



**ISO/IEC 15189:2012 Checklist for
Medical Laboratories**

F07/06C

For office use: EAS Acc. No					
Laboratory: Field of operation:					
Assessor/s & Observers:					
Laboratory Representative:					
Date of Evaluation:					
This report covers the following:					
Type of Assessment (Tick box):	Initial:		Follow Up		Re-assessment:
Document Review only:	Site Visit only:		Document Review and Site visit:		Other:

Laboratories wishing to apply for accreditation shall indicate how requirements have been addressed, documented and implemented on the comment side of each requirement. Assessors can use the space provide to write evidence for the assessment findings on the comment side of each requirement. (Key: C = Comply, NC = not comply, NA = not applicable)

CLAUSE	REQUIREMENTS	Filled by CAB indicating in which document & clause No. the requirements are addressed	Document review by team leader (Reference Documents)	C/NC/NA	On site assessment Objective Evidence (Provide supporting information to prove implementation; describe the observations; note which records were reviewed.)	C/NC/NA
4	MANAGEMENT REQUIREMENTS					
4.1	Organization and management responsibility					
4.1.1	<u>Organization:</u> Indicate how the following requirements are addressed/ implemented.					
4.1.1.1	<u>General:</u> Does the medical laboratory (hereinafter referred to as 'the laboratory') meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities?					
4.1.1.2	<u>Legal entity:</u> Is the laboratory or the organization of which it is part an entity that can be held legally responsible?					
4.1.1.3	<u>Ethical conduct:</u> Does laboratory management have arrangements in place to ensure the following: a) There is no involvement in any activities that					

	would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity?					
	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?					
	c) where potential conflicts in competing interests may exist, they shall be openly and appropriately declared?					
	d) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements?					
	e) confidentiality of information is maintained?					
4.1.1.4	<u>Laboratory director:</u> Is the laboratory directed by a person or persons with the competence and delegated responsibility for the services provided?					
	Do the responsibilities of the laboratory director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory?					
	May the laboratory director 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?					
	Are the duties and responsibilities of the laboratory director documented?					
	Does the laboratory director (or the designates for delegated duties) have the necessary competence, authority and resources in order to fulfill the requirements of this International Standard?					
	Does the laboratory director (or designate/s)					
	a) provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities?					
	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?					

	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?				
	d) ensure the implementation of the quality policy?				
	e) implement a safe laboratory environment in compliance with good practice and applicable requirements?				
	f) serve as a contributing member of the medical staff for those facilities served, 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?				
	h) select and monitor laboratory suppliers?				
	i) select referral laboratories and monitor the quality of their service?				
	j) provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations?				
	k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services? NOTE: This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.				
	l) monitor all work performed in the laboratory to determine that clinically relevant information is being generated?				
	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)?				
	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? NOTE: Contingency plans should be periodically tested.				
	o) plan and direct research and development, where appropriate?				
4.1.2	Management responsibility: Indicate how the following requirements are addressed/ implemented.				

4.1.2.1	<p><u>Management commitment:</u> Does laboratory management provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:</p> <p>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?</p>					
	b) establishing the quality policy (see 4.1.2.3)?					
	c) ensuring that quality objectives and planning are established (see 4.1.2.4)?					
	d) defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5)?					
	e) establishing communication processes (see 4.1.2.6)?					
	f) appointing a quality manager, however named (see 4.1.2.7);					
	g) conducting management reviews (see 4.15)?					
	h) ensuring that all personnel are competent to perform their assigned activities (see 5.1.6)?					
	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).					
4.1.2.2	<p><u>Needs of users:</u> Does laboratory management 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).</p>					
4.1.2.3	<p><u>Quality policy:</u> Does laboratory management define the intent of its quality management system in a quality policy?</p>					
	Does laboratory management ensure that the quality policy:					
	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	<u>Quality objectives and planning:</u> Does laboratory management establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization?				
	Do the quality objectives be measurable and consistent with the quality policy?				
	Does laboratory management ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives?				
	Does laboratory management ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?				
4.1.2.5	<u>Responsibility, authority and interrelationships:</u> Does laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization?				
	Does this include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel.				
4.1.2.6	<u>Communication:</u> Does laboratory management have an effective means for communicating with staff (see also 4.14.4)?				
	Are Records kept of items discussed in communications and meetings?				
	Does laboratory management ensure that appropriate communication processes are established between the laboratory and its stakeholders?				
	Does that communication take place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system?				
4.1.2.7	<u>Quality manager:</u> Does laboratory management appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:				
	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: Does the laboratory establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard?				
	Does the quality management system provide for the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users?				
	Does the laboratory:				
	a) determine the processes needed for the quality management system and ensure their application throughout the laboratory?				
	b) determine the sequence and interaction of these processes?				
	c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective?				
	d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes?				
	e) monitor and evaluate these processes?				
	f) implement actions necessary to achieve planned results and continual improvement of these processes?				
4.2.2	Documentation requirements				
4.2.2.1	General: Does the quality management system documentation include:				
	a) statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4)?				
	b) a quality manual (see 4.2.2.2)?				
	c) procedures and records required by this International Standard?				
	d) documents, and records (see 4.13) determined by the laboratory to ensure the effective planning, operation and control of its processes?				
	e) copies of applicable regulations, standards and other normative documents? NOTE The documentation can be in any form or type				

