INTRODUCTION

1. Purpose

This checklist is prepared for the following purposes:

1.1 To assist both the laboratory staff and the assessment team in checking that all criteria for accreditation are satisfied.

1.2 To index documentation of the quality system and use as part of the preparation for the introduction of ISO 15189 and an assessment; and

1.3 To provide essential background information for briefing PAB assessment team and relevant information during the assessment process.

This checklist provides only a brief summary of the clauses of the Standard.

2. Structure and Use of the Checklist

2.1 Compliance with PAB General Requirements

2.2 All PAB accredited laboratories are required to comply with the accreditation requirements and the basic technical and management system requirements for laboratories based on ISO 15189:2012.

2.3 PAB needs to obtain and maintain information on the specific technical resources available in the laboratory and to be aware of the desired scope of the accreditation by PAB (the approved examinations or tests) and for approved signatories (the specific people authorized to sign PAB endorsed test reports).

3. Preparation of Laboratory Quality Manuals

Each accredited laboratory is required to implement a documented management system as one of the fundamental conditions for PAB accreditation.

The documented management system includes all of the laboratory's policies and operational procedures established to meet the requirements for accreditation.

The manner in which a laboratory's documented management system is structured is the choice of the laboratory. The purpose of the documentation is primarily to advice the laboratory's staff of the policies and procedures expected by its management to be implemented by all staff.

Typically, a laboratory's management system is documented in a Laboratory Quality Manual and supporting procedures and records. In some cases, a Laboratory Quality Manual includes supporting procedures. In other cases, some of the subjects of a Laboratory Quality Manual may be incorporated in an organization's more general Quality Manual or procedures.

