluating the need for preventive action to prevent the occurrence of nonconformities;	Records of potential root causes to determine the appropriate preventive action to be taken
	d	determining and implementing preventive action needed;	Record of preventive actions implemented
	e	recording the results of preventive action taken (see 4.13);	Record of the outcome of the preventive action taken
	f	reviewing the effectiveness of the preventive action taken.	Record of follow-up action taken
	4.12 Continual improvement	The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews tocompare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action plans for improvement shall bedeveloped, documented and implemented, as appropriate. The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned (see also 4.14.5).	- Reports of management review meeting - Records of corrective and preventive actions - Record of improvement activities - Facility's action plan - Internal audit reports
		Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall communicate to staff improvement plans and related goals.	- Records of improvement activities - Evidence of communication with laboratory staff (minutes of meetings, memos, letters)
	4.13 Control of records	The laboratory shall have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records.	Availability of SOP covering identification, collection, indexing, access, storage, maintenance,

			amendment and safe disposal of quality and safety records
		Records shall be created concurrently with performance of each activity that affects the quality of the examination.	- Sample log - Records containing each activity that affect the quality of the examination with date and time (Eg: worksheet, temperature chart, expiry date of reagents)
		The date and where relevant, the time of amendments to records shall be captured along with the identity ofpersonnel making the amendments.	- SOP - Evidence of any amendment indicating date, time and identity of personnel
		The laboratory shall define the time period that various records pertaining to the quality management system,including pre-examination, examination and post-examination processes, are to be retained. The length of time that records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation.	- Policy on retention - SOP detailing retention criteria for quality and technical records to include but not limited to a-v below - Evidence of compliancewith SOP by examining documents listed a-v below - Retrievability of records -
		Records shall include, at least, the following:	
	a	supplier selection and performance, and changes to the approved supplier list;	
	b	staff qualifications, training and competency records;	
	c	request for examination;	
	d	records of receipt of samples in the laboratory;	
	e	information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);	
	f	laboratory work books or work sheets;	
	g	instrument printouts and retained data and information;	
	h	examination results and reports;	
	i	instrument maintenance records, including internal and external calibration records;	
	j	calibration functions and conversion factors;	
	k	quality control records;	
	l	incident records and action taken;	
	m	accident records and action taken;	
	n	risk management records;	

Commented [L1]: Does not exist in standard document

	o	nonconformities identified and immediate or corrective action taken;	
	p	preventive action taken;	
	q	complaints and action taken;	
	r	records of internal and external audits;	
	s	Inter-laboratory comparisons of examination results;	
	t	records of quality improvement activities;	
	u	minutes of meetings that record decisions made about the laboratory's quality management activities;	
	v	records of management reviews.	
	4.14 Evaluation and audits		
	4.14.1 General	The laboratory shall plan and implement the evaluation and internal audit processes needed to:	- Policy on evaluation and audits - Evaluation and internal audit Plan - Evidence of implementation
	a	demonstrate that the pre-examination, examination and post-examination and supporting processes arebeing conducted in a manner that meets the needs and requirements of users;	Feedback from users (e.g minutes of meetings with clinicians, clients' evaluation report)
	b	ensure conformity to the quality management system;	Internal audit reports
	c	continually improve the effectiveness of the quality management system. The results of evaluation and improvement activities shall be included in the input to the managementreview (see 4.15).	- Continual improvement plan and record - Minutes of management review meeting
	4.14.2 Periodic review of requests, and suitability of procedures and sample requirements	Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. The laboratory shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.	- Evidence of review by authorized personnel as specified in the quality manual or SOP - SOP for review of sample volume, collection device and preservative requirements for various body fluids and other sample types
	4.14.3 Assessment of user feedback	The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the	SOP for assessment of users' feedback Evaluation tool duly completed by users and processed by the laboratory for continual

		laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.	improvement
	4.14.4 Staff suggestions	Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.	- SOP or guideline for processing staff suggestions - Record of staff suggestions and action taken by laboratory management
	4.14.5 Internal audit	The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:	- Policy on internal audit - SOP for internal audit that contains the ingredients in a-b below - Audit plan - Audit reports that comply with the SOP requirements
	a	conform to the requirements of this International Standard and to requirements established by the laboratory	Internal audit Checklist that conforms to the requirement of ISO 15189 standards
	b	are implemented, effective, and maintained.	- Audit plan - Audit report - Corrective Action plan - Follow-up plan
	NOTE	The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The laboratory may decide to focus ona particular activity without completely neglecting the others.	Audit plan
		Audits shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit programme shall take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined and documented.	- Record of audit training - Audit plan - Audit follow-up plan
		Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall, wherever resources permit, be independent of the activity to be audited.	- Duty roster - Identity of the auditor
		The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records	SOP for internal audit

