Western Sussex Hospitals NHS
NHS Foundation Trust

INTEGRATED PATHOLOGY SERVICE
GENERAL PATHOLOGY DOCUMENT

TEMPLATE FOR GAP ANALYSIS AGAINST ISO 15189:2012

[QF-PAT-ISO15189:2012Gap]

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Remember - "If it isn't documented, it didn't happen"

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Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
4.1.1.2	**Legal entity**				
	Is the laboratory or the organization of which it is part an entity that can be held legally responsible				
4.1.1.3	**Ethical conduct**				
What arrangements are in place that ensures that:					
a	There is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity				
b	management and personnel are free from any undue commercial, financial or other pressures or 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	**Laboratory Director**				
	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?				
	If the laboratory director delegates selected duties and/or responsibilities, is it clear that the laboratory director maintains the ultimate responsibility for the overall operation and administration of the laboratory?				

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Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Are the duties and responsibilities of the laboratory director documented?				
Does the documented duties and responsibilities of the laboratory director (whether delegated or not) identify ultimate responsibility for:					
a	providing effective leadership of the medical laboratory service including budget planning and financial management, in accordance with institutional assignment of such responsibilities;				
b	relating and functioning 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	ensuring 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	ensuring the implementation of the quality policy;				
e	implementing a safe laboratory environment in compliance with good practice and applicable requirements;				
f	serving as a contributing member of the medical staff for those facilities served if applicable and appropriate;				
g	ensuring the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;				
h	selection and monitoring of laboratory suppliers;				
i	selection of referral laboratories and monitoring the quality of their service (see also 4.5);				
j	providing professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;				
k	defining, implementing and monitoring standards of performance and quality improvement of the medical laboratory service or services;				
l	monitoring of all work performed in the laboratory to determine that clinically relevant information is being generated;				

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m	addressing any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3, 4.14.4);				
n	designing and implementing a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;				
o	planning and directing research and development, where appropriate.				
	Are contingency plans (as above) periodically tested?				
4.1.2.1 Management commitment					
What evidence is available to show the commitment of laboratory management to the development and implementation of the quality management system and its continual improvement in effectiveness, in respect of:					
a	communicating to laboratory personnel the importance of meeting the needs and requirements of users (see also 4.1.2.2) as well as regulatory and accreditation requirements;				
b	establishing the quality policy (see also 4.1.2.3)				
c	ensuring that quality objectives and planning are established (see also 4.1.2.4)				
d	defining responsibilities, authorities and interrelationships of all personnel (see also 4.1.2.5)				
e	establishing communication processes (see also 4.1.2.6)				
f	appointing a quality manager, however named (see also 4.1.2.7)				
g	conducting management reviews (see also 4.15)				
h	ensuring that all personnel are competent to perform their assigned activities (see also 5.1.6)				
i	ensuring the availability of adequate resources (see also 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see also 5.4. 5.5 and 5.7)				

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4.1.2.2	**Needs of users**				
	Does laboratory management ensure that laboratory services, including appropriate advisory and interpretive services, meet the needs of patients and those using the laboratory services? (see also 4.4 and 4.14.3)				
4.1.2.3	**Quality policy**				
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 ISO 15189:2012 and continual improvement of the quality of laboratory services;				
c	provides a framework for establishing and reviewing quality objectives;				
d	is communicated and understood within the organization;				
e	is reviewed for continuing suitability.				
4.1.2.4	**Quality objectives and planning**				
	Has laboratory management established quality objectives including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization?				
	Are the quality objectives 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 also 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	**Responsibility, authority and interrelationships**				
	Does laboratory management ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization?				

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	Does this include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel (although it is recognized that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function)				
4.1.2.6	**Communication**				
	Does laboratory management have an effective means of 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 and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system?				
4.1.2.7	**Quality manager**				
	Has laboratory management appointed a quality manager?				
Does the quality manager, irrespective of other responsibilities, have 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.				
4.2.1	**Quality management system – General requirements**				
	Has the laboratory established, documented, implemented and maintained a quality management system				
	Does the laboratory continually improve the effectiveness of the quality management system in accordance with the requirements of ISO 15189:2012?				

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	Does the quality management system provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of its 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.				
4.2.2.1 Documentation requirements (General)					
Does the quality management system documentation include:					
a	Statements of a quality policy (see also 4.1.2.3) and quality objectives (see also 4.1.2.4);				
b	A quality manual (see also 4.2.2.2)				
c	Procedures and records required by ISO 15189:2012;				
d	Documents, and records (see also 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.				