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
4	**Management Requirements**		
4.1	**Organization and management responsibility**		
4.1.1	**Organization**		
4.1.1.1 General	Does the laboratory management system cover work carried out in: - Permanent facilities? - Sites away from its permanent facilities? - Associated temporary facilities? - Mobile facilities?		
4.1.1.2 Legal Identity	Is the laboratory or the organisation legally responsible?		
4.1.1.3 Ethical conduct	Does the laboratory/management have arrangement to ensure that: a. No involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity. b. Management and personnel are free from - undue internal and external commercial pressure? - financial pressure? - Other pressure that influences that may adversely affect the quality of work? c. Where potential conflicts in competing interests may exist, they shall be openly and appropriately declared d. Appropriate procedures to ensure human samples, tissues or remains according to relevant legal requirements? e. Policies and procedures to confidentiality of information?		
4.1.1.4 Laboratory Director	Is the laboratory directed by a person or persons with competence and delegated responsibility for the services provide?		
	Do the responsibilities of the laboratory/facility director or designees include professional, scientific, consultative, advisory, organisational, administrative, and educational matters?		
4.1.1.4 Laboratory Director	Does the laboratory director (or designates for delegated duties) have the necessary competence, authority and resources in order to fulfil the requirements of this international standard?		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	The duties and responsibilities of the laboratory director (or designate/s) shall be documented and include the following: a) Provide effective leadership of the medical laboratory service, including budget planning and financial management. b) Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required; c) Ensure that there are appropriate numbers of staff, d) Ensure the implementation of the quality policy, e) Implement a safe laboratory environment, f) Serve as contributing member of the medical staff, g) Ensure the provision of clinical advise, h) Select and monitor laboratory suppliers, i) Select referral laboratories and monitor the quality of their services, j) Provide professional development programs for lab. Staff, k) Define, implement and monitor standards of performance and quality improvement, l) Monitor all work performed in the laboratory, m) Address any complaints, request or suggestion from staff and/or users of lab. Services, n) Design and implement a contingency plan to ensure that essential services are available. (contingency plan should be periodically tested) o) Plan and direct research and development, where appropriate. (The laboratory/facility director need not perform all responsibilities personally. However, it is the laboratory/facility director's responsibility for the overall operation		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	and administration of the laboratory/facility, for ensuring that quality services are provided for patients.)		
4.1.2	**Management responsibility**		
4.1.2.1 Management commitment	The laboratory management shall provide evidences of its commitment to develop and implement the quality management system and to continually improve its effectiveness by: a) Communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements. b) establishing quality policy; c) ensuring that quality objectives and planning are established; d) Defining the responsibilities, authorities and interrelationships of all personnel. e) Establishing communication processes; f) Appointment of quality manager; g) Conducting management review. h) Ensuring that all personnel are competent to perform their assigned activities; i) Ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities.		
4.1.2.2 Needs of user	Does the medical laboratory / facility services, including appropriate interpretation and advisory services meet : -the needs of patients and all personnel responsible for patient care?		
4.1.2.3 Quality Policy	Is the Quality Policy: - defined under the authority of laboratory/ facility management? - and include the following: a) Appropriate to the purpose of the organization. b) The laboratory's commitment to good professional practice, examinations that are fit for intended use, c) Compliance with the requirements of this International Standards,		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	and continual improvement of the quality of laboratory services, d) A framework for establishing and reviewing quality objectives, e) Communicated and understood within the organization, f) Reviewed for continuing suitability.		
4.1.2.4 Quality Objectives and Planning	The laboratory management establish quality objectives that are measurable and consistent with the quality policy. Does it meet the needs and requirements of the users, at relevant functions and levels within the organisation? The planning of the quality management system shall meet the requirements and the quality objectives.		
4.1.2.5 Responsibility, authority and interrelationships	Ensure that responsibilities, authorities and interrelationships are defined, documented and communicated. Appointment of person(s) responsible for each laboratory function. Appointment of deputies for key managerial and technical personnel.		
4.1.2.6 Communication	Are there records of items discussed in communications and meetings with the laboratory staff? Are records kept of items discussed in communications and meetings? Are appropriate communication processes established between the laboratory and its stakeholders in relation to laboratory's pre-examination, examination and post-examination processes and quality management system?		
4.1.2.7 Quality Manager	The laboratory shall appoint Quality Manager. Does the responsibilities and authority includes: a) Ensuring that processes needed for the quality management system are established, implemented and maintained, b) Reporting to the laboratory management, at a level which		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	decision are made to laboratory policy, objectives and resources, on the performance of the quality management system and any need for improvement? c) Promoting the awareness of users' needs and requirements throughout the laboratory organisation?		