		(see 4.13).	
		Personnel responsible for the area being audited shall ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action shall be taken without undue delay to eliminate the causes of the detected nonconformities (see 4.10).	Corrective action plan
	4.14.6 Risk management	The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.	- SOP or guideline on risk management - Record of risk assessments, Risks identified and action taken
	4.14.7 Quality indicators	The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.	- SOP on selection and monitoring of quality indicators - Record of selected quality indicators
		The process of monitoring quality indicators shall be planned, which includes establishing the objectives,methodology, interpretation, limits, action plan and duration of measurement.	Evidence of quality indicator monitoring plan
		The indicators shall be periodically reviewed, to ensure their continued appropriateness.	Evidence of periodic review of quality indicators
	NOTE 1	Quality indicators to monitor non-examination procedures, such as laboratory safety and environment, completeness of equipment and personnel records, and effectiveness of the document control system may providevaluable management insights.	Evidence of quality indicators that monitor non-examination procedures such as lab safety and environment
	NOTE 2	The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12)	
		The laboratory, in consultation with the users, shall establish turnaround times for each of its examinations thatreflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the establishedturnaround times.	- SOP or guideline for establishment and monitoring of turn around time - Evidence of establishedturn around time - Evidence of evaluation of meeting the established turn around times
	4.14.8 Reviews by external organizations	When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities,the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken.	- Record of review by external organization and follow up action by the laboratory
	4.15 Management		

	review		
	4.15.1 General	Laboratory management shall review the quality management system at planned intervals to ensure itscontinuing suitability, adequacy and effectiveness and support of patient care.	- Management review meeting plans - Minutes of management review meetings
	4.15.2 Review input	The input to management review shall include information from the results of evaluations of at least the following:	The review meeting agenda and minutes should include all the inputs required (a) – (o).
	a	the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);	
	b	assessment of user feedback (see 4.14.3);	
	C	staff suggestions (see 4.14.4);	
	d	internal audits (see 4.14.5);	
	e	risk management (see 4.14.6)	
	F	use of quality indicators (see 4.14.7);	
	g	reviews by external organizations (see 4.14.8);	
	h	results of participation in inter -laboratory comparison programmes (PT/EQA) (see 5.6.3);	
	I	monitoring and resolution of complaints (see 4.8);	
	J	performance of suppliers (see 4.6);	
	K	identification and control of nonconformities (see 4.9);	
	L	results of continual improvement (see 4.12) including current status of corrective actions (see 4.10) and preventive actions (see 4.11);	
	M	follow-up actions from previous management reviews;	
	N	changes in the volume and scope of work, personnel, and premises that could affect the quality management system;	
	O	recommendations for improvement, including technical requirements.	
	4.15.3 Review activities	The review shall analyze the input information for causes of nonconformities, trends and patterns that indicate process problems.	Report of these activities in the minutes of the review meetings
		This review shall include assessing these opportunities for improvement and the need for changes to thequality management system, including the quality policy and quality objectives.	Report of these activities in the minutes of the review meetings
		The quality and appropriateness of the laboratory's contribution to patient care shall, to	Report of these activities in the minutes of the review meetings

		the extent possible,also be objectively evaluated.	
	4.15.4 Review output	The output from the management review shall be incorporated into a record that documents any decisions made and actions taken during management review related to:	Minutes of review meetings indication decisions taken and action plan addressing (a) – (c).
	A	improvement of the effectiveness of the quality management system and its processes;	
	B	improvement of services to users;	
	C	resource needs.	
	NOTE	The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established.	
		Findings and actions arising from management reviews shall be recorded and reported to laboratory staff.	Evidence of communication to staff
		Laboratory management shall ensure that actions arising from management review are completed within adefined timeframe.	Follow-up action within defined timeframe
	5 Technical requirements		
	5.1 Personnel		
	5.1.1 General	The laboratory shall have a documented procedure for personnel management and maintain records for allpersonnel to indicate compliance with requirements.	- SOPs on personnel management. - Up to date personnel file.
	5.1.2 Personnel qualifications	Laboratory management shall document personnel qualifications for each position. The qualifications shallreflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate tothe tasks performed.	Guideline defining personnel qualificationsthat reflect appropriate education, training, experience and skills.
		The personnel making judgments with reference to examinations shall have the applicable theoretical andpractical background and experience.	Guideline defining personnel qualificationsthat reflect appropriate education, training, experience and skills.
	5.1.3 Job descriptions	The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.	Approved Job descriptions detailing responsibilities, authorities and tasks for all personnel.
	5.1.4 Personnel introduction to the organizational environment	The laboratory shall have a programme to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safetyrequirements (including fire and emergency), and occupational health services.	Guideline on staff orientation. Record of staff orientation in personnel file.
	5.1.5 Training	The laboratory shall provide training for all personnel which includes the following areas:	Training policy, training manual or plan that