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4.2.2.2	**Quality manual**				
Has the laboratory established and maintained a quality manual that includes:					
a	the quality policy (see also 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 ISO 15189:2012				
e	a description of the structure and relationships of the documentation used in the quality management system;				
f	the documented policies established for the quality management system and reference to the managerial and technical activities that support them.				
	Do all laboratory staff have access to and are instructed on the use and application of the quality manual and the referenced documents?				
4.3	**Document control**				
	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" • authority for issue				
c	Current authorized editions and their distribution are identified by means of a list (e.g. document register, log or master index)				

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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.				
	Unintended use of any obsolete document is prevented.				
4.4.1	**Establishment of service agreements**				
	Does the laboratory have a documented procedure(s) for the establishment and review of agreements for providing medical laboratory services?				
Does the procedure(s) for these reviews ensure that when the laboratory enters into an agreement to provide medical laboratory services:					
a	The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used shall be defined, documented and understood (see also 5.4.2 and 5.5)				
b	The laboratory shall have the capability and resources to meet the requirements				
c	Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examination				
d	Examination procedures selected shall be appropriate and able to meet the customers' needs (see also 5.5.1)				

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e	Customers and users shall be informed of deviations from the agreement that impact upon the examination results				
f	Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant				
4.4.2	**Review of service agreements**				
	Are records of these reviews (which shall include all aspects of the agreement) kept, including any changes to the agreement and any pertinent discussions?				
	If an agreement needs to be amended after laboratory services have commenced, is the same review process repeated and any amendments communicated to all affected parties?				
4.5.1	**Selecting and evaluating referral laboratories and consultants**				
	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 above 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 ISO 15189:2012 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 from all samples referred are kept for a pre-defined period				

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4.5.2	**Provision of examination results**				
	Unless specified in the agreement, is the referring laboratory and not the referral laboratory responsible for ensuring the examination results of the referral laboratory are provided to the person making the request?				
	If the referring laboratory prepares the report, does the report contain all the essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation?				
	Does the report clearly indicate which examinations were performed by the referral laboratory or consultant?				
	The referring laboratory may elect to provide additional interpretive remarks to those, if any, of the referral laboratory or consultant in the context of the patient and/or the local medical environment. If this is the case, does the report clearly indicate the author of these additional remarks?				
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?				
	Are criteria for the selection of suppliers established?				
	Is 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 required criteria?				
4.7	**Advisory services**				
Has the laboratory established arrangements with users on the following:					

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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 judgements on the interpretation of the results of examinations (see also 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 complaints**				
	Does the laboratory have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties?				
	Is documentation relating to all complaints and their investigation and actions taken, maintained?				
4.9	**Identification and control of nonconformities**				
	Does the laboratory have a documented procedure for the identification and management of nonconformities in any aspect of the quality management system, including pre-examination, examination and post-examination processes?				
Does any such 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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
e	the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual 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.				
	If the laboratory determines 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)?				
	How is the corrective action to be taken determined and documented (see also 4.10)?				
4.10	**Corrective action**				
Does the laboratory have a documented procedure for:					
a	reviewing nonconformities;				
b	determining the root cause 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 also 4.13);				
f	reviewing the effectiveness of corrective action taken (see also 4.14.5).				
4.11	**Preventive action**				
Does the laboratory have a documented procedure for:					

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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 also 4.13);				
f	Reviewing the effectiveness of the preventive action taken.				
4.12	**Continual improvement**				
	Does the laboratory continually improve the effectiveness of its 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?				
	Are improvement activities directed at areas of highest priority based on risk assessments?				
	Are action plans for improvement, developed documented and implemented, as appropriate?				
	Is the effectiveness of the actions taken determined through a focused review or audit of the area concerned (see also 4.14.5)?				
	How does laboratory management ensure participation 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 these regardless of where they occur?				
	How does laboratory management communicate improvement plans and related goals to staff?				

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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?				
	Are all records legible and stored in such a way that they are readily accessible and protected from unauthorized alterations?				
	Has the laboratory determined the time period that various records pertaining to the quality management system (including pre-examination, examination and post-examination processes) are to be retained?				
	Is the environment(s) for the storage of records suitable so as to prevent damage, deterioration loss or unauthorized access?				
Do retained records include (but not necessarily limited to):					
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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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				
	Are all of these quality and technical records available for laboratory management review (see also 4.15)?				
4.14.2	**Periodic review of requests, and suitability of procedures and sample requirements**				
	Do authorized personnel periodically review the examinations provided by the laboratory to ensure they are clinically appropriate for the requests received?				
	Does the laboratory periodically review 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?				
	Are records kept of information collected and actions taken?				