4.2	**Quality management system**		
4.2.1 General requirements	The laboratory shall establish, document, implement and maintain quality management system and continually improve its effectiveness. The laboratory shall: a) Determine the processes needed for the quality management system and ensure their application throughout the laboratory; b) Determine the sequence and interaction of these processes; c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective. d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes. e) Monitor and evaluate these processes; f) Implement actions necessary to achieve planned results and continual improvement of these processes.		
4.2.2	**Documentation requirements**		
4.2.2.1 General	Quality management system documentation shall include: a) Statement of Quality Policy and Quality Objectives b) Quality manual c) Procedures and records required by ISO 15189 d) Documents and records, 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.		
4.2.2.2	The laboratory shall establish and		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
Quality manual	maintain Quality Manual that includes: a) Quality policy or makes reference to it b) Scope of the quality management system c) Organization and management structure d) Roles and responsibilities of laboratory management (including the laboratory director and quality manager) e) Document structure f) Documented policies for the quality management system and reference to the managerial and technical activities. All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.		
4.3	**Document control**		
	The laboratory shall control documents required by the quality management system. Ensure unintended use of any obsolete document is prevented. Shall have documented procedure to ensure the following conditions are met: a) All documents, including those maintained in computerized system are reviewed and approved by authorized personnel before issue. b) All documents are identified to include: - title - unique identifier on each page, - date of current edition and/or edition number - page number to total number of pages - authority to issue c) List of documents with current authorized editions and their distributions. d) Only current authorized editions of applicable documents are available at points of use. e) Procedure and authorities for the amendment of documents by		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	hand. 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 specified requirements.		
4.4	**Service agreements**		
4.4.1 Establishment of service agreements	The laboratory shall have procedures established and maintained for review of agreements. The following conditions shall be met when the laboratory enters into an agreement: a) The requirements, including the methods to be used are: - Defined - Documented - Understood b) Capability and resources meet the requirements. c) Laboratory personnel have the skills and expertise necessary for the performance of the intended examination. d) Appropriate method is selected and capable of meeting the customers' needs. e) Customers and users are informed of deviations from the agreement. f) References shall be made to any work referred by the laboratory.		
4.4.2 Review of service agreements	Are records of these reviews and any significant changes maintained? If the contract needs to be amended after the work commence: - Is the same contract review process repeated? - Are any amendments communicated to all affected parties?		
4.5	**Examination by referral laboratories**		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
4.5.1 Selecting and evaluating referral laboratories and consultants	The laboratory shall have documented procedures available to evaluate and select: - Referral laboratories? - Consultants who provide second opinions and interpretation for complex testing in any discipline. The procedure shall ensure that the following conditions are met: a) Laboratory management responsible for selecting and monitoring the quality of referral laboratories and consultants. Referral laboratory or consultant is competent to perform the requested examinations. b) Arrangements with referral laboratories and consultants periodically reviewed and evaluated. c) Records of such periodic reviews are maintained. d) Maintains register of all referral laboratories and consultants. e) Requests and results of all samples referred are kept for a pre-defined period.		
4.5.2 Provision of examination results	The referring laboratory, and not the referral laboratory/facility, shall be responsible to ensure that examination results and findings are provided to the clinician making the request. The report shall have all the essential elements of the results if it is reported by the referral laboratory, without alterations that could affect any clinical interpretations. The report shall indicate which examinations were performed by a referral laboratory or consultant. The author of any additional remarks shall be clearly identified.		
4.6	**External services and supplies**		
	The laboratory shall have procedure for selection purchasing of services, equipment, reagents and consumable supplies it uses that affect the quality of its services. The laboratory shall select and approved suppliers.		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	Criteria for selection of suppliers shall be established A list of selected and approved suppliers of equipment, reagents and consumables shall be maintained. Purchasing information shall describe the requirements for the product or service to be purchased. The laboratory shall monitor the performance of suppliers.		
4.7	**Advisory services**		
	The laboratory shall establish arrangements for communicating with users on the following: a) Advising on choice of - examination and use of the services - required type of samples - clinical indications - limitations of examination procedures - frequency of requesting the examination b) Advising on individual clinical cases, c) Professional judgments on the interpretation of the results of examinations, 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**		
	The laboratory shall have documented procedure for the management of complaints or other feedback. Records of all complaints, investigation and action taken shall be maintained.		