			covers the areas listed in (a) – (f). Evidence of trainings conducted for personnel (training certificates, training logs, attendance etc and as applicable).
	a	the quality management system;	
	b	assigned work processes and procedures;	
	c	the applicable laboratory information system;	
	d	health and safety, including the prevention or containment of the effects of adverse incidents;	
	e	ethics;	
	f	confidentiality of patient information.	
		Personnel that are undergoing training shall be supervised at all times.	Supervisory reviews on quality / testing operations performed by trainees including bench procedures.
		The effectiveness of the training programme shall be periodically reviewed.	Evidence of the review of training program e.g report showing impact of training on personnel as well as the system,
	5.1.6 Competence assessment	Following appropriate training, the laboratory shall assess the competence of each person to perform assignedmanagerial or technical tasks according to established criteria.	Policy and documented procedure for competency assessment. Records of competency assessment in personnel files.
		Reassessment shall take place at regular intervals. Retraining shall occur when necessary.	Evidence of retraining and / reassessment when required by the outcome of the competency assessment.
	NOTE	Competence of laboratory staff can be assessed by using any combination or all of the following approachesunder the same conditions as the general working environment	
	a	direct observation of routine work processes and procedures, including all applicable safety practices;	
	b	direct observation of equipment maintenance and function checks;	
	c	monitoring the recording and reporting of examination results;	
	d	review of work records;	
	e	assessment of problem solving skills;	
	f	examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples.	
	5.1.7 Reviews of staff performance	In addition to the assessment of technical competence, the laboratory shall ensure that reviews of staffperformance consider the needs of the laboratory and of the individual in order to	SOP on review of staff performance. Record of review e.g annual appraisal.

		maintain or improve thequality of service given to the users and encourage productive working relationships.	
	5.1.8 Continuing education and professional development	A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.	- Documented evidence of staff participation in CPD e.g training certificates etc that is relevant to their roles in the laboratory - Review of the effectiveness of CPD programs on performance of lab. Staff.
		Personnel shall take part in regular professional development or other professional liaison activities.	Record of participation in professional activities e.g Annual General Meetings of professional associations, Workshops, Step down meetings, scientific meetings.
	5.1.9 Personnel records	Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel shall be maintained.	Personnel records detailing (a) - (k)
		These records shall be readily available to relevant personnel and shall include but not be limited to:	
	a	educational and professional qualifications;	
	b	copy of certification or license, when applicable;	
	c	previous work experience;	
	d	job descriptions;	
	e	introduction of new staff to the laboratory environment;	
	f	training in current job tasks;	
	g	competency assessments;	
	h	records of continuing education and achievements;	
	i	reviews of staff performance;	
	j	reports of accidents and exposure to occupational hazards;	
	k	immunization status, when relevant to assigned duties.	
	5.2 Accommodation and environmental conditions		

	5.2.1 General	The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.	
		Where applicable, similar provisions shall be made for primary sample collection and examinations at sitesother than the main laboratory premises, for example point-of-care testing (POCT) under the management of the laboratory.	
	5.2.2 Laboratory and office facilities	The laboratory and associated office facilities shall provide an environment suitable for the tasks to beundertaken, to ensure the following conditions are met.	
	a	Access to areas affecting the quality of examinations is controlled. Access control should take into consideration safety, confidentiality, quality and prevailing practices.	
	b	Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.	
	c	Facilities for examination allow for correct performance of examinations. These include, for example,energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.	
	d	Communication systems within the laboratory are appropriate to the size and complexity of the facility toensure the efficient transfer of information.	
	e	Safety facilities and devices are provided and their functioning regularly verified.	
	5.2.3 Storage facilities	Storage space and conditions shall be provided that ensure the continuing integrity of sample materials,documents, equipment, reagents, consumables, records, results and any other items that could affect thequality of examination results.	
		Clinical samples and materials used in examination processes shall be stored in a manner to prevent crosscontamination.	
		Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements.	
	5.2.4 Staff facilities	There shall be adequate access to washrooms, to a supply of drinking water and to facilities for storage ofpersonal protective equipment and clothing.	
	5.2.5 Patient	Patient sample collection facilities shall have	

	sample collection facilities	separate reception/waiting and collection areas. Considerationshall be given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection.	
		Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall enable thesample collection to be undertaken in a manner that does not invalidate the results or adversely affect thequality of the examination.	
		Sample collection facilities shall have and maintain appropriate first aid materials for both patient and staff needs.	
	5.2.6 Facility maintenance and environmental conditions	Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.	
		The laboratory shall monitor, control and record environmental conditions, as required by relevant specificationsor where they may influence the quality of the sample, results, and/or the health of staff. Attention shall be paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.	
		There shall be effective separation between laboratory sections in which there are incompatible activities. Procedures shall be in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.	
		The laboratory shall provide a quiet and uninterrupted work environment where it is needed.	
	5.3 Laboratory equipment, reagents, and consumables		
	5.3.1 Equipment		
	5.3.1.1 General	The laboratory shall have a documented procedure for the selection, purchasing and management of equipment.	
		The laboratory shall be furnished with all equipment needed for the provision of services	

		(including primarysample collection, sample preparation, sample processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure thatthe requirements of this International Standard are met.	
		The laboratory shall replace equipment as needed to ensure the quality of examination results.	
	5.3.1.2 Equipment acceptance testing	The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned (see also 5.5.1)	
	5.3.1.3 Equipment instructions for use	Equipment shall be operated at all times by trained and authorized personnel.	
		Current instructions on the use, safety and maintenance of equipment, including any relevant manuals anddirections for use provided by the manufacturer of the equipment, shall be readily available.	
		The laboratory shall have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.	
	5.3.1.4 Equipment calibration and metrological traceability	The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:	
	a	taking into account conditions of use and the manufacturer's instructions;	
	b	recording the metrological traceability of the calibration standard and the traceable calibration of the itemof equipment;	
	c	verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;	
	d	recording the calibration status and date of recalibration;	
	e	ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors arecorrectly updated;	
	f	safeguards to prevent adjustments or tampering that might invalidate examination results.	
		Metrological traceability shall be to a reference material or reference procedure of the higher metrologicalorder available.	