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4.14.4	**Staff suggestions**				
	How does laboratory management encourage staff to make suggestions for the improvement of any aspect of the laboratory service?				
	Are suggestions evaluated, implemented as appropriate and is feedback provided to the staff?				
	Are records of suggestions and actions taken by 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 ISO 15189:2012 and to standards established by the laboratory; and				
b	Are implemented, effective and maintained.				
c	Are audits conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system?				
d	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?				
e	Is the audit criteria, scope, frequency and methods defined and documented?				
f	How do the selection of auditors and the conduct of audits ensure the objectivity and impartiality of the audit process?				
g	Where resources permit, are auditors independent of the activity to be audited?				
h	Does the laboratory have a documented procedure that defines the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records?				
i	Do personnel responsible for the area being audited ensure that appropriate action is promptly undertaken when nonconformities are identified?				
j	Is corrective action taken without undue delay to eliminate the causes of the detected nonconformities?				

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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?				
	Does the laboratory modify processes to reduce or eliminate the identified risks and are these decisions and actions documented?				
4.14.7	**Quality indicators**				
	Has the laboratory established quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes?				
	Is the process for monitoring quality indicators planned (including establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement)?				
	Are the quality indicators periodically reviewed to ensure their continued appropriateness?				
	Has the laboratory, in consultation with the users established 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**				
	Does the laboratory, when reviews by external organizations indicate it has nonconformities or potential nonconformities, take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of ISO 15189:2012?				
	Does the laboratory keep records of the reviews and of the corrective actions and preventive actions taken?				
4.15.1	**Management review (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?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
4.15.2	**Review input**				
Does the input to the management review include information from the results of evaluation of at least:					
a	The periodic review of requests, and suitability of procedures and sample requirements (see also 4.14.2);				
b	Assessment of user feedback (see also 4.14.3);				
c	Staff suggestions (see also 4.14.4);				
d	Internal audits (see also 4.14.5)				
e	Risk management (see also 4.14.6);				
f	Use of quality indicators (see also 4.14.7);				
g	Reviews by external organizations (see also 4.14.8);				
h	Result of participation in interlaboratory comparison programmes (PT/EQA) (see also 5.6.3);				
i	Monitoring and resolution of complaints (see also 4.8);				
j	Performance of suppliers (see also 4.6);				
k	Identification and control of nonconformities (see also 4.9);				
l	Results of continual improvement (see also 4.12) including current status of corrective actions (see also 4.10) and preventive actions (see also 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.				
	Does the review analyze the input information for causes of nonconformities, trends and patterns that indicate process problems?				
	Does the review include assessing the opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives?				

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	Is the quality and appropriateness of the laboratory's contribution to patient care, to the extent possible, objectively evaluated?				
4.15.4	**Review output**				
	Has the output from the management review been 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.				
	Is the interval between management reviews no greater than 12 months?				
	Are the 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?				
5.1.1	**Personnel (General)**				
	Does the laboratory have a documented procedure for personnel management?				
5.1.2	**Personnel qualifications**				
	Does laboratory management document personnel qualifications for each position that reflect the appropriate education, training, experience and demonstrated skills needed, that are appropriate to the tasks performed?				
	Do the personnel that are making judgements with reference to examinations have the applicable theoretical and practical background and experience?				
5.1.3	**Job descriptions**				
	Does the laboratory have job descriptions that describe responsibilities, authorities and tasks for all personnel?				

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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 are undergoing training supervised at all times?				
	Is 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?				
	Does the laboratory reassess competence at regular intervals?				
	If identified at competence assessment, does retraining occur?				
Is the competence of laboratory staff 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;				

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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.				
	Does competency assessment for professional judgement, which is specific and fit for purpose, occur?				
5.1.7	**Review of staff performance**				
	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?				
	Do staff who undertake staff performance reviews receive appropriate training?				
5.1.8	**Continuing education and professional development**				
	Is there a continuing education programme available to all personnel who participate in managerial and technical processes?				
	Do all personnel who participate in managerial and technical processes take part in continuing education?				
	Is 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**				
Are the following personnel records readily available to relevant personnel (whether internal or external to the laboratory:					

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
a	education 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.				
5.2.1	**Accommodation and environmental conditions (General)**				
	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 users and the health and safety of laboratory personnel, patients and visitors?				
	Has the laboratory evaluated and determined the sufficiency and adequacy of the space allocated for the performance of the work?				
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;				
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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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.				
5.2.3	**Storage facilities**				
	Are storage areas 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?				
	Does the way in which clinical samples and materials used in examination processes are stored prevent cross contamination?				
	Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials and are as specified by applicable requirements?				
5.2.4	**Staff facilities**				
Do staff facilities provide access to:					
	washrooms				
	a supply of drinking water				
	facilities for storage of personal protective equipment and clothing				
	quiet study/meetings area				
	rest area				
5.2.5	**Patient sample collection facilities**				
	Do the patient sample collection facilities have separate reception/waiting and collection areas?				
Do the facilities ensure:					
	patient privacy;				
	comfort and needs (e.g. disabled access, toilet facility);				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection.				
	Do the facilities at which patient sample collection procedures are performed (e.g. phlebotomy) enable sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination?				
	Do the sample collection facilities have and maintain appropriate first-aid materials for both patient and staff needs?				
5.2.6	**Facility maintenance and environmental conditions**				
	Are laboratory premises maintained in a functional and reliable condition?				
	Are 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, examination and/or the health of staff, including, where appropriate:					
	light;				
	sterility;				
	dust;				
	noxious or hazardous fumes;				
	electromagnetic interference;				
	radiation;				
	humidity;				
	electrical supply;				
	temperature;				
	sound;				
	vibration levels;				
	workflow logistics.				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	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 nor being separated?				
	Does the laboratory provide a quiet and uninterrupted work environment where it is needed (e.g. cytopathology screening, microscopy)?				
5.3.1.1	**Equipment (General)**				
	Does the laboratory have a documented procedure for the selection, purchasing and management of equipment?				
	Is the laboratory furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage)?				
	In order to ensure the quality of examination results is there evidence that equipment is replaced when needed?				
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)?				
	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 for use, safety and maintenance of equipment, including any relevant manuals and directions for use that have been provided by the manufacturer, readily available?				
	Does the laboratory have written procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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 the above procedure include:					
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 the metrological traceability to a reference material of reference procedure of the higher metrological order available?				
If this is not possible or relevant, are other means for providing confidence in the results applied which include, but not limited to:					
	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?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Is equipment maintained in a safe working condition and in working order, at a minimum using manufacturer's schedules, instructions or both?				
Does this include:					
	examination of electrical safety;				
	emergency stop devices where they exist;				
	safe handling and disposal of chemical, radioactive and biological materials by authorized persons.				
	If equipment is found to be defective, is it taken out of service and clearly labelled?				
	How does the laboratory ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria?				
	How does the laboratory examine the effects of any defects on previous examinations and institute immediate action or corrective action (see also 4.10)?				
	Does the laboratory decontaminate equipment before service, repair or decommissioning?				
	Does the laboratory take reasonable steps to provide suitable space for repairs and provide personal protective equipment?				
	If 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**				
	Are adverse incidents and accidents that can be attributed directly to specific equipment, investigated and reported to the manufacturer and appropriate authorities, as required?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
5.3.1.7	**Equipment records**				
For equipment that contributes to the performance of examinations, are records maintained for each item including, but not limited to:					
a	identity of the equipment;				
b	manufacturer's name, model and serial number or other unique identification;				
c	contact information for the supplier or 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?				
	Are the records listed above maintained and readily available for the lifespan of the equipment, or longer, as specified in the laboratory's Control of Records procedure (see also 4.13)?				
5.3.2.1	**Reagents and consumables (General)**				
	Does the laboratory have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
5.3.2.2	**Reagents and consumables – Reception and storage**				
	If 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 reagents and consumables according to manufacturer's specifications?				
5.3.2.3	**Reagents and consumables – Acceptance testing**				
	Where there is a new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, does the laboratory verify these for performance before use in examinations?				
	Are consumables that can affect the quality of examinations, verified for performance before use in examinations?				
5.3.2.4	**Reagents and consumables – Inventory management**				
	Has the laboratory established an inventory control system for reagents and consumables?				
	Does 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 supplied 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**				
For reagents and consumables that contribute to the performance of examinations are records maintained that include, but not limited to:					
a	identity of the reagent or consumables;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
b	manufacturer's name and batch code or lot number;				
c	contact information for the supplier or 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 above, reference to the person or persons undertaking their preparation and the date of preparation?				
5.4.2	**Information for patients and users**				
Does the laboratory have information available for patients and users of the laboratory services that includes:					
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				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
h	instructions for the 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 examinations and of 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 the 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 limited to, the following:					
a	patient identification, including gender, date of birth and the location/contact details of the patient, and a unique identifier (includes an alpha and/or numeric 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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
e	clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;				
f	date and, where relevant, time of primary sample collection;				
g	date and time of sample receipt				
	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?				
5.4.4.1	**Primary sample collection and handling (General)**				
	Does the laboratory have documented procedures for the proper collection and handling of primary samples?				
	Are the documented procedures available to those responsible for primary sample collection, whether or not the collectors are laboratory staff?				
	If the user requires deviations and exclusions from, or additions to, the collection procedure, are these recorded and included in all documents containing examination results and communicated to the appropriate personnel?				
5.4.4.2	**Instructions for pre-collection activities**				
Do 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).				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
5.4.4.3	**Instructions for collection activities**				
Do 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 shall be determined and communicated to the appropriate clinical staff;				
e	instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;				
f	recording of the identity of the person collecting the primary sample and the collection date and, where 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 transportation of samples to ensure 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 for sample collection and handling and with the designated preservatives to ensure the integrity of samples;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
c	in a manner which ensures the integrity of the samples and the safety of the carrier, the general public and the receiving laboratory , in compliance with established requirements.				
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 shall 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 shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.				
e	Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).				
f	Where relevant, there shall be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.				
	How does the laboratory ensure that all portions of the primary sample are 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.				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Do such laboratory procedures include time limits for requesting additional examinations or further examinations on the same primary sample?				
5.5.1.1	**Selection, verification and validation of examination procedures (General)**				
	Are all examination procedures the laboratory selects to use validated for their intended use?				
	Is the identity of persons performing activities in examination processes recorded?				
5.5.1.2	**Verification of examination procedures**				
	Have all validated examination procedures, used without modification, been 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 laboratory ensure that the performance claims for the examination procedure, confirmed during the verification process, are relevant to the intended use of the examination results?				
	Has the laboratory documented the procedure used for the verification and recorded the results obtained?				
	Do staff that review the verification results and record the review have the appropriate authority?				
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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
d	validated methods subsequently modified.				
	Are the validations as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled?				
	Has the laboratory documented the procedure used for the validation and recorded the results obtained?				
	Do staff that review the validation results and record the review have the appropriate authority?				
	When changes are made to a validated examination procedure, is the influence of such changes documented and, where appropriate, is a new validation carried out?				
5.5.1.4	**Measurement uncertainty of measured quantity values**				
	Has the laboratory determined measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples?				
	Has the laboratory defined the performance requirements for the measurement uncertainty of each measurement procedure?				
	Does the laboratory regularly review estimates of measurement uncertainty?				
	Does the laboratory consider measurement uncertainty when interpreting measured quantity values?				
	Does the laboratory, upon request, make its estimates of measurement uncertainty available to laboratory users?				
	For examinations that include a measurement step, but do not report a measured quantity value, has the laboratory calculated the uncertainty of 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**				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Has the laboratory defined the biological reference intervals or clinical decision values, documented the basis for the reference intervals or decision values and communicated this information to users?				
	Where a particular biological reference interval or decision value is no longer relevant for the population served, are 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 appropriate?				
5.5.3	**Documentation of examination procedures**				
	Are all examination procedures documented?				
	Are they written in a language commonly understood by the staff in the laboratory and available in appropriate locations?				
	Are all documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, subject to document control?				
Do examination procedures, in addition to document control identifiers include the following, when applicable to the examination procedure:					
a	purpose of the examination;				
b	principle and method of the procedure used for examinations;				
c	performance characteristics (see also 5.5.1.2 and 5.5.1.3);				
d	type of specimen (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 (metrologiocal traceability);				
j	procedural steps;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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 of clinical decision values;				
o	reportable interval for 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.				
	When the laboratory is considering changing an existing examination procedure such that results or their interpretations could be significantly different, does the laboratory explain the implications to users of the laboratory services, after validating the procedure?				
5.6.2.1	**Quality control (General)**				
	Has the laboratory designed quality control procedures that verify the attainment of the intended quality of results?				
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?				
	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?				
5.6.2.3	**Quality control data**				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure?				
	If quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, are 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 evaluate results from patient samples that were examined after the last successful quality control event?				
	Is quality control data reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system?				
	When such trends are noted, are preventive actions taken and recorded?				
5.6.3.1	**Interlaboratory comparisons (Participation)**				
	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?				
	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?				
	Has the laboratory established 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?				
	Does the 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	**Interlaboratory comparisons (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?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure?				
	If this approach is taken, does the laboratory, wherever possible, use authorized materials?				
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?				
	Are interlaboratory comparison samples examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples?				
	Does the laboratory ensure that it does 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 ensure it doesn't refer interlaboratory comparison samples for confirmatory examinations before submission of the data, even if this would routinely be done with patient samples?				
5.6.3.4	**Evaluation of laboratory performance**				
	Is the performance in interlaboratory comparisons reviewed and discussed with relevant staff?				
	When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), do staff participate in the implementation and recording of corrective action?				
	Is the effectiveness of such corrective action monitored				
	Are the returned results evaluated for trends that indicate potential nonconformities and is preventive action taken?				
5.6.5	**Comparability of examination results**				
	Has the laboratory a defined means for comparing procedures, equipment and methods used to compare results for patient samples throughout the clinically appropriate intervals (this is applicable to the same or different procedures, equipment, different sites, or all of these)?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Does the laboratory notify users in 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 the results from the comparisons performed?				
	If problems or deficiencies are identified, are these acted upon and records of actions retained?				
5.7.1	**Review of results**				
	Does the laboratory have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against quality control and, as appropriate, available clinical information and previous examination				
	When the procedure for reviewing results involves automatic selection and reporting, have the review criteria been established, approved and documented?				
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?				
	Has the laboratory defined the length of time clinical samples are to be retained?				
	Is the safe disposal of samples carried out in accordance with local regulations or recommendations for waste management?				
5.8.1	**Reporting of results (General)**				
	How does the laboratory ensure that the results of each examination are reported accurately, clearly, unambiguously, and in accordance with any specific instructions in the examination procedures?				
	Has the laboratory defined 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?				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
	Does the laboratory have a procedure to ensure the correctness of transcription of laboratory results?				
	Does the laboratory have a process for notifying the requester when an examination is delayed that could compromise patient care?				
5.8.2	**Report attributes**				
How 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 also 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 bby 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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
i	examination results reported in SI units, units traceable to SI units, or other applicable units;				
j	biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values , where applicable;				
k	interpretation of results, where appropriate;				
l	other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure)				
m	identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;				
n	identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);				
o	date of the report and time of release (if not contained in the report, readily available when needed);				
p	page number to total number of pages (e.g. page 1 of 5)				
5.9.1	**Release of results (General)**				
	Has the laboratory established documented procedures for the release of examination results, including who may release results and to whom?				
Do the procedures ensure the following conditions are met:					
a	When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report				
b	***When examination results fall within established "alert" or "critical" intervals:***				
	A physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see also 4.5)];				
	Records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified, and examination results conveyed, and any difficulties encountered in notifications;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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 shall be followed by a written report. There shall be a record of all oral results provided.				
5.9.2	**Automated selection and reporting of results**				
If the laboratory has implemented a system for automated selection and reporting of results, has it established a documented procedure that ensures that:					
a	the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff;				
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, where appropriate;				
e	results selected for automatic reporting shall be 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**				
Does the laboratory have written instructions, when an original report is revised, 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;				

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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.				
	Are 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, is a record kept of changes or alterations?				
5.10.1	**Laboratory information management (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?				
5.10.2	**Authorities and responsibilities**				
	Has the laboratory ensured that the authorities and responsibilities for the management of the information system, including the maintenance and modification to the information system(s), that may affect patient care, are defined?				
Has the laboratory defined 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**				
Has the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information been:					
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;				

Remember - "If it isn't documented, it didn't happen"

Clause	Requirement	Evidence	Finding	Complies Y/N	Action / NC No.
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, provide 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 reporting of system failures and the appropriate immediate and corrective actions;				
g	shown to be compliant 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 sub-contracted to an alternative provider does laboratory management remain responsible for ensuring that the provider or operator of the system complies with all applicable requirements of ISDO 15189:2012.				