



CHECKLIST

Medical Testing Laboratories

Assessment Standard ISO 15189

Client:

Assessment Date:

Assessment Coordinator:

Signature:

Column Key:	√ or X	- tick or cross to indicate inclusion in quality system documentation
	QM	- Record specific section where clause is found in quality system documentation
	Comments	- space for additional comments relating to clause

4 Management requirements

4.1 Organisation and management

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.1.1	The medical laboratory or the organisation of which the laboratory is a part shall be legally identifiable.			
4.1.2	Medical laboratory services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.			
4.1.3	The medical laboratory (hereafter referred to as "the Laboratory") shall meet the relevant requirements of this standard when carrying out work in its permanent facilities, or at sites other than the permanent facilities for which it is responsible.			
4.1.4	The responsibilities of personnel in the laboratory with an involvement or influence on the examination of primary samples shall be defined in order to identify conflicts of interest. Financial or political considerations (e.g., inducements) should not influence testing.			
4.1.5	The laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system. This shall include the following:			
a)	Management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties;			
b)	Arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial, or other pressures and influences that may adversely affect the quality of their work;			
c)	Policies and procedures for ensuring the protection of confidential information (See. Annex C);			
d)	Policies and procedures for avoiding involvement in any activities that would diminish confidence in its competence, impartiality, judgement, or operational integrity;			
e)	The organisational and management structure of the laboratory and its relationship to any other organisation with which it may be associated;			
f)	Specified responsibilities, authority, and interrelationships of all personnel;			
g)	Adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures, and assessment of results of the relevant examination procedures;			
h)	Technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory procedures;			
i)	Appointment of a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality management system, who shall report directly to the level of laboratory management where decisions are made on laboratory policy and resources;			
j)	Appointment of deputies for all key functions, while recognising that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.			

4.2 Quality management system

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.2.1	Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.			
4.2.2	The quality management system shall include, but not be limited to, internal quality control and participation in organised interlaboratory comparisons such as external quality assessment schemes.			
4.2.3	Policies and objectives of the quality management system shall be defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual. This policy shall be readily available to appropriate personnel, shall be concise, and shall include the following:			
a)	The scope of service the laboratory intends to provide;			
b)	The laboratory management's statement of the laboratory's standard of service;			
c)	The objectives of the quality management system;			
d)	A requirement that all personnel concerned with examination activities familiarise themselves with the quality documentation and implement the policies and procedures at all times;			
e)	The laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system;			
f)	The laboratory management's commitment to compliance with this International Standard.			
4.2.4	A quality manual shall describe the quality management system and the structure of the documentation used in the quality management system. The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation in the quality system. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual. All personnel shall be instructed on the use and application of the quality manual and all referenced documents, and of the requirements for their implementation. The quality manual shall be kept up to date under the authority and responsibility of [see 4.1.5 i)] an individual appointed to be responsible for quality by the laboratory management.			
	The table of contents of a quality manual for a medical laboratory might be as follows:			
a)	Introduction.			
b)	Description of the medical laboratory, its legal identity, resources, and main duties.			
c)	Quality policy.			
d)	Staff education and training.			
e)	Quality assurance.			
f)	Document control.			
g)	Records, maintenance, and archiving.			
h)	Accommodation and environment.			
i)	Instruments, reagents, and/or relevant consumables management.			
j)	Validation of examination procedures.			
k)	Safety.			
l)	Environmental aspects (transportation, consumables, waste disposal in addition to, and different from h), and i)).			
m)	Research and development (if appropriate.).			
n)	List of examination procedures.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
o)	Request protocols, primary sample collection, and handling of laboratory samples.			
p)	Validation of results.			
q)	Quality control (including interlaboratory comparisons).			
r)	Laboratory information system (see Annex B).			
s)	Reporting of results.			
t)	Remedial actions and handling of complaints.			
u)	Communications and other interactions with patients, health professionals, referral laboratories and suppliers.			
v)	Internal Audits.			
w)	Ethics (see Annex C).			
4.2.5	The laboratory management shall establish and implement a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents, and analytical systems. It shall also have a documented and recorded programme of preventive maintenance and calibration (cf. 5.3.2), which, at a minimum, follows manufacturer's recommendations.			