4.9	Identification and control of nonconformities		
	The laboratory shall have documented procedure to identify and manage nonconformities in any aspects of the quality management system, including pre-examination, examination or post-examination processes. The procedure shall ensure that:		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	a) Responsible person for handling nonconformities are designated. b) Define immediate actions taken. c) The extent of nonconformity is determined d) Examinations are halted and reports withheld as necessary; e) The medical significance of the non- conforming tests is considered and requesting clinicians informed where appropriate. f) Non-conforming test results and examinations already released are recalled? g) The responsibility for authorization of the resumption of work is defined? h) Details of the non-conformity is documented and recorded and reviewed at regular specified intervals to detect trends and initiate preventive actions? If evaluation of the non-conformity determines recurrence, then are procedures established and implemented to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented.		
4.10	**Corrective action**		
	The laboratory shall take corrective actions appropriate to the effects of the nonconformities encountered. The laboratory shall have documented procedure for: a) Reviewing nonconformities b) Determining root causes of nonconformities c) Evaluating the need for corrective action to ensure that nonconformities do not recur. d) Determining and implementing corrective actions needed. e) Recording the results of corrective action taken f) Reviewing the effectiveness of the corrective action taken.		
4.11	**Preventive action**		
	The laboratory shall determine action to eliminate the causes of potential nonconformities to prevent its occurrence.		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	The laboratory shall have documented procedures for: a) reviewing of laboratory data and information to determine potential nonconformities. b) determining root cause(s) of potential nonconformities. c) evaluating of the need for preventive action to prevent occurrence of nonconformities. d) determining and implementing of preventive action needed. e) recording of the results of preventive action taken. f) reviewing the effectiveness of the preventive action taken.		
4.12	**Continual improvement**		
	The laboratory shall continually improve the effectiveness of the quality management system through the use of management reviews, corrective actions and preventive actions with its intention, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action plans for improvement shall be: - developed, - documented, - implemented, as appropriate? The effectiveness of the actions taken shall determine through a focused review or audit of the area concerned. The laboratory management shall ensure the following: - the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care? - where there are opportunities for improvement, are these issues addressed regardless of where they occur? - improvement plans and related goals shall be communicated to staff		
4.13	**Control of records**		
	The laboratory/facility shall establish and maintain a documented procedures for:		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	- identification - collection - indexing - access - storage - maintenance - amendment - safe disposal of quality and technical records? Records shall be created concurrently with performance of each activity that affects the quality of the examination. (Records can of any form/ type of medium as long as they are readily accessible, protected from unauthorized alterations and in accordance to local, national, or regional legal requirements.) The date and, where relevant, time of amendments to records captured along with the identity of personnel making the amendments. The laboratory shall define retention time of all records pertaining to the quality management system, including pre-examination, examination and post-examination processes. The retention time may vary, however, reported results defined to allow records to be retrievable for as long as medically relevant or as required by regulation. The facilities shall have suitable environment for storage of records to: - prevent damage or deterioration? - prevent loss? - prevent unauthorized access?		
	Records shall include, at least, the following: a) supplier selection and performance, and changes to the approved supplier list b) staff qualification, training and competency records c) request forms (including the patient chart or medical record only if used as the request form), d) Records of receipt of samples in the		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	laboratory, e.g. accession records e) Information on reagents and materials used for examination (lot documentation, certificates of supplies, package inserts) f) laboratory work-books or work sheets, g) instrument printouts and retained date and information h) examination results and reports, i) instrument maintenance records including internal and external calibration records j) calibration functions and conversion factors k) quality control records, l) incident records and action taken, m) accident records and action taken n) risk management records o) nonconformities identified and immediate or corrective action taken p) preventive action taken q) complaints and action taken r) records of internal and external audits s) interlaboratory comparisons of examination results t) records of quality improvement activities u) minutes of meetings that record decisions made about the laboratory's quality management system v) records of management reviews (All these records shall be available for laboratory management review)		
4.14	**Evaluation of audits**		
4.14.1 General	The evaluation and internal audit processes shall be planned and implemented to: a) demonstrate that laboratory's processes are conducted in a manner that meets the needs and requirements of users? (e.g users' feedback) b) ensure conformity to the quality management system c) continually improve the effectiveness of the quality management system Are the results of evaluation and		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	improvement activities included as part of management review?		