	of medium, providing it is readily accessible and protected from unauthorized changes and undue deterioration					
4.2.2.2	Quality manual					
	Does the laboratory shall establish and maintain a quality manual that includes:					
	a) the quality policy (see 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) Do the documented policies established for the quality management system and reference to the managerial and technical activities that support them?					
	Do all laboratory staff have access to and instructed on the use and application of the quality manual and the referenced documents?					
4.3	Document control					
	Does the laboratory control documents required by the quality management system and ensure that unintended use of any obsolete document is prevented? NOTE 1 Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken. NOTE 2 Records contain information from a particular point in time stating results achieved or providing evidence of activities performed and are maintained according to the requirements given in 4.13 ,Control of records					
	Does the laboratory have a documented					

	procedure to ensure that the following conditions are met :				
	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?				
	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? NOTE 'Edition' is used to mean one of a number of printings issued at separate times that incorporates alterations and amendments. 'Edition' can be regarded as synonymous with 'revision or version'.				
	c) Current authorized editions and their distribution are identified by means of a list (e.g. document register, log or master index)?				
	d) Only current, authorized editions of applicable documents are available at points 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, initialled and dated, and a revised document is issued within a specified time period?				
	f) Changes to documents are identified?				
	g) Documents remain legible?				
	h) Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose?				
	i) Obsolete controlled documents are dated 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?				
4.4	Service agreements				
4.4.1	<u>Establishment of service agreements:</u> Does the laboratory have documented procedures for the establishment and review of				

	agreements for providing medical laboratory services?				
	Does each request accepted by the laboratory for examination(s) considered an agreement?				
	Do the agreements to provide medical laboratory services take into account the request, the examination and the report?				
	Does the agreement specify the information needed on the request to ensure appropriate examination and result interpretation?				
	Does the following conditions 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 , defined, documented and understood (see 5.4.2 and 5.5)?				
	b) The laboratory have the capability and resources to meet the requirements?				
	c) Laboratory personnel have the skills and expertise necessary for the performance of the intended examinations?				
	d) Examination procedures selected appropriate and able to meet the customers' needs (see 5.5.1)?				
	e) Customers and users informed of deviations from the agreement that impact upon the examination results?				
	f) Reference made to any work referred by the laboratory to a referral laboratory or consultant? NOTE 1 Customers and users may include Clinicians, health care organizations, third party payment organizations or agencies, pharmaceutical companies, and patients. NOTE 2 Where patients are customers (e.g. when patients have the ability to directly request examinations), changes in service should be reflected in explanatory information and laboratory reports.				
	NOTE 3 Laboratories should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of examinations or patients or interfere with the practitioner's independent assessment of what is best for the patient.				

4.4.2	Review of service agreements				
	Do reviews of agreements to provide medical laboratory services include all aspects of the agreement?				
	Do records of these reviews include any changes to the agreement and any pertinent discussions?				
	If an agreement needs to be amended after laboratory services have commenced:				
	<ul style="list-style-type: none"> • is the same agreement review process repeated ? 				
	<ul style="list-style-type: none"> • are any amendments communicated to all affected parties? 				
4.5	Examination by referral laboratories				
4.5.1	<u>Selecting and evaluating referral laboratories and consultants</u> Does the laboratory have a documented procedure for selecting and evaluating referral laboratories and Consultants who provide opinions as well as interpretation for complex testing in any discipline?				
	Does the procedure ensure that the following conditions are met:				
	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?				
	b) Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met?				
	c) Records of such periodic reviews are maintained?				
	d) A register of all referral laboratories, and consultants from whom opinions are sought, is maintained?				
	e) Requests and results of all samples referred are kept for a pre-defined period?				
	If the contract needs to be amended after the work commences:				
	<ul style="list-style-type: none"> • is the same contract review process repeated? 				
	<ul style="list-style-type: none"> • are any amendments communicated to all affected parties? 				
4.5.2	Provision of examination results				

	Is the referral laboratory's able to meet the requirements and there are no conflicts of interest? Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) responsible for ensuring that examination results of the referral laboratory are provided to the person making the request?				
	When the referring laboratory prepares the report, does it include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation?				
	Does the report indicate which examinations were performed by a referral laboratory or consultant?				
	Does the author of any additional remarks clearly identified?				
	Do laboratories 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, does this process hindered by commercial or financial considerations?				
4.6	External services and supplies				
	Does the laboratory 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)?				
	Does the laboratory 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 fulfil this requirement. Criteria for selection established?				
	Does a list of selected and approved suppliers of equipment, reagents and consumables maintained?				
	Does Purchasing information describe the requirements for the product or service to be purchased?				
	Does the laboratory monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria?				
4.7	Advisory services				
	Does the laboratory establish arrangements for				

	communicating with users on the following:				
	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?				
	b) advising on individual clinical cases?				
	c) professional judgments on the interpretation of the results of examinations (see 5.1.2 and 5.1.6)?				
	d) promoting the effective utilization of laboratory services?				
	e) consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria?				
4.8	Resolution of complaint				
	Does the laboratory have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties?				
	Do Records maintained of all complaints and their investigation and the action taken (see also 4.14.3)?				
4.9	Identification and control of nonconformities				
	Does the laboratory have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes?				
	Does the procedure ensure that:				
	a) the responsibilities and authorities for handling nonconformities are designated?				
	b) the immediate actions to be taken are defined?				
	c) the extent of the nonconformity is determined?				
	d) examinations are halted and reports withheld as necessary?				
	e) the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed?				
	f) the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary?				
	g) the responsibility for authorization of the resumption of examinations is defined?				
	h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action?				

	NOTE Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, interlaboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.					
	When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, does the laboratory take action to identify, document and eliminate the cause(s)? Is corrective action to be taken determined and documented (see also 4.10)?					
4.10	Corrective action					
	Does the laboratory take corrective action to eliminate the cause(s) of nonconformities?					
	Do Corrective actions appropriate to the effects of the nonconformities encountered?					
	Does the laboratory have a documented procedure for:					
	a) reviewing nonconformities?					
	b) determining the root causes of nonconformities?					
	c) evaluating the need for corrective action to ensure that nonconformities do not recur?					
	d) determining and implementing corrective action needed?					
	e) recording the results of corrective action taken (see 4.13)?					
	f) reviewing the effectiveness of the corrective action taken (see 4.14.5)? NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered "immediate" action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered "corrective" action.					
4.11	Preventive action					

	Does the laboratory determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?				
	Does Preventive actions appropriate to the effects of the potential problems?				
	Does the laboratory have a documented procedure for:				
	a) reviewing laboratory data and information to determine where potential nonconformities exist?				
	b) determining the root cause(s) of potential nonconformities?				
	c) evaluating the need for preventive action to prevent the occurrence of nonconformities?				
	d) determining and implementing preventive action needed?				
	e) recording the results of preventive action taken (see 4.13)?				
	f) reviewing the effectiveness of the preventive action taken? NOTE Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).				
4.12	Continual improvement				
	Does the laboratory continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare 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?				
	Does Improvement activities directed at areas of highest priority based on risk assessments?				
	Do action plans for improvement developed, documented and implemented, as appropriate?				
	Do the effectiveness of the actions taken determined through a focused review or audit of the area concerned (see also 4.14.5)?				
		Does	laboratory		

		management 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, does laboratory management address them regardless of where they occur?					
	Does laboratory management communicate to staff improvement plans and related goals?					
4.13	Control of records					
	Does the laboratory have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records?					
	Do records created concurrently with performance of each activity that affects the quality of the examination? NOTE 1 Records can be in any form or type of medium providing they are readily accessible and protected from unauthorized alterations.					
	Does the date and, where relevant, the time of amendments to records captured along with the identity of personnel making the amendments (see 5.8.6)?					
	Does the laboratory define the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are retained?					
	If the length of time that records are retained may vary; however, do reported results retrievable for as long as medically relevant or as required by regulation? NOTE 2 Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain records for much longer periods than for other records					
	Do facilities provide a suitable environment for storage of records to prevent damage, deterioration, loss or unauthorized access (see 5.2.6)?					

	NOTE 3 For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location (see 5.9.4).				
	Do records 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?				
	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) interlaboratory 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?				
	Do all of these quality and technical records available for laboratory management review (see 4.15)?				
4.14	Evaluation and audits				

4.14.1	General Does the laboratory plan and implement the evaluation and internal audit processes needed to:				
	a) demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users?				
	b) ensure conformity to the quality management system?				
	c) continually improve the effectiveness of the quality management system?				
	Do the results of evaluation and improvement activities included in the input to the management review (see 4.15)? NOTE For improvement activities, see 4.10, 4.11, and 4.12				
4.14.2	Periodic review of requests, and suitability of procedures and sample requirements				
	Does authorized personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received?				
	Does the laboratory periodically review its sample volume, collection device and preservative requirements for 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?				
4.14.3	Assessment of user feedback				
	Does the laboratory seek information relating to user perception as to whether the service has met the needs and requirements of users?				
	Do the methods for obtaining and using this information include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users?				
	Do records kept of information collected and actions taken?				
4.14.4	Staff suggestions				
	Does laboratory management encourage staff to make suggestions for the improvement of any aspect of the laboratory service?				
	Do suggestions evaluated, implemented as				

	appropriate and feedback provided to the Staff?				
	Do records of suggestions and action taken by the management maintained?				
4.14.5	Internal audit				
	Does the laboratory conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:				
	a) conform to the requirements of this International Standard and to requirements established by the laboratory? And				
	b) are implemented, effective, and maintained?				
	NOTE 1 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 on a particular activity without completely neglecting the others.				
	Does audits conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system?				
	Does the audit programme 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?				
	Does the audit criteria, scope, frequency and methods defined and documented?				
	Are selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process?				
	Are auditors wherever resources permit, independent of the activity to be audited?				
	NOTE 2 See ISO 19011 for guidance.				
	Does the laboratory have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records?				
	Are personnel responsible for the area being audited ensured that appropriate action is promptly undertaken when nonconformities are identified?				

	Does corrective action taken without undue delay to eliminate the causes of the detected nonconformities (see 4.10)?					
4.14.6	Risk management					
	Does the laboratory evaluate the impact of work processes and potential failures on examination results as they affect patient safety? and					
	Does the laboratory modify processes to reduce or eliminate the identified risks and document decisions and actions taken?					
4.14.7	Quality indicators					
	Does the laboratory establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes? EXAMPLE Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports.					
	Does the process of monitoring quality indicators planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement?					
	Are the indicators periodically reviewed, to ensure their continued appropriateness? 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 provide valuable management insights. NOTE 2 The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12).					
	Does the laboratory, in consultation with the users, establish turnaround times for each of its examinations that reflect clinical needs?					

	Does the laboratory periodically evaluate whether or not it is meeting the established turnaround times?				
4.14.8	Reviews by external organizations				
	When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, does the laboratory take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard?				
	Do records kept of the reviews and of the corrective actions and preventive actions taken? NOTE Examples of reviews by external accreditation organizations include: accreditation assessments, regulatory agencies' inspections, and health and safety inspections.				
4.15	Management review				
4.15.1	General Does laboratory management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care?				
4.15.2	Review input				
	Does the input to management review include information from the results of evaluations of at least the following:				
	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 interlaboratory 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				
	Does the review analyse the input information for causes of nonconformities, trends and patterns that indicate process problems?				
	Is the quality and appropriateness of the laboratory's contribution to patient care, to the extent possible, also objectively evaluated?				
4.15.4	Review output				
	Does the output from the management review incorporated into a record that documents any decisions made and actions taken during management review related to:				
	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.				
	Do findings and actions arising from management reviews recorded and reported to laboratory staff?				
	Does laboratory management ensure that actions arising from management review are completed within a defined timeframe?				
5	Technical requirements				
5.1	Personnel				
5.1.1	<u>General</u> Does the laboratory have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements?				
5.1.2	Personnel qualifications				

	Does laboratory management document personnel qualifications for each position?				
	Do the qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and appropriate to the tasks performed?				
	Are the personnel making judgments with reference to examinations have the applicable theoretical and practical background and experience? NOTE Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values, and should be in accordance with national, regional and local regulations and professional guidelines				
5.1.3	Job descriptions				
	Does the laboratory have job descriptions that describe responsibilities, authorities and tasks for all personnel?				
5.1.4	Personnel introduction to the organizational environment				
	Does the laboratory 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 safety requirements (including fire and emergency), and occupational health services?				
5.1.5	Training				
	Does the laboratory provide training for all personnel which includes the following areas:				
	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?				
	Are Personnel that undergoing training supervised at all times?				
	Does the effectiveness of the training programme periodically reviewed?				
5.1.6	Competence assessment				

	Following appropriate training, does the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria?					
	Is reassessment take place at regular intervals?					
	Is retraining occur when necessary? NOTE 1 Competence of laboratory staff can be assessed by using any combination or all of the following approaches under 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, interlaboratory comparison materials, or split samples? NOTE 2 Competency assessment for professional judgment should be designed as specific and fit for purpose.					
5.1.7	Reviews of staff performance					
	In addition to the assessment of technical competence, does the laboratory ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships? NOTE Staff performing reviews should receive appropriate training.					
5.1.8	Continuing education and professional development					
	Is a continuing education programme available to personnel who participate in managerial and technical processes?					

	Do personnel take part in continuing education?				
	Does the effectiveness of the continuing education Programme periodically reviewed?				
	Do personnel take part in regular professional development or other professional liaison activities?				
5.1.9	Personnel records				
	Do records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel maintained?				
	Do these records readily available to relevant personnel and 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) immunisation status, when relevant to assigned duties? NOTE The records listed above are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as needed.				
5.2	Accommodation and environmental conditions				
5.2.1	<u>General</u>				
	Does the laboratory 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?				
	Does the laboratory evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work?				

	Where applicable, do similar provisions made for primary sample collection and examinations at sites other 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				
	Does the laboratory and associated office facilities provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met:				
	a) Access to areas affecting the quality of examinations is controlled? NOTE 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 to ensure the efficient transfer of information?				
	e) Safety facilities and devices are provided and their functioning regularly verified? EXAMPLE Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc.				
5.2.3	Storage facilities				
	Are storage space and conditions provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results?				
	Are clinical samples and materials used in examination processes stored in a manner to prevent cross contamination?				
	Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials and as specified by applicable requirements?				
5.2.4	Staff facilities				

	<p>Are there adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing?</p> <p>NOTE When possible, the laboratory should provide space for staff activities such as meetings and quiet study and a rest area.</p>					
5.2.5	Patient sample collection facilities					
	Do patient sample collection facilities have separate reception/waiting and collection areas?					
	Is consideration 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?					
	Are facilities at which patient sample collection procedures are performed (e.g. phlebotomy) enable the sample collection to undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination?					
	<p>Do sample collection facilities have and maintain appropriate first aid materials for both patient and staff needs?</p> <p>NOTE Some facilities may need equipment appropriate for resuscitation; local regulations may apply.</p>					
5.2.6	Facility maintenance and environmental conditions					
	Does laboratory premises maintained in a functional and reliable condition?					
	Do work areas clean and well maintained?					
	Does the laboratory monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff?					
	Is attention 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?					
	Is there effective separation between laboratory sections in which there are incompatible activities?					
	Are procedures in place to prevent cross-contamination where examination procedures pose a					

	hazard or where work could be affected or influenced by not being separated?					
	<p>Does the laboratory provide a quiet and uninterrupted work environment where it is needed?</p> <p>NOTE Examples of a quiet and uninterrupted work area include cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutations results.</p>					
5.3	Laboratory equipment, reagents, and consumables					
	<p>NOTE 1 For the purposes of this International Standard, laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems.</p> <p>NOTE 2 Reagents include reference materials, calibrators and quality control materials; consumables include culture media, pipette tips, glass slides, etc.</p> <p>NOTE 3 See 4.6 for information concerning the selection and purchasing of external services, equipment, reagents and consumables.</p>					
5.3.1	Equipment					
5.3.1.1	General					
	Does the laboratory have a documented procedure for the selection, purchasing and management of equipment?					
	Does the laboratory furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage)?					
	In those cases where the laboratory needs to use equipment outside its permanent control, does laboratory management ensure that the requirements of this International Standard are met?					
	Does the laboratory replace equipment as needed to ensure the quality of examination results?					
5.3.1.2	Equipment acceptance testing					
	Does the laboratory 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)?					
	NOTE This requirement applies to: equipment used in					

	the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.					
	Is each item of equipment uniquely labelled, marked or otherwise identified?					
5.3.1.3	Equipment instructions for use					
	Is equipment operated at all times by trained and authorized personnel?					
	Are current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, readily available?					
	Does the laboratory 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					
	Does the laboratory have a documented procedure for the calibration of equipment that directly or indirectly affects examination results? Does 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 item of 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 are correctly updated?					
	f) safeguards to prevent adjustments or tampering that might invalidate examination results?					
	Is metrological traceability to a reference material or reference procedure of the higher metrological order available? NOTE Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.					

	Where this is not possible or relevant, Do other means for providing confidence in the results 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				
	Does the laboratory have a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions?				
	Is equipment maintained in a safe working condition and in working order? Does this include examination of 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 or instructions, or both used?				
	Whenever equipment is found to be defective, is it taken out of service and clearly labeled?				
	Does the laboratory ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria?				
	Does the laboratory examine the effect of any defects on previous examinations and institute immediate action or corrective action (see 4.10)?				
	Does the laboratory 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, does the laboratory ensure that its performance is verified before being returned to laboratory use?				
5.3.1.6	Equipment adverse incident reporting				
	Do adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to the manufacturer and appropriate authorities, as required?				
5.3.1.7	Equipment records				
	Do records maintained for each item of equipment that contributes to the performance of examinations?				
	Are these equipment records 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?				
	Do the performance records referred to in j) 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 fulfil part or all of this requirement?				
	Do these records maintained and 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	<u>General:</u> Does the laboratory 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, does it verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration?				
	Does the laboratory store received reagents and consumables according to manufacturer's specifications?				
5.3.2.3	Reagents and consumables — Acceptance testing				
	Does each new formulation of examination kits with changes in reagents or procedure, or a new lot or				

	shipment, verified for performance before use in examinations?				
	Do consumables that can affect the quality of examinations verified for performance before use in examinations?				
5.3.2.4	Reagents and consumables — Inventory management				
	Does the laboratory establish an inventory control system for reagents and consumables?				
	Is the system for inventory control 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				
	Are instructions for the use of reagents and consumables, including those provided by the manufacturers, readily available?				
5.3.2.6	Reagents and consumables — Adverse incident reporting				
	Are adverse incidents and accidents that can be attributed directly to specific reagents or consumables investigated and reported to the manufacturer and appropriate authorities, as required?				
5.3.2.7	Reagents and consumables — Records				
	Do records maintained for each reagent and consumable that contributes to the performance of Examinations?				
	Do these records include but not 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?				
	Where the laboratory uses reagents prepared or completed in-house, do the records 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: Does the laboratory have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations?				
5.4.2	Information for patients and users				
	Does the laboratory have information available for patients and users of the laboratory services?				
	Does the information include as appropriate: a) the location of the laboratory?				
	b) types of clinical services offered by the laboratory including examinations referred to other laboratories?				
	c) opening hours of the laboratory?				
	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?				
	e) instructions for completion of the request form?				
	f) instruction for preparation of the patient?				
	g) instructions for patient-collected samples?				
	h) instructions for transportation of samples, including any special handling needs?				
	i) any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed)?				
	j) the laboratory's criteria for accepting and rejecting samples?				
	k) a list of factors known to significantly affect the performance of the examination or the interpretation of the results?				
	l) availability of clinical advice on ordering of examinations and on interpretation of examination results?				
	m) the laboratory's policy on protection of personal information?				
	n) the laboratory's complaint procedure?				
	Does the laboratory have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent?				
	Is Importance of provision of patient and family information, where relevant (e.g. for interpreting				

	genetic examination results), explained to the patient and user?					
5.4.3	Request form information					
	Does the request form or an electronic equivalent allow space for the inclusion of, but not be limited to, the following:					
	a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier? NOTE Unique identification includes an alpha and/or numerical identifier such as a hospital number, or personal health number.					
	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?					
	c) type of primary sample and, where relevant, the anatomic site of origin?					
	d) examinations requested?					
	e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes? NOTE Information needed for examination performance and results interpretation may include the patient's ancestry, family history, travel and exposure history, communicable diseases and other clinically relevant information. Financial information for billing purposes, financial audit, resource management and utilization reviews may also be collected. The patient should be aware of the information collected and the purpose for which it is collected.					
	f) date and, where relevant, time of primary sample collection?					
	g) date and time of sample receipt? NOTE The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the users of laboratory services.					
	Does the laboratory have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time?					
	Does the laboratory willing to cooperate with users or their representatives in clarifying the user's request?					

5.4.4	Primary sample collection and handling				
5.4.4.1	<u>General:</u> Does the laboratory have documented procedures for the proper collection and handling of primary samples?				
	Do the documented procedures available to those responsible for primary sample collection whether or not the collectors are laboratory staff?				
	Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, do these recorded and included in all documents containing examination results and communicated to the appropriate personnel? NOTE 1 All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, venipuncture. Patients in a hospital bed should normally be given the opportunity to refuse.				
	Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, do need a more detailed explanation and, in some cases, written consent?				
	In emergency situations, consent might not be possible; under these circumstances is it acceptable to carry out necessary procedures, provided they are in the patient's best interest? NOTE 2 Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.				
5.4.4.2	Instructions for pre-collection activities				
	Does the laboratory's instructions for pre-collection activities include the following:				
	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				
	Does the laboratory's instructions for collection activities include the following:				
	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 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				
	Do the laboratory's instructions for post-collection activities include packaging of samples for transportation?				
	Does the laboratory have a documented procedure for monitoring the transportations of samples to ensure they are transported:				
	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?				
	NOTE A laboratory which is not involved in primary sample collection and transportation is considered to have satisfied clause 5.4.5 c) above when, upon receipt of a sample whose integrity was compromised or which could have jeopardized the safety of the carrier or the general public, the sender is contacted immediately and informed about measures to be taken to eliminate recurrence.				
5.4.6	Sample reception				
	Does the laboratory's procedure for sample reception ensure that the following conditions are met.				
	a) Samples are unequivocally traceable, by request and labelling, to an identified patient or site?				
	b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied?				
	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 indicate the nature of the problem and, where applicable, that caution is required when interpreting the result?				
	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 recorded. Whenever possible, the identity of the person receiving the sample also recorded?				
	e) Authorized personnel evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s)?				
	f) Where relevant, there instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions 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?				
	Do all portions of the primary sample unequivocally traceable to the original primary sample?				
5.4.7	Pre-examination handling, preparation and storage				

	Does the laboratory have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage?				
	Do laboratory procedures include time limits for requesting additional examinations or further examinations on the same primary sample?				
5.5	Examination processes				
5.5.1	Selection, verification and validation of examination procedures				
5.5.1.1	General: Does the laboratory select examination procedures which have been validated for their intended use?				
	Do the identity of persons performing activities in examination processes recorded?				
	Are the specified requirements (performance specifications) for each examination procedure related to the intended use of that examination? NOTE Preferred procedures are those specified in the instructions for use of in vitro medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus Standards or guidelines, or national or regional regulations.				
5.5.1.2	Verification of examination procedures				
	Do validated examination procedures used without modification subject to independent verification by the laboratory before being introduced into routine use?				
	Does the laboratory obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure?				
	Does the independent verification by the laboratory confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met?				
	Does the performance claims for the examination procedure confirmed during the verification process those relevant to the intended use of the examination results?				
	Does the laboratory document the procedure used for the verification and record the results obtained?				

	Does staff with the appropriate authority review the verification results and record the review?				
5.5.1.3	Validation of examination procedures				
	Does the laboratory validate examination procedures derived from the following sources:				
	a) non-standard methods?				
	b) laboratory designed or developed methods?				
	c) standard methods used outside their intended scope?				
	d) validated methods subsequently modified?				
	Is the validation as extensive as 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? NOTE Performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.				
	Does the laboratory document the procedure used for the validation and record the results obtained?				
	Does staff with the authority review the validation results and record the review?				
	When changes are made to a validated examination procedure, is the influence of such changes documented and, when appropriate, a new validation carried out?				
5.5.1.4	Measurement uncertainty of measured quantity values				
	Does the laboratory determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples?				
	Does the laboratory define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty? NOTE 1 The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of				

	<p>the measured value.</p> <p>NOTE 2 Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent and calibrator batches, different operators, scheduled instrument maintenance.</p> <p>NOTE 3 Examples of the practical utility of measurement uncertainty estimates might include confirmation that patients' values meet quality goals set by the laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value.</p>					
	Does the laboratory consider measurement uncertainty when interpreting measured quantity values?					
	Upon request, does the laboratory make its estimates of measurement uncertainty available to laboratory users?					
	Where examinations include a measurement step but do not report a measured quantity value, does the laboratory calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result?					
5.5.2	Biological reference intervals or clinical decision values					
	Does the laboratory 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?					
	When a particular biological reference interval or decision value is no longer relevant for the population served, do appropriate changes made and communicated to the users?					
	When the laboratory changes an examination procedure or pre-examination procedure, does the laboratory review associated reference intervals and clinical decision values, as applicable?					
5.5.3	Documentation of examination procedures					
	Do examination procedures documented?					
	Are they written in a language commonly understood by the staff in the laboratory and be available in					

	appropriate locations?				
	<p>Is any condensed document format (e.g. card files or similarly used systems) correspond to the documented procedure?</p> <p>NOTE 1 Working instructions, card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a full documented procedure is available for reference.</p> <p>NOTE 2 Information from product instructions for use may be incorporated into examination procedures by reference.</p>				
	Are all documents associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, subject to document control?				
	In addition to document control identifiers, does documentation include, when applicable to the examination procedure, the following:				
	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?				
	<p>If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, does the implications explained to users of the laboratory services after validating the procedure?</p> <p>NOTE 3 This requirement can be accomplished in different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the examination report itself.</p>				
5.6	Ensuring quality of examination results				
5.6.1	<p>General: Does the laboratory ensure the quality of examinations by performing them under defined conditions?</p>				
	Does appropriate pre and post-examination processes implemented (see 4.14.7, 5.4, 5.7 and 5.8)?				
	Does the laboratory not fabricate any results?				
5.6.2	Quality control				
5.6.2.1	<p>General Does the laboratory design quality control procedures that verify the attainment of the intended quality of results? NOTE In several countries, quality control, as referred to in this subclause, is also named “internal quality control.”</p>				
5.6.2.2	Quality control materials				
	Does the laboratory use quality control materials that react to the examining system in a manner as close as possible to patient samples?				
	<p>Are quality control materials periodically 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?</p> <p>NOTE 1 The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made.</p>				
	NOTE 2 Use of independent third party control				

	materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.					
5.6.2.3	Quality control data					
	Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure?					
	When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, does the results rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified?					
	Does the laboratory also evaluate the results from patient samples that were examined after the last successful quality control event?					
	<p>Is Quality control data reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system?</p> <p>When such trends are noted, do preventive actions taken and recorded?</p> <p>NOTE Statistical and non-statistical techniques for process control should be used wherever possible to continuously monitor examination system performance.</p>					
5.6.3	Interlaboratory comparisons					
5.6.3.1	<u>Participation:</u>					
	Does the laboratory participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results?					
	<p>Does the laboratory monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled?</p> <p>NOTE The laboratory should participate in interlaboratory comparison programmes that substantially fulfil the relevant requirements of</p>					

	ISO/IEC 17043.					
	Does the laboratory establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme?					
	Is interlaboratory comparison programme(s) chosen by the laboratory, 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?					
5.6.3.2	Alternative approaches					
	Whenever an interlaboratory comparison is not available, does the laboratory develop other approaches and provide objective evidence for determining the acceptability of examination results? Whenever possible, does this mechanism utilize appropriate materials? NOTE 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 interlaboratory comparison programmes.					
5.6.3.3	Analysis of interlaboratory comparison samples					
	Does the laboratory integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples?					

	Do interlaboratory comparison samples examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples?				
	Does the laboratory not communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data?				
	Does the laboratory not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples?				
5.6.3.4	Evaluation of laboratory performance				
	Does the performance in interlaboratory comparisons reviewed and discussed with relevant staff?				
	When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), does staff participate in the implementation and recording of corrective action?				
	Is the effectiveness of corrective action monitored? Do the returned results evaluated for trends that indicate potential nonconformities and preventive action taken?				
5.6.4	Comparability of examination results				
	Is there a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals?				
	Is this applicable to the same or different procedures, equipment, different sites, or all of these? NOTE In the particular case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable.				
	Does the laboratory 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?				

	Does the laboratory document, record and, as appropriate, expeditiously act upon results from the comparisons performed?				
	Do problems deficiencies or identified acted upon and records of actions retained?				
5.7	Post-examination processes				
5.7.1	<u>Review of results:</u>				
	Do the laboratory procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results?				
	When the procedure for reviewing results involves automatic selection and reporting, does review criteria established, approved and documented (see 5.9.1)?				
5.7.2	Storage, retention and disposal of clinical samples				
	Does the laboratory have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples?				
	Does the laboratory define the length of time clinical samples are to be retained?				
	Is retention time defined by the nature of the sample, the examination and any applicable requirements? NOTE Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain samples for much longer periods than for other samples.				
	Do safe disposal of samples carried out in accordance with local regulations or recommendations for waste management?				
5.8	Reporting of results				
5.8.1	<u>General:</u> Do the results of each examination reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures?				
	Does the laboratory 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?				

	Does the laboratory have a procedure to ensure the correctness of transcription of laboratory results?				
	Do reports include the information necessary for the interpretation of the examination results?				
	Does the laboratory have a process for notifying the requester when an examination is delayed that could compromise patient care? Report attributes				
5.8.2					
	Does the laboratory ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:				
	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 interpretation of automatically selected and reported results (see 5.9.1) in the final report?				
5.8.3	Report content				
	Does the report include, but not be limited to, the following:				
	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?				

	<p>j) biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable?</p> <p>NOTE Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.</p>				
	<p>k) interpretation of results, where appropriate?</p> <p>NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.</p>				
	<p>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)?</p>				
	<p>m) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available?</p>				
	<p>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)?</p>				
	<p>o) date of the report, and time of release (if not contained in the report, readily available when needed)?</p>				
	<p>p) page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.)?</p>				
5.9	Release of results				
5.9.1	<p>General: Does the laboratory establish documented procedures for the release of examination results, including details of who may release results and to whom. ?</p>				
	<p>Do the procedures ensure that the following conditions are met.</p>				
	<p>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?</p>				
	<p>b) When examination results fall within established “alert” or “critical” intervals:</p> <p>— a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)]?</p>				

	— 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 and use 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 only authorized recipients. Results provided orally followed by a written report. Is there a record of all oral results provided? NOTE 1 For the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling. NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses. See also 4.9.					
5.9.2	Automated selection and reporting of results					
	If the laboratory implements a system for automated selection and reporting of results, does it establish a documented procedure to ensure that:					
	a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff? NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values. b) the criteria are validated for proper functioning 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 automated selection and reporting criteria, when appropriate?				
	e) results selected for automated reporting, identifiable at the time of review before release and include 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 is there written instructions regarding the revision so that:				
	a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in 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 the change?				
	d) the original report entries remain in the record when revisions are made?				
	Do results that have been made available for clinical decision making and revised retained in subsequent cumulative reports and clearly identified as having been revised?				
	When the reporting system cannot capture amendments, changes or alterations, does a record of such kept?				
5.10	Laboratory information management				
5.10.1	General Does the laboratory have access to the data and information needed to provide a service which meets the needs and requirements of the user?				
	Does the laboratory have a documented procedure to ensure that the confidentiality of patient information is maintained at all times? NOTE In this International Standard, "information systems" includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and stand alone systems using generic				

	software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports					
5.10.2	Authorities and responsibilities					
	Does the laboratory ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care?					
	Does the laboratory define the authorities and responsibilities of all personnel who use the system, in particular those who:					
	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					
	Does the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information:					
	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? NOTE Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation, hospital patient administration systems and systems in primary care.					
	b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users?					
	c) protected from unauthorized access?					
	d) safeguarded against tampering or loss?					
	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?					

	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?				
	g) in compliance with national or international requirements regarding data protection?				
	Does the laboratory verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to 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, does the laboratory verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory?				
	Does the laboratory 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?				
	When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, does laboratory management responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard?				
	Additional Requirements (Required for Follow up and reaccreditations assessments)				
	Use of the Symbol				
	Is the accredited laboratory utilizing the correct symbol?				
	Is the symbol reproduced in a size that is clearly distinguishable?				
	Is the symbol reproduced in accordance with the EAS "Conditions for use of accreditation symbols or reference to accreditation by EAS accredited facilities"?				
	Is the symbol identifiable?				
	Is the accredited laboratory properly using the symbol				

	<p>on:</p> <ul style="list-style-type: none"> a) Promotional material and business stationary? b) Test certificates or labels? (See note 1) c) Website? d) Technical literature? e) Business reports f) Quotations or proposals for work? (symbols may only be listed for accredited work) <p>Note: Where statements of opinion and interpretation are outside the scope of the accreditation, the laboratory shall include statement such as “the opinions/interpretations expressed on this report are outside the scope of this laboratory’s accreditation.” in the report.</p>					
	<p>Is the accredited laboratory appropriately using the symbol by not placing the symbol on:</p> <ul style="list-style-type: none"> a) Legal documents, contracts or cheques? b) On test certificates or any other material referencing work or items not covered by scope of accreditation? c) Any documentation of sites that are not accredited by EAS? d) On sub-contractor’s certificates or documentation ? e) On products or items which laboratory has tested? 					
	<p>Where tests outside the scope of the accreditation are included on reports, certificates or enclosed letters with results, has the laboratory clearly defined “This laboratory is not accredited for the tests marked”?</p>					
	<p>Proficiency Testing Requirements for Applicant and Accredited Laboratories</p>					
	<p>For applicant laboratories: Is there objective evidence for PT activity for each item to be included within proposed scope of accreditation?</p>					
	<p>Are the results meaningful i.e. demonstrating the laboratory’s competence in performing specified test?</p>					
	<p>For accredited laboratories: Is there a documented proficiency testing plan or schedule?</p>					
	<p>Does this plan or schedule include all items included on the scope of accreditation to be tested within a five year period?</p>					
	<p>Has the laboratory completed at least one proficiency test each year?</p>					
	<p>Has the proficiency plan or schedule been approved by EAS?</p>					

Follow-up on Findings of Previous Assessment:

Nominated representative		Team Leader		
Signature		signature:		
Date		Date:		