4.3 Document control

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.3.1	The laboratory shall define, document, and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define a retention period. These controlled documents may be maintained on any appropriate medium, including, or not, paper. National, regional and local regulations concerning document retention could apply. NOTE In this context, "document" is any information or instructions including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, documents of external origin such as regulations, standards or examination procedures.			
4.3.2	Procedures shall be adopted to ensure that:			
a)	All documents issued to laboratory personnel as part of the quality management system are reviewed and approved by authorised personnel prior to issue;			
b)	A list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained;			
c)	Only currently authorised versions of appropriate documents are available for active use at relevant locations;			
d)	Documents are periodically reviewed, revised when necessary, and approved by authorised personnel;			
e)	Invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use;			
f)	Retained or archived superseded documents are appropriately identified to prevent their inadvertent use;			
g)	if the laboratory's documentation 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 while amendments are clearly marked, initialled, and dated and a revised document is formally re-issued as soon as practicable; and			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
h)	Procedures shall be established to describe how changes to documents maintained in computerised systems are to be made and controlled.			
4.3.3	All documents relevant to the quality management system shall be uniquely identified, to include:			
a)	Title;			
b)	Edition or current revision date, or revision number, or all these.			
c)	Number of pages (where applicable);			
d)	Authority for issue; and			
e)	Source identification.			

4.4.1 Review of contracts

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.4.1	Where a laboratory enters into a contract to provide medical laboratory services, it shall establish and maintain procedures for review of contracts. The policies and procedures for these reviews leading to a change in the arrangements for examinations or contracts shall ensure that the:			
a)	Requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5);			
b)	The laboratory has the capability and resources to meet the requirements;			
c)	Appropriate procedures selected are able to meet the contract requirements and clinical needs. (see 5.5)			
4.4.2	Records of reviews, including any significant changes and pertinent discussions, shall be maintained (see 4.13.3).			
4.4.3	The review shall also cover any work referred by the laboratory (see 4.5).			
4.4.4	Clinicians (e.g., clinicians, health care bodies, health insurance companies, pharmaceutical companies) shall be informed of any deviation from the contract.			
4.4.5	If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected parties.			

4.5 Examination by referral laboratories

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.5.1	The laboratory shall have an effective, documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology, and related disciplines. Laboratory management, with the advice of users of laboratory services where appropriate, shall be responsible for selecting and monitoring the quality of referral laboratories and consultants and shall ensure that the referral laboratory or referral consultant is competent to perform the requested examinations.			
4.5.2	Arrangements with referral laboratories shall be reviewed periodically to ensure that:			
a)	Requirements, including the pre-examination and post-examination procedures are adequately defined, documented, and understood;			
b)	The referral laboratory is able to meet the requirements and that there are no conflicts of interest;			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
c)	Selection of examination procedures is appropriate for the intended use; and			
d)	Respective responsibilities for the interpretation of examination results are clearly defined. Records of such reviews shall be maintained in accordance with national, regional, or local requirements.			
4.5.3	The laboratory shall maintain a register of all referral laboratories that it uses. A register shall be kept of all samples that have been referred to another laboratory. The name and address of the laboratory responsible for the examination result shall be provided to the user of laboratory services. A duplicate of the laboratory report shall be retained in both the patient record and in the permanent file of the laboratory.			
4.5.4	The referring laboratory and not the referral laboratory shall be responsible for ensuring that referral laboratory examination results and findings are provided to the person making the request. If the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretation. However, this does not require that the referring laboratory report include every word and have the exact format of the referral laboratory report, unless national/local laws or regulations require it. The referring laboratory director may elect to provide additional interpretative remarks to those, if any, of the referral laboratory, in the context of the patient and the local medical environment. The author of such added remarks should be clearly identified.			

4.6 External services and supplies

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.6.1	Laboratory management shall define and document its policies and procedures for the selection and use of purchased external services, equipment, and consumable supplies that affect the quality of its service. Purchased items shall consistently meet the laboratory's quality requirements. National, regional, or local regulations may require records of purchased items.. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.			
4.6.2	Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable. Documentation of the supplier's conformance with its quality management system may also be used for verification.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.6.3	There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies, and purchased products shall be established and maintained for a period of time as defined in the quality management system. This system should include the recording of lot numbers of all relevant reagents, control materials, and calibrators; the date of receipt in the laboratory; and the date the material is placed in service. All of these quality records shall be available for laboratory management review.			
4.6.4	The laboratory shall evaluate suppliers of critical reagents, supplies, and services, that affect the quality of examinations, and shall maintain records of these evaluations and list those approved.			

4.7 Advisory services

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
	Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services, including repeat frequency and required type of sample. Where appropriate, interpretation of the results of examinations shall be provided. There should be regular documented meetings of professional staff with the clinical staff regarding the use of the laboratory services, and for the purpose of consultation on scientific matters. The professional staff should participate in clinical rounds, enabling advice on effectiveness in general as well as in individual cases.			

4.8 Resolution of complaints

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
	The laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients, or other parties. Records of complaints and of investigations and corrective actions taken by the laboratory shall be maintained, as required (see 4.13.3). NOTE Laboratories are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way (e.g., surveys).			

4.9 Identification and control of nonconformities

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.9.1	Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinician. These shall ensure that:			
a)	Personnel responsible for problem resolution are designated;			
b)	The actions to be taken are defined;			
c)	The medical significance of the nonconforming examinations is considered, and where appropriate, the requesting clinician informed;			
d)	Examinations are halted and reports withheld as necessary;			
e)	Corrective action is taken immediately;			
f)	The results of nonconforming examinations already released are recalled or appropriately identified, if necessary;			
g)	The responsibility for authorisation of the resumption of examinations is defined; and			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
h)	Each episode of nonconformity is documented and recorded with these records being reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action. NOTE Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, quality control indications, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.			
4.9.2	If it is determined that nonconforming examinations could recur or that there is doubt about the laboratory's compliance with its own policies or procedures as given in the quality manual, procedures to identify, document, and eliminate the root cause(s) shall be promptly implemented (see 4.11).			
4.9.3	The laboratory shall define and implement procedures for the release of results in the case of nonconformities, including the review of such results. These events shall be recorded.			

4.10 Corrective action

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.10.1	Procedures for corrective action shall include an investigation process to determine the underlying cause or causes of the problem. These shall, where appropriate, lead to preventive actions. Corrective action shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.			
4.10.2	Laboratory management shall document and implement any changes required to its operational procedures resulting from corrective action investigations.			
4.10.3	Laboratory management shall monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems.			
4.10.4	When the identification of non-conformance or the corrective action investigation casts doubt on compliance with policies and procedures or the quality management system, laboratory management shall ensure that appropriate areas of activity are audited in accordance with 4.14. The results of corrective actions shall be submitted for laboratory management review.			

4.11 Preventive action

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.11.1	Needed improvements and potential sources of nonconformities, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.			
4.11.2	Procedures for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective. Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend and risk-analyses and external quality assurance. . NOTE Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.			

4.12 Continual Improvement

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.12.1	All operational procedures shall be systematically reviewed by laboratory management at regular intervals, as defined in the quality management system, in order to identify any potential sources of nonconformance or other opportunities for improvement in the quality management system or technical practices. Action plans for improvement shall be developed, documented, and implemented, as appropriate.			
4.12.2	After action has been taken resulting from the review, laboratory management shall evaluate the effectiveness of the action through a focused review or audit of the area concerned.			
4.12.3	The results of action following the review shall be submitted to laboratory management for review and implementation of any needed changes to the quality management system.			
4.12.4	Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. When this programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.			
4.12.5	Laboratory management shall provide access to suitable educational and training opportunities for all laboratory personnel and relevant users of laboratory services.			

4.13 Quality and technical records

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.13.1	The laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance, and safe disposal of quality and technical records.			
4.13.2	All records shall be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional, or local legal requirements (see Note, 4.3.1). Facilities shall provide a suitable environment to prevent damage, deterioration, loss, or unauthorised access.			
4.13.3	The laboratory shall have a policy that defines the length of time various records pertaining to the quality management system and examination results are to be retained. Retention time shall be defined by the nature of the examination or specifically for each record. NOTE National, regional and local regulations may apply. These records may include but are not limited to the following:			
a)	Request forms (including the patient chart or medical record only if used as the request form);			
b)	Examination results and reports;			
c)	Instrument printouts;			
d)	Examination procedures;			
e)	Laboratory workbooks or sheets;			
f)	Accession records;			
g)	Calibration functions and conversion factors;			
h)	Quality control records;			
i)	Complaints and action taken;			
j)	Records of internal and external audits;			
k)	External quality assessment records/interlaboratory comparisons;			
l)	Quality improvement records;			
m)	Instrument maintenance records, including internal and external calibration records;			
n)	Lot documentation, certificates of supplies, package inserts;			
o)	Incident/accident records and action taken; and			
p)	Staff training and competency records.			

4.14 Internal audits

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.14.1	To verify that operations continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical, shall be conducted at intervals defined by the system itself. The internal audit shall progressively address these elements and emphasise areas of critically important to patient care.			
4.14.2	Audits shall be formally planned, organised, and carried out by the quality manager or designated qualified personnel. Personnel shall not audit their own activities. The procedures for internal audits shall be defined and documented and include the types of audits, frequencies, methodologies, and required documentation. When deficiencies or opportunities for improvement are noted, the laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed-upon time. The main elements of the quality system should normally be subject to internal audit once every twelve months.			
4.14.3	The results of internal audits shall be submitted to laboratory management for review.			

4.15 Management review

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
4.15.1	The laboratory management shall review the laboratory's quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care, and to introduce any necessary changes or improvements. The results of the review shall be incorporated into a plan that includes goals, objectives, and action plans. A typical period for conducting a management review is once every twelve months.			
4.15.2	Management review shall take account of, but not be limited to:			
a)	Follow-up of previous management reviews;			
b)	Status of corrective actions taken and required preventive action;			
c)	Reports from managerial and supervisory personnel;			
d)	The outcome of recent internal audits;			
e)	Assessment by external bodies;			
f)	The outcome of external quality assessment and other forms of interlaboratory comparison;			
g)	Any changes in the volume and type of work undertaken;			
h)	Feedback, including complaints and other relevant factors, from clinicians, patients, and other parties;			
i)	Quality indicators for monitoring the laboratory's contribution to patient care;			
j)	Nonconformities;			
k)	Monitoring of turnaround time;			
l)	Results of continuous improvement processes; and			
m)	Evaluation of suppliers. Shorter intervals between reviews should be adopted when a quality management system is being established. This will allow early action to be taken in response to areas identified as requiring amendment of the quality management system or other practices.			
4.15.3	The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, be monitored and evaluated objectively. NOTE Data available will differ according to laboratory type or location (e.g., hospital, clinic, or referral laboratory).			
4.15.4	Findings and the actions that arise from management reviews shall be recorded, and laboratory staff shall be informed of these findings and the decisions made as a result of the review. Laboratory management shall ensure that arising actions are discharged within an appropriate and agreed-upon time			

5 Technical requirements

5.1 Personnel

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.1.1	Laboratory management shall have an organisational plan, personnel policies, and job descriptions that define qualifications and duties for all personnel.			
5.1.2	The laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. This information shall be readily available to relevant personnel and may include:.			
a)	Certification or license, if required;			
b)	References from previous employment;			
c)	Job descriptions;			
d)	Records of continuing education and achievements;			
e)	Competency evaluations; and			
f)	Provision for untoward incident or accident reports. Other records available to authorised persons relating to personnel health may include: records of exposure to occupational hazards; and records of immunisation status.			
5.1.3	The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided. NOTE Competence is here understood as the product of basic academic, postgraduate, and continuing education, as well as training and experience of several years in a medical laboratory.			
5.1.4	The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory, organisational, administrative, and educational matters. These shall be relevant to the services offered by the laboratory. The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the following responsibilities:			
a)	Provide advice to those requesting information about the choice of tests, the use of the laboratory service, and the interpretation of laboratory data;			
b)	Serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate;			
c)	Relate and function effectively (including contractual arrangements, if necessary), with 1) applicable accrediting and regulatory agencies, 2) appropriate administrative officials, 3) the healthcare community, and 4) the patient population served;			
d)	Define, implement, and monitor standards of performance and quality improvement of the medical laboratory service or services;			
e)	Implement the quality management system (the laboratory director and professional laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable).;			
f)	Monitor all work performed in the laboratory to determine that reliable data are being generated;			
g)	Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory;			
h)	Plan, set goals, develop and allocate resources appropriate to the medical environment;			
i)	Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;			
j)	Provide educational programs for the medical and laboratory staff, and participate in educational programs of the institution;			
k)	Plan and direct research and development appropriate to the facility;			
CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
l)	Select and monitor all referral laboratories for quality of service;			
m)	Implement a safe laboratory environment in compliance with good practice and applicable regulations;			

n)	Address any complaint, request, or suggestion from users of laboratory services; and			
o)	Ensure good staff morale. The laboratory director need not perform all responsibilities personally. However, it is the laboratory director who remains responsible for the overall operation and administration of the laboratory to ensure that quality services are provided for patients.			
5.1.5	There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system.			
5.1.6	Personnel shall have training specific to quality assurance and quality management for services offered.			
5.1.7	Laboratory management shall authorise personnel to perform particular tasks such as sampling, examination, operation of particular types of equipment, including use of computers in the laboratory information system (see Annex B).			
5.1.8	Policies shall be established which define who may use the computer system, who may access patient data and who is authorised to enter and change patient results, correct billing, or modify computer programs(see Annexes B and C).			
5.1.9	There shall be a continuing education program available to staff at all levels.			
5.1.10	Employees shall be trained to prevent or contain the effects of adverse incidents.			
5.1.11	The competency of each person to perform assigned tasks shall be assessed following training, and periodically thereafter. Retraining and reassessment shall occur when necessary.			
5.1.12	The personnel making professional judgements with reference to examinations shall have the applicable theoretical and practical background as well as recent experience. 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. Personnel shall take part in regular professional development or other professional liaison.			
5.1.13	Confidentiality of information regarding patients shall be maintained by all personnel.			

5.2 Accommodation and environmental conditions

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.2.1	The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safety of personnel, or patient care services. The laboratory director shall determine the adequacy of this space. The resources shall be of a degree necessary to support the activities of the laboratory. Laboratory resources shall be maintained in a functional and reliable condition. Similar provisions should be made for primary sample collection and examinations at sites other than the permanent laboratory facility.			
5.2.2	The laboratory shall be designed for the efficiency of its operation, to optimise the comfort of its occupants, and to minimise the risk of injury and occupational illness. Patients, employees, and visitors shall be protected from recognised hazards.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.2.3	When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort, and privacy, in addition to the optimisation of collection conditions.			
5.2.4	The laboratory design and environment shall be suitable for the tasks carried out therein. The environment in which the primary sample collection or examinations or both are undertaken shall not invalidate the results, or adversely affect the required quality, of any measurement. Laboratory facilities for examination should allow correct performance of examinations. These include, but are not limited to, energy sources, lighting, ventilation, water, waste and refuse disposal, and environmental conditions. The laboratory should have procedures for checking that the environment does not adversely affect the performance of specimen collection and equipment.			
5.2.5	The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. Attention should be paid to sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature and sound and vibration levels as appropriate to the technical activities concerned.			
5.2.6	There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination. EXAMPLES Where examination procedures pose a hazard (e.g., mycobacteriology, radionuclides); work could be affected or influenced by not being separated (e.g., nucleic acid amplifications); an environment conducive to quiet and uninterrupted work is required (e.g., cytopathology screening); or where work requires a controlled environment such as for large computer systems.			
5.2.7	Access to and use of areas affecting the quality of the examinations shall be controlled. Appropriate measures shall be taken to safeguard samples and resources from unauthorised access.			
5.2.8	Communication systems within the laboratory shall be those needed for the size and complexity of the facility and for the efficient transfer of messages.			
5.2.9	Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records, and results.			
5.2.10	Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations. Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures and training for personnel may be necessary to that end.			

5.3 Laboratory equipment

NOTE For the purpose of this international standard, instruments, reference materials, consumables, reagents, and analytical systems are included as laboratory equipment, as applicable.

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.3.1	The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and processing, examination, and storage). In those cases where the laboratory needs to use equipment outside its permanent control, the laboratory management shall ensure that the requirements of this standard are met. When selecting equipment, account should be taken of the use of energy and future disposal (care of the environment).			
5.3.2	Equipment shall be shown (upon installation, and in routine use) to be capable of achieving the performance required, and shall comply with specifications relevant to the examinations concerned. Laboratory management shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents, and analytical systems. It shall also have a documented and recorded programme of preventive maintenance (cf. 4.2.5), which, at a minimum, follows the manufacturer's recommendations. When manufacturer's instructions, operator's manuals, or other documentation are available, they may be used to establish requirements, comply with relevant standards, or to specify requirements for periodic calibration, as appropriate, to fulfil part or all of this requirement.			
5.3.3	Each item of equipment shall be uniquely labelled, marked, or otherwise identified.			
5.3.4	Records shall be maintained for each item of equipment contributing to the performance of examinations. These records shall include at least the following:			
a)	Identity of the equipment;			
b)	Manufacturer's name, type identification, and serial number or other unique identification;			
c)	Manufacturer's contact person and telephone number, as appropriate;			
d)	Date of receiving and date of putting into service;			
e)	Current location, where appropriate;			
f)	Condition when received (e.g., new, used, reconditioned);			
g)	Manufacturer's instructions, if available, or reference to their location;			
h)	Equipment performance records that confirm equipment's suitability for use;			
i)	Maintenance carried out and that planned for the future;			
j)	Damage to, or malfunction, modification or repair of the equipment;			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
k)	Predicted replacement date, if possible. The performance records referred to in h) should include copies of reports/certificates of all calibrations and/or verifications including dates, time, and results, adjustments, the acceptance criteria, and due date of the next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration, as appropriate, to fulfil part or all of this requirement. Manufacturer's instructions may be used to establish acceptance criteria, procedures, and frequency of verification for maintenance or calibration or both, as appropriate, to fulfil part or all of this requirement. These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law or regulation.			
5.3.5	Equipment shall be operated by authorised personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) shall be readily available to laboratory personnel.			
5.3.6	Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices, and the safe handling and disposal of chemical, radioactive and biological materials by authorised persons. Manufacturer's specifications or instructions or both shall be used, as appropriate.			
5.3.7	Whenever equipment is found to be defective, it shall be taken out of service, clearly labelled, and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. The laboratory shall examine the effect of this defect on previous examinations and institute the procedure given in 4.9. The laboratory shall take reasonable measures to decontaminate equipment prior to service, repair, or decommissioning.			
5.3.8	A list of the measures taken to reduce contamination shall be provided to the person working on the equipment. The laboratory shall provide suitable space for repairs and appropriate personal protective equipment.			
5.3.9	Whenever practicable, equipment under the control of the laboratory which requires calibration or verification shall be labelled or otherwise coded, to indicate the status of calibration or verification and the date when recalibration or reverification is due.			
5.3.10	When equipment is removed from the direct control of the laboratory, or is repaired or serviced, the laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.			
5.3.11	When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory shall ensure that:			
a)	Computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility;			
b)	Procedures are established and implemented for protecting the integrity of data at all times;			
c)	Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary to maintain the integrity of data; and			
d)	Computer programmes and routines shall be adequately protected to prevent access, alteration, or destruction by casual or unauthorised persons. See also Annex B.			
5.3.12	The laboratory shall have procedures for safe handling, transport, storage, and use of equipment to prevent its contamination or deterioration.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.3.13	Where calibrations give rise to a set of correction factors, the laboratory shall have procedures for ensuring that copies of prior correction factors are correctly updated.			
5.3.14	Equipment, including hardware, software, reference materials, consumables, reagents, and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results.			

5.4 Pre-examination procedures

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.4.1	The request form shall contain information sufficient to identify the patient and the authorised requester, as well as providing pertinent clinical data. National, regional, or local requirements shall apply. The request form or an electronic equivalent should allow space for the inclusion of, but not be limited to, the following:			
a)	Unique identification of the patient;			
b)	Name or other unique identifier of physician or other person legally authorised to request examinations or use medical information together with the destination for the report. The requesting clinician's address should be provided as part of the request form information when it is different from that of the receiving laboratory.			
c)	Type of primary sample and the anatomic site of origin, where appropriate;			
d)	Examinations requested;			
e)	Clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes;			
f)	Date and time of primary sample collection;			
g)	Date and time of receipt of samples by the laboratory. 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.			
5.4.2	Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management (see 4.2.4) and made available to those responsible for primary sample collection. These instructions shall be contained in a primary sample collection manual.			
5.4.3	The primary sample collection manual shall include the following:			
a)	Copies of or references to:			
i)	Lists of available laboratory examinations offered;			
ii)	Consent forms, when applicable;			
iii)	Information and instructions provided to patients in relation to their own preparation before primary sample collection; and			
iv)	Information for users of laboratory services on medical indications and appropriate selection of available procedures.			
b)	Procedures for:			
i)	Preparation of the patient (e.g., instructions to caregivers and phlebotomists);			
ii)	Identification of primary sample; and			
iii)	Primary sample collection (e.g., phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives.			
c)	Instructions for:			
i)	Completion of request form or electronic request;			
ii)	The type and amount of the primary sample to be collected;			
iii)	Special timing of collection, if required;			
iv)	Any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery, etc.);			
v)	Labelling of primary samples;			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
vi)	clinical information (e.g., history of administration of drugs);			
vii)	Positive identification, in detail, of the patient from whom a primary sample is collected;			
viii)	Recording the identity of the person collecting the primary sample; and			
ix)	Safe disposal of materials used in the collection.			
d)	Instructions for:			
i)	Storage of examined samples;			
ii)	Time limits for requesting additional examinations;			
iii)	Additional examinations; and			
iv)	Repeat examination due to analytical failure or further examinations of same primary sample.			
5.4.4	The primary sample collection manual shall be part of the document control system (see 4.3.1).			
5.4.5	<p>Primary samples shall be traceable, normally by a request form, to an identified individual. Primary samples lacking proper identification shall not be accepted or processed by the laboratory.</p> <p>Where there is uncertainty in the identification of the primary sample, or instability of the analytes in the primary sample (cerebrospinal fluid, biopsy, etc.), and the primary sample is irreplaceable or critical, the laboratory may choose initially to process the sample but not release the results until the requesting physician or person responsible for the primary sample collection takes responsibility for identifying and accepting the sample, or for providing proper information, or all these. In such an instance, the signature of that person taking responsibility for the primary sample identification should be recorded on, or traceable to, the request form. If this requirement is not met for any reason, the person responsible should be identified in the report if the examination is carried out. Samples to be set aside for future examination (e.g., viral antibodies, metabolites relevant to the clinical syndrome) should also be identifiable.</p>			
5.4.6	The laboratory shall monitor the transportation of samples to the laboratory such that 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 in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples; and			
c)	In a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with national, regional, or local regulatory requirements.			
5.4.7	All primary samples received shall be recorded in an accession book, worksheet, computer, or other comparable system. The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded.			
5.4.8	Criteria shall be developed and documented for acceptance or rejection of primary samples. If compromised primary samples are accepted, the final report shall indicate the nature of the problem and, if applicable, that caution is required when interpreting the result.			
5.4.9	The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.			
5.4.10	Authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.4.11	The laboratory shall, if relevant, have a documented procedure for the receipt, labelling, processing, and reporting of those primary samples received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labelling of the request form and primary sample, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.			
5.4.12	Sample portions shall also be traceable to the original primary sample.			
5.4.13	The laboratory shall have a written policy concerning verbal requests for sample examinations.			
5.4.14	Samples shall be stored for a specified time, under conditions that ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations.			

5.5 Examination procedures

NOTE Some of the following might not be applicable to all disciplines in the scope of laboratory medicine.

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.5.1	The laboratory shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or as international, national or regional guidelines. If in-house procedures are used, they shall be appropriately validated for their intended use and fully documented.			
5.5.2	The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The validations shall be as extensive as are necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained and the procedure used for the validation. The methods and procedures selected for use shall be evaluated and found to give satisfactory results before being used for medical examinations. A review of procedures by the laboratory director or designated person shall be undertaken initially and at defined intervals. Such a review is normally carried out annually. These reviews shall be documented.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.5.3	<p>All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory.</p> <p>Card files or similar systems that summarise key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.</p> <p>The procedure shall be based in whole or in part on the instructions for use (e.g. package insert) written by the manufacturer, provided that they are in accordance with 5.5.1 and 5.5.2 and that they describe the procedure as it is performed in the laboratory and are written in a language commonly understood by the staff of the laboratory. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Each new version of examination kits with major changes in reagents or procedure shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorised as for other procedures.</p> <p>In addition to document control identifiers, documentation should include, when applicable, the following:</p>			
a)	Purpose of the examination;			
b)	Principle of the procedure used for examinations;			
c)	Performance specifications (e.g., linearity, precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, sensitivity, and specificity);			
d)	Primary sample system (e.g. plasma, serum, urine);			
e)	Type of container and additive;			
f)	Required equipment and reagents;			
g)	Calibration procedures (metrological traceability);			
h)	Procedural steps;			
i)	Quality control procedures;			
j)	Interferences (e.g., lipemia, hemolysis, bilirubinemia) and cross reactions;			
k)	Principle of procedure for calculating results, including measurement uncertainty;			
l)	Biological reference intervals;			
m)	Reportable interval of patient examination results;			
n)	Alert/critical values, where appropriate;			
o)	Laboratory interpretation;			
p)	Safety precautions;			
q)	<p>Potential sources of variability.</p> <p>Electronic manuals are acceptable provided that the above-specified information is included. The same requirements for document control should also apply to electronic manuals.</p> <p>The laboratory director shall be responsible for ensuring that the contents of examination procedures are complete, current, and has been thoroughly reviewed.</p>			
5.5.4	Performance specifications for each procedure used in an examination shall relate to the intended use of that procedure.			
5.5.5	Biological reference intervals shall be periodically reviewed. If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action. A review of biological reference intervals shall also take place when the laboratory changes an examination procedure or pre-examination procedure, if appropriate.			
5.5.6	The laboratory shall make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements available to users of laboratory services upon request.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.5.7	If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing prior to the introduction of the change. NOTE This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters, or part of the examination report itself.			

5.6 Assuring quality of examination procedures

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.6.1	The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.			
5.6.2	The laboratory shall determine the uncertainty of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample, and changes of operator.			
5.6.3	A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference. Where none of these are possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:			
a)	Participation in a suitable programme of interlaboratory comparisons;			
b)	Use of suitable reference materials, certified to indicate the characterisation of the material;			
c)	Examination or calibration by another procedure;			
d)	Ratio or reciprocity-type measurements;			
e)	Mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed upon by all parties concerned;			
f)	Documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.			
5.6.4	The laboratory shall participate in interlaboratory comparisons such as those organised by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled. Interlaboratory comparison programs shall be in substantial agreement with ISO/IEC Guide 43-1. External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.			
5.6.5	Whenever a formal interlaboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilise externally derived challenge materials such as exchange of samples with other laboratories. Laboratory management shall monitor the results of this mechanism of interlaboratory comparison and participate in the implementation and recording of corrective actions.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.6.6	For those examinations performed using different procedures or equipment or at different sites, or all these, there shall be a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals. Such verification shall be performed at defined periods of time appropriate to the characteristics of the procedure or instrument.			
5.6.7	The laboratory shall document, record, and, as appropriate, expeditiously act upon results from these comparisons. Problems or deficiencies identified shall be acted upon and records of actions retained.			

5.7 Post-examination process

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.7.1	Authorised personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorise the release of the results.			
5.7.2	Storage of the primary sample and other laboratory samples shall be in accordance with approved policy.			
5.7.3	Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.			

5.8 Reporting of results

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.8.1	Laboratory management shall be responsible for formatting reports. The format of the report form (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory should be determined in discussion with the users of laboratory services.			
5.8.2	Laboratory management shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval.			
5.8.3	Results shall be legible, without mistakes in transcription, and reported to persons authorised to receive and use medical information. The report shall also include, but not be limited to the following:			
a)	Clear unambiguous identification of the examination including, where appropriate, the measurement procedure;			
b)	The identification of the laboratory that issued the report;			
c)	Unique identification and location of the patient, where possible, and destination of the report;			
d)	Name or other unique identifier of the requester and the requester's address;			
e)	Date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory;			
f)	Date and time of release of report, which, if not on the report, shall be readily accessible when needed.;			
g)	Source and system (or primary sample type);			
h)	Results of the examination reported in SI units or units traceable to SI units (see ISO Guide 31), where applicable;			
i)	Biological reference intervals, where applicable;			
j)	Interpretation of results, where appropriate;			
k)	Other comments (e.g., quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure); the report should identify examinations undertaken as part of a development programme and for which no specific claims on measurement performance are made, and, where applicable, information on detection limit and uncertainty of measurement should be provided upon request.			
l)	Identification of the person authorising the release of the report;			
m)	If relevant, original and corrected results;			
n)	Signature or authorisation of the person checking or releasing the report, where possible. NOTE In reference to i), under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services and sites where reports are received.			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.8.4	<p>As appropriate, the description of examinations performed and their results should follow the vocabulary and syntax recommended by one or more of the following organisations:</p> <ul style="list-style-type: none"> - International Council for Standardization in Haematology (ICSH); - International Society of Haematology (ISH); - International Federation of Clinical Chemistry and Laboratory Medicine (IFCC); - International Union of Pure and Applied Chemistry (IUPAC); - International Society of Thrombosis and Haemostasis (ISTH); - European Committee for Standardisation (CEN); <p>As appropriate, the description and results should follow the nomenclature recommended by one or more of the following organisations:</p> <ul style="list-style-type: none"> - International Union of Biochemistry and Molecular Biology (IUBMB); - International Union of Microbiological Societies (IUMS); - International Union of Immunological Societies (IUIS); - SNOMED International (College of American Pathologists); - World Health Organization (WHO). <p>NOTE National, regional and local regulations may require the name and location of the examining (or referral) laboratory to be shown in the final report.</p>			
5.8.5	The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the result.			
5.8.6	Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by national, regional, or local requirements.			
5.8.7	The laboratory shall have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established "alert" or "critical" intervals. This includes results received on samples sent to referral laboratories for examination.			
5.8.8	In order that local clinical needs can be served, the laboratory shall determine the critical properties and their "alert/critical" intervals, in agreement with the clinicians using the laboratory. This applies to all examinations, including nominal and ordinal properties.			
5.8.9	For results transmitted as an interim report, the final report shall always be forwarded to the requester.			
5.8.10	Records of actions taken in response to results in the critical intervals shall be maintained. These shall include date, time, responsible laboratory staff member, person notified, and examination results. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.			
5.8.11	<p>Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect the clinical needs.</p> <p>There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to it shall be monitored, recorded, and reviewed by laboratory management. Where necessary, corrective action shall be taken to address any problems so identified.</p> <p>This does not mean that the clinical personnel are to be notified of all delays in examination, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and laboratory personnel.</p>			

CLAUSE	REQUIREMENT	√ or X	QM	COMMENTS
5.8.12	When examination results from a referral laboratory need to be transcribed by the referring laboratory, procedures for verifying the correctness of all transcriptions shall be in place.			
5.8.13	The laboratory shall have clearly documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall also include guidelines for the release of results directly to patients.			
5.8.14	The laboratory shall establish policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorised receivers. Results provided verbally shall be followed by a properly recorded report.			
5.8.15	The laboratory shall have written policies and procedures regarding the alteration of reports. When altered, the record must show the time, date, and name of the person responsible for the change. Original entries shall remain legible when alterations are made. Original electronic records shall be retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.			
5.8.16	Results that have been available for clinical decision-making and revised shall be retained in subsequent cumulative reports and be clearly identified as having been revised. If the reporting system cannot capture amendments, changes, or alterations, an audit log shall be used.			