Commented [L2]: Explanation for a – f above

		Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following: — use of certified reference materials; — examination or calibration by another procedure; — mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.	
	5.3.1.5 Equipment maintenance and repair	The laboratory shall have a documented programme of preventive maintenance which, at a minimum, followsthe manufacturer's instructions.	
		Equipment shall be maintained in a safe working condition and in working order. This shall include examinationof electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical,radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules orinstructions, or both, shall be used.	
		Whenever equipment is found to be defective, it shall be taken out of service and clearly labeled. The laboratoryshall ensure that defective equipment is not used until it has been repaired and shown by verification to meetspecified acceptance criteria. The laboratory shall examine the effect of any defects on previous examinationsand institute immediate action or corrective action (see 4.10).	
		The laboratory shall take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.	
		When equipment is removed from the direct control of the laboratory, the laboratory shall ensure that itsperformance is verified before being returned to laboratory use.	
	5.3.1.6 Equipment adverse incident reporting	Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated andreported to the manufacturer and appropriate authorities, as required.	
	5.3.1.7 Equipment records	Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following:	
	a	identity of the equipment;	
	b	manufacturer's name, model and serial number or other unique identification;	
	c	contact information for the supplier or the manufacturer;	

	d	date of receiving and date of entering into service;	
	e	location;	
	f	condition when received (e.g. new, used or reconditioned);	
	g	manufacturer's instructions;	
	h	records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;	
	i	maintenance carried out and the schedule for preventive maintenance;	
	j	equipment performance records that confirm the equipment's ongoing acceptability for use;	
	k	damage to, or malfunction, modification, or repair of the equipment.	
	l	The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfill part or all of this requirement.	
	m	These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure (see 4.13).	
	5.3.2 Reagents and consumables		
	5.3.2.1 General	The laboratory shall have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.	
	5.3.2.2 Reagents and consumables — Reception and storage	Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.	
		The laboratory shall store received reagents and consumables according to manufacturer's specifications.	
	5.3.2.3 Reagents and consumables — Acceptance testing	Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before use in examinations.	
		Consumables that can affect the quality of examinations shall be verified for performance before use inexaminations.	
	5.3.2.4 Reagents and consumables — Inventory management	The laboratory shall establish an inventory control system for reagents and consumables.	
		The system for inventory control shall segregate	

		uninspected and unacceptable reagents and consumables from those that have been accepted for use.	
	5.3.2.5 Reagents and consumables — Instructions for use	Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available.	
	5.3.2.6 Reagents and consumables — Adverse incident reporting	Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to the manufacturer and appropriate authorities, as required.	
	5.3.2.7 Reagents and consumables — Records	Records shall be maintained for each reagent and consumable that contributes to the performance ofexaminations. These records shall include but not be limited to the following:	
	a	identity of the reagent or consumable;	
	b	manufacturer's name and batch code or lot number;	
	c	contact information for the supplier or the manufacturer;	
	d	date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service;	
	e	condition when received (e.g. acceptable or damaged);	
	f	manufacturer's instructions;	
	g	records that confirmed the reagent's or consumable's initial acceptance for use;	
	h	performance records that confirm the reagent's or consumable's ongoing acceptance for use.	
	i.	Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.	
	5.4 Pre-examination processes		
	5.4.1 General	The laboratory shall have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.	Sample collection manualor SOPs addressing all the pre-examination processes. (e.gpatient preparation, sample collection, transportation, handling, processing, storage)
	5.4.2 Information for patients and users	The laboratory shall have information available for patients and users of the laboratory services. The information shall include as appropriate:	Laboratory User Handbook addressing each of the sub-parts (a-m) described below.
	A	the location of the laboratory;	Physical address of the

			lab
	B	types of clinical services offered by the laboratory including examinations referred to other laboratories;	Range or scope of services provided by the laboratory such as Clinical Chemistry, Haematology, Bacteriology, Histopathology, Immunology. List of tests that are performed in other labs.
	C	opening hours of the laboratory;	Laboratory working hours (including call hours where applicable)
	d	the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values;	List of tests performed by the laboratory, sample type and volume for each test or group of tests, TAT for each test or group of tests provided. List of biological reference ranges and values required to establish diagnosis for each test.
	E	instructions for completion of the request form;	Guidance on how the lab request form should be completed, including a list of the information to be provided on the form.
	F	instruction for preparation of the patient;	Description of the conditions that should be met, and precautions to take before sample collection within or outside the laboratory.
	G	instructions for patient-collected samples;	Guidance on how patients can collect their own samples for the relevant sample type e.g. urine, stool, sputum etc.
	H	instructions for transportation of samples, including any special handling needs;	Guidance on transportation of samples to the laboratory, including temperature requirements and special packaging.
	I	any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);	Statement describing the kind of consent required.

	J	the laboratory's criteria for accepting and rejecting samples;	Sample rejection and acceptance criteria
	K	a list of factors known to significantly affect the performance of the examination or the interpretation of the results;	Critical interfering substances, assay limitations.
	L	availability of clinical advice on ordering of examinations and on interpretation of examination results;	Statement on how advisory services are provided to lab users on test selection and result interpretation
	M	the laboratory's policy on protection of personal information;	Policy statement that guarantees the confidentiality of patient information.
	n	the laboratory's complaint procedure.	Steps for receiving, analyzing and resolving complaints from lab users, and communicating feedback.
		The laboratory shall have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), shall be explained to the patient and user.	Statements describingthe tests that will require informed consent oflab users.
	5.4.3 Request form information	The request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:	Test request form that provides space for the following sub-parts of the clause
	A	patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;	Space for patient name, sex, date of birth or age, clinic, ward, or hospital name. Hospital number or other special identifiers
	B	name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;	Space for the name, location (clinic, ward, hospital, or physical address) and contact (phone number) of authorized requestor.
	C	type of primary sample and, where relevant, the anatomic site of origin;	Type of sample required for each laboratory exam, and site in cases of histopathological samples.
	D	examinations requested;	Space for the test to be performed.
	E	clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;	Space for provisional diagnosis, drug treatment, medical history.

	F	date and, where relevant, time of primary sample collection;	Space for date and time of sample collection.
	G	date and time of sample receipt.	Space for date and time when sample was received in the laboratory.
		The laboratory shall have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.	SOP or section of SOP describing how a verbal requestwill be received in the laboratory and the time limit for receiving the filled request form.
		The laboratory shall be willing to cooperate with users or their representatives in clarifying the user's request.	Observation on how clarifications are provided to lab users.
	5.4.4 Primary sample collection and handling		
	5.4.4.1 General	The laboratory shall have documented procedures for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.	SOP for sample collection and handling that has been made available at all points of sample collection within and outside the laboratory. Document distribution log.
		Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these shall be recorded and included in all documents containing examination results and shall be communicated to the appropriate personnel.	Record of deviation on documented procedure for sample collection.
		Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.	Description of special test procedures requiring special explanations and written informed consent.Observation at the sample collection point how patients' consents are granted.
		In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.	Description of some conditions under which patients may not be poised to grant informed consent.
	5.4.4.2 Instructions for pre-collection activities	The laboratory's instructions for pre-collection activities shall include the following:	SOP or Guideline on sample collection addressing (a) – (e)
	A	completion of request form or electronic request;	
	B	preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and	

		patients);	
	c	type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;	
	D	special timing of collection, where needed;	
	E	clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).	
	5.4.4.3 Instructions for collection activities	The laboratory's instructions for collection activities shall include the following:	SOP or Guideline for sample collection addressing (a) – (h).
	A	determination of the identity of the patient from whom a primary sample is collected;	
	B	verification that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.];	
	C	instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;	
	D	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;	
	E	instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;	
	F	recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;	
	g	instructions for proper storage conditions before collected samples are delivered to the laboratory;	
	H	safe disposal of materials used in the collection.	
	5.4.5 Sample transportation	The laboratory's instructions for post-collection activities shall include packaging of samples for transportation.	SOP or Guideline for sample packaging and transportation.
		The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported:	Sample transportation SOP addressing (a) – (c).
	A	within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;	
	B	within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;	
	C	in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in	

		compliance with established requirements.	
	5.4.6 Sample reception	The laboratory's procedure for sample reception shall ensure that the following conditions are met.	Evidence that laboratory procedure for sample reception are met as in (a) - (f)
	A	Samples are unequivocally traceable, by request and labelling, to an identified patient or site.	Sample IDs should be unique and traceable to an identified patient or site
	B	Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.	Laboratory's adherence to its sample acceptance and rejection criteria.
	C	Where there are problems with 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, where applicable, that caution is required when interpreting the result.	Appropriate comments should be provided in the final report when samples that do not meet acceptance criteria are processed and tested.
	D	All samples received are recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.	Sample logbook or specimen reception register (electronic or paper-based) containing date and time sample was received in the laboratory. Identity of person receiving sample where possible.
	e	Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).	Assigned responsibilities for evaluating samples against the acceptance and rejection criteria. Evidence of adherence to the criteria.
	F	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.	Section of sample collection SOP describing steps for handling urgent samples (from sample receipt to reporting of result)
		All portions of the primary sample shall be unequivocally traceable to the original primary sample.	Similar relationships should exist between identifiers on primary sample and aliquots.
	5.4.7 Pre-examination handling,	The laboratory shall have procedures and appropriate facilities for securing patient samples and avoidingdeterioration, loss or damage during	Guideline for sample storage.

	preparation and storage	pre-examination activities and during handling, preparation and storage.	Appropriate facilities e.g freezers, refrigerators, designated for sample storage. Secured storage facilities.
		Laboratory procedures shall include time limits for requesting additional examinations or further examinations on the same primary sample.	Defined time interval within which additional tests can be requested from a stored sample.
	5.5 Examination processes		
	5.5.1 Selection, verification and validation of examination procedures		
	5.5.1.1 General	The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded.	Evidence that examination procedures have been validated. Record of persons performing examination processes.
		The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination.	Evidence that specified performance specifications for each examination procedure has been met
	5.5.1.2 Verification of examination procedures	Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.	Record of independent verification of validated examination procedures by the laboratory.
		The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure.	Information from manufacturer/method developer on performance characteristics.
		The independent verification by the laboratory shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results.	Evidence of independent verification of the examination procedure by the laboratory.
		The laboratory shall document the procedure used for the verification and record the results obtained. Staff with the appropriate authority shall review the verification results and record the review.	Method verification SOP Record of the results obtained from the

			independent verification of the examination procedures. Record of staff who performed the verification review.
	5.5.1.3 Validation of examination procedures	The laboratory shall validate examination procedures derived from the following sources:	Record of validation carried out on any of the following procedures (a) – (d)
	a	non-standard methods;	
	b	laboratory designed or developed methods;	
	c	standard methods used outside their intended scope;	
	d	validated methods subsequently modified.	
		The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.	Validation protocol. Record of validation.
		The laboratory shall document the procedure used for the validation and record the results obtained. Staff with the authority shall review the validation results and record the review.	Method validation SOP Record of results obtained. Designated authority for review of validation results.
		When changes are made to a validated examination procedure, the influence of such changes shall bedocumented and, when appropriate, a new validation shall be carried out.	Record of changes made on validated examination procedure. Where applicable, evidence of re-validation
	5.5.1.4 Measurement uncertainty of measured quantity values	The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.	Defined measurement uncertainty for each test. Record of review of estimates of measurement uncertainty.
		The laboratory shall consider measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory shall make its estimates of measurement uncertainty available to laboratory users.	Record of estimates of measurement uncertainty. Evidence that measurement uncertainty has been shared with lab users upon request.
		Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in	Record of measuring uncertainty preceding analytical phase in qualitative analysis.

		assessing the reliability of the examination procedure or has influence on the reported result.	
	5.5.2 Biological reference intervals or clinical decision values	The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.	Evidence of defined reference ranges or clinical decision values and communication tousers Basis for adopted /defined reference ranges.
		When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes shall be made and communicated to the users.	Evidence of changes in biological reference intervals and communication to the users.
		When the laboratory changes an examination procedure or pre-examination procedure, the laboratory shall review associated reference intervals and clinical decision values, as applicable.	Evidence of changes in examination or pre-examination procedure with associated review of reference intervals and clinical decision values where applicable.
	5.5.3 Documentation of examination procedures	Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.	SOP for individual test methods written in a language commonly understood by the staff Availability in appropriate location.
		Any condensed document format (e.g. card files or similarly used systems) shall correspond to the documented procedure.	Format of abridged versions of documents should correspond with the main document e.g. Job aids
		All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, shall be subject to document control.	Evidence of document control features in all examination procedure documents.
		In addition to document control identifiers, documentation shall include when applicable to the examination procedure, the following:	Evidence that examination SOPs format includes (a) – (t) where applicable.
	a	purpose of the examination;	
	b	principle and method of the procedure used for examinations;	
	c	performance characteristics (see 5.5.1.2 and 5.5.1.3);	
	d	type of sample (e.g. plasma, serum, urine);	
	e	patient preparation;	
	f	type of container and additives;	
	g	required equipment and reagents;	
	h	environmental and safety controls;	

	i	calibration procedures (metrological traceability);	
	j	procedural steps;	
	k	quality control procedures;	
	l	interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;	
	m	principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values;	
	n	biological reference intervals or clinical decision values;	
	o	reportable interval of examination results;	
	p	instructions for determining quantitative results when a result is not within the measurement interval;	
	q	alert/critical values, where appropriate;	
	r	laboratory clinical interpretation;	
	s	potential sources of variation;	
	t	references.	
		If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure.	Procedure for communicating changes in examination processes and interpretation to users.
	5.6 Ensuring quality of examination results		
	5.6.1 General	The laboratory shall ensure the quality of examinations by performing them under defined conditions.	Documented conditions under which examinations are performed. Evidence that conditions are met.
		Appropriate pre and post-examination processes shall be implemented (see 4.14.7, 5.4, 5.7 and 5.8).	Record of appropriate pre and post examination processes as implemented.
		The laboratory shall not fabricate any results.	Traceability of results through the laboratory path of work flow
	5.6.2 Quality control		
	5.6.2.1 General	The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.	Quality control (QC) procedure.
	5.6.2.2 Quality control materials	The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples.	Evidence that quality control materials used in the lab mimic patient samples.
		Quality control materials shall be periodically	Define frequency for

		examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.	performing QC for each test.
	5.6.2.3 Quality control data	The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.	Policy and Procedure that prevents the release of result in the event of QC failure.
		When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall also evaluate the results from patient samples that were examined after the last successful quality control event.	Evidence of selected QC rules Record of rejected QC and patient results Record of root causes and corrective actions for rejected QC result .
		Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions shall be taken and recorded.	Evidence of review of quality control data using LJ Chart, Westgard Rule etc. Record of preventive action taken.
	5.6.3 Interlaboratory comparisons		
	5.6.3.1 Participation	The laboratory shall participate in an inter-laboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the inter-laboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.	Evidence of participation in an EQA or PT programme for all test performed in the lab. Record of review of results and corrective action taken.
		The laboratory shall establish a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison programme.	Documented procedure for inter-laboratory comparison. Criteria for participation.
		Inter-laboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.	Evidence that panels used in inter-laboratory comparison mimic patient samples and where possible checks the entire path of work flow.
	5.6.3.2 Alternative approaches	Whenever an inter-laboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination	Record of other alternative approaches for PT e.g. Examination on samples split with another laboratory,

		results.	direct observation of technique dependent tests, etc. Evidence of acceptability criteria.
	NOTE	Whenever possible, this mechanism shall utilize appropriate materials. Examples of such materials may include: — certified reference materials; — samples previously examined; — material from cell or tissue repositories; — exchange of samples with other laboratories; — control materials that are tested daily in inter-laboratory comparison programmes.	Stock samples, control materials etc
	5.6.3.3 Analysis of inter-laboratory comparison samples	The laboratory shall integrate inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.	Policy and procedure for handling inter-laboratory comparison samples Traceability across the path of work flow.
		Inter-laboratory comparison samples shall be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.	Evidence that PT samples were tested by the same personnel responsible for routine testing using the same procedure.
		The laboratory shall not communicate with other participants in the inter-laboratory comparison programme about sample data until after the date for submission of the data.	Policy that forbids communication on PT results between labs before submission deadline.
		The laboratory shall not refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.	Policy that forbids referral of PT samples to other labs for confirmation before submission deadline.
	5.6.3.4 Evaluation of laboratory performance	The performance in inter-laboratory comparisons shall be reviewed and discussed with relevant staff.	Record of review of inter-laboratory comparison performance.
		When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff shallparticipate in the implementation and recording of corrective action. The effectiveness of corrective actionshall be monitored. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.	Record of corrective action for all unsatisfactory PT results. Record of follow-up action taken. Record ofpreventive action taken on potential nonconformities.
	5.6.4 Comparability of examination results	There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different	Instructions for comparing procedures, equipment and methods used. Records of comparison

		procedures, equipment, different sites, or all of these.	conducted.
		The laboratory shall notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.	Procedure for notifying users of any differences in comparability of results Records of notification of differences to users. .
		The laboratory shall document, record and, as appropriate, expeditiously act upon results from the comparisonsperformed. Problems or deficiencies identified shall be acted upon and records of actions retained.	Record of comparisons performed. Recordsof deficiencies and action taken.
	5.7 Post-examination processes		
	5.7.1 Review of results	The laboratory shall have procedures to ensure that authorized personnel review the results of examinationsbefore release and evaluate them against internal quality control and, as appropriate, available clinicalinformation and previous examination results.	SOP for review of results Sample of reviewed lab result
		When the procedure for reviewing results involves automatic selection and reporting, review criteria shall beestablished, approved and documented (see 5.9.1).	Criteria for automatic review of results
	5.7.2 Storage, retention and disposal of clinical samples	The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.	SOP addressing all the requirements
		The laboratory shall define the length of time clinical samples are to be retained. Retention time shall bedefined by the nature of the sample, the examination and any applicable requirements.	Evidence of defined retention criteria
		Safe disposal of samples shall be carried out in accordance with local regulations or recommendations forwaste management.	SOP/ Guidelines for Safe disposal of samples in accordance with local regulations. Adherence to SOP
	5.8 Reporting of results		
	5.8.1 General	The results of each examination shall be reported accurately, clearly, unambiguously and in accordance withany specific instructions in the examination procedures.	Retained copies of issued lab reports, SOP for result reporting Confirm accuracy with result log
		The laboratory shall define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory.	Format and medium of communication defined for result reporting in Quality Manual and

			SOP.
		The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results.	Procedure for verification of transcription errors.
		Reports shall include the information necessary for the interpretation of the examination results.	Reference range and provision for comments in report sheet
		The laboratory shall have a process for notifying the requester when an examination is delayed that couldcompromise patient care.	Procedure for notifying requesters when examinations are delayed Retained copies of or documented evidence of such requester notification
	5.8.2 Report attributes	The laboratory shall ensure that the following report attributes effectively communicate laboratory results andmeet the users' needs:	Comment on completed report addressing (a) – (d)
	a	comments on sample quality that might compromise examination results;	
	b	comments regarding sample suitability with respect to acceptance/rejection criteria;	
	c	critical results, where applicable;	
	d	interpretive comments on results, where applicable, which may include the verification of the interpretationof automatically selected and reported results (see 5.9.1) in the final report.	
	5.8.3 Report content	The report shall include, but not be limited to, the following:	Lab reports that meet requirements (a) -(p)
	a	a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;	
	b	the identification of the laboratory that issued the report;	
	c	identification of all examinations that have been performed by a referral laboratory;	
	d	patient identification and patient location on each page;	
	e	name or other unique identifier of the requester and the requester's contact details;	
	f	date of primary sample collection (and time, when available and relevant to patient care);	
	g	type of primary sample;	
	h	measurement procedure, where appropriate;	
	i	examination results reported in SI units, units traceable to SI units, or other applicable units;	
	j	biological reference intervals, clinical decision values, or diagrams/ nomograms supporting clinical decisionvalues, where applicable;	
	k	interpretation of results, where appropriate;	
	l	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);	
	m	identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;	
	n	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);	
	o	date of the report, and time of release (if not contained in the report, readily available when needed);	
	p	page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.).	
	5.9 Release of results		
	5.9.1 General	The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.	SOPs for release of examination results that addresses (a) – (e) Adherence to SOPs
	a	When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.	
	b	When examination results fall within established “alert” or “critical” intervals: — a physician (or other authorized health professional) is notified immediately [this includes resultsreceived on samples sent to referral laboratories for examination (see 4.5)]; — records are maintained of actions taken that document date, time, responsible laboratory staff member,person notified and examination results conveyed, and any difficulties encountered in notifications.	
	c	Results are legible, without mistakes in transcription, and reported to persons authorized to receive anduse the information.	
	d	When results are transmitted as an interim report, the final report is always forwarded to the requester.	
	e	There are processes for ensuring that results distributed by telephone or electronic means reach onlyauthorized recipients. Results provided orally shall be followed by a written report. There shall be a recordof all oral results provided.	
	5.9.2 Automated selection and reporting of results	If the laboratory implements a system for automated selection and reporting of results, it shall establish adocumented procedure to ensure that:	Documented procedure and criteria for automated selection and reporting of results that takes account (a) – (f)

	a	the criteria for automated selection and reporting are defined, approved, readily available and understoodby the staff;	
	b	the criteria are validated for proper function before use and verified after changes to the system that might affect their functioning;	
	c	there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia)that may alter the results of the examination;	
	d	there is a process for incorporating analytical warning messages from the instruments into the automatedselection and reporting criteria, when appropriate;	
	e	results selected for automated reporting shall be identifiable at the time of review before release andinclude date and time of selection;	
	f	there is a process for rapid suspension of automated selection and reporting.	
	5.9.3 Revised reports	When an original report is revised there shall be written instructions regarding the revision so that:	Procedure for revision or alteration of reports addressing (a) – (d) Adherence to procedure
	a	the revised report is clearly identified as a revision and includes reference to the date and patient's identityin the original report;	
	b	the user is made aware of the revision;	
	c	the revised record shows the time and date of the change and the name of the person responsible for thechange;	
	d	the original report entries remain in the record when revisions are made.	
		Results that have been made available for clinical decision making and revised shall be retained in subsequentcumulative reports and clearly identified as having been revised.	Procedure for management of revised results Adherence to procedure or guidelines
		When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.	Evidence of such amendment
	5.10 Laboratory information management		
	5.10.1 General	The laboratory shall have access to the data and information needed to provide a service which meets theneeds and requirements of the user.	Access to necessary data and information for service provision
		The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.	policy and procedure on confidentiality of patient information

	5.10.2 Authorities and responsibilities	The laboratory shall ensure that the authorities and responsibilities for the management of the informationsystem are defined, including the maintenance and modification to the information system(s) that may affectpatient care.	Defined authorities and responsibilities of personnel who manage and maintain the information system
		The laboratory shall define the authorities and responsibilities of all personnel who use the system, inparticular those who:	Definition of authorities and responsibilities of all personnel who use the system to meet requirements (a) - (d)
	a	access patient data and information;	
	b	enter patient data and examination results;	
	c	change patient data or examination results;	
	d	authorize the release of examination results and reports.	
	5.10.3 Information system management	The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:	
	a	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;	Evidence of validation by the suppliers of LIMS Policy and procedure for verification of information management system
	b	documented, and the documentation, including that for day to day functioning of the system, is readily available to authorized users;	Procedures(SOP) for operation of information management system available to authorized users Evidence of authorization
	c	protected from unauthorized access;	Evidence of access control
	d	safeguarded against tampering or loss;	Evidence of access control and backup
	e	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;	Supplier's specifications and adherence
	f	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;	Service and maintenance records, corrective action log and records of root cause analysis for the information systems
	g	in compliance with national or international requirements regarding data protection.	Reference to national or international requirements regarding data protection

			Adherence to the requirement.
		The laboratory shall verify that the results of examinations, associated information and comments areaccurately reproduced, electronically and in hard copy where relevant, by the information systems externalto the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail,website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.	Procedures for and records of verifications
		The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.	Documented contingency plan Backup systems
		When the information system(s) are managed and maintained off-site or subcontracted to an alternativeprovider, laboratory management shall be responsible for ensuring that the provider or operator of the systemcomplies with all applicable requirements of this International Standard.	Evidence of contract agreement / MOU

Follow up on last year findings

Other Observation and Comments

Name and Signature of Assessor with date