4.14.2 Periodic review of requests, and suitability of procedures and sample requirements	Authorized personnel shall periodically review the examinations provided by the laboratory to ensure they are clinically appropriate for the requests received. The laboratory shall periodically review its: - sample volume - collection device - preservative requirements for blood, urine, other body fluids, tissue and other sample types to ensure neither insufficient nor excessive amounts of samples are collected and samples are properly collected to preserve the measurand?		
4.14.3 Assessment of users feedback	The laboratory shall seek user feedback on the laboratory's performance and whether the service has met the needs and requirements of users. Records of such information and action taken shall be retained and reviewed.		
4.14.4 Staff suggestion	The laboratory shall encourage staff make suggestions for the improvement of any aspect of the laboratory services. Suggestions shall be - evaluated - implemented, as appropriate - feedback provided to the staff Records of suggestions and action taken shall maintained		
4.14.5 Internal Audit	The laboratory shall conduct internal audits at planned intervals and covers all activities in the quality management system (including pre-examination, examination and post-examination procedures) to determine: - conformance to the requirements stated in ISO 15189, relevant PAB documents and internal laboratory procedures - implementation, effectiveness and maintenance of the quality management system. - Are such audits carried out by		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	personnel trained to assess the performance of managerial and technical processes of the quality management system? How does the laboratory ensure objectivity and impartiality of the audit process? Are selected auditors, wherever resources permit, independent of the activity to be audited? Does the audit programme include: - the status and importance of the processes, the technical and management areas to be audited - the results of previous audits The procedures for internal audit shall define the criteria, scope, frequency, methodology, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining records. The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records. The personnel responsible for the area being audited shall ensure that appropriate action is promptly undertaken when non conformities are identified. Corrective actions shall be taken without delay to eliminate the causes of the detected non conformities.		
4.14.6 Risk management	The laboratory shall evaluate the impact of work processes and potential failures on examination results that affect patient safety. The laboratory shall modify processes to reduce or eliminate the identified risks and document decisions and action taken.		
4.14.7 Quality indicators	The laboratory shall establish quality indicators to monitor and evaluate the performance of the critical aspects of		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	pre-examination, examination and post-examination procedures. The process of monitoring the quality indicators shall be planned which include: - objectives - methodology - interpretation - limits - action plan - duration of measurement Are the indicators periodically reviewed? Are turnaround times for each of its examinations that reflect clinical needs established? Does the laboratory periodically evaluate its performance to meet the established turnaround time? (The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care)		
4.14.8 Review of external organization	When external organisations indicate the laboratory has non conformities or potential non conformities, the laboratory shall take appropriate immediate actions and as appropriate corrective action or preventive action to ensure continue compliance with ISO 15189:2012. The laboratory shall retain records of reviews by external organizations and of the corrective actions and preventive actions taken.		
4.15	**Management Review**		
4.15.1 General	The laboratory management shall review the quality management system at planned intervals to ensure continuing suitability, adequacy and effectiveness in support of patient care		
4.15.2 Review input	The input to management review shall include information from the results of evaluation of at least the following: a) periodic review of requests, suitability of procedures and sample requirements		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	b) assessment of user feedback c) staff suggestions d) the outcome of recent internal audits? e) risk management f) use of quality indicators g) reviews by external organizations h) interlaboratory comparison programmes (PT/ EQA) performance i) monitoring and resolution of complaints j) supplier evaluation k) identification and control of non-conformities l) results of continual improvement (including current status of corrective actions and preventive actions m) Follow-up actions from previous management reviews n) Changes in volume and scope of work, personnel and premises that could affect the quality management system o) Recommendation for improvement, including technical requirements		
4.15.3 Review activities	The management review shall: - analyse of the causes of nonconformities, trends and patterns that indicate process problem - include assessment of opportunities for improvement and the need for changes to the quality management system, including its quality policy and quality objectives. - objectively evaluate the quality and appropriateness of the laboratory's contribution to patient care, to the extent possible.		
4.15.4 Review output	The laboratory shall document the decisions made and action taken during management review related to: - Improvement of the effectiveness of the quality management system and its processes - Improvement of services to users - Resource needs The findings and actions arising from the management review shall be recorded and communicated to		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	the laboratory staff. The actions from management reviews shall be carried out within an appropriate and agreed timescale.		
5	**Technical Requirements**		
5.1.1 General	The laboratory/facility management shall have documented procedures for personnel management. The management shall maintain records for all personnel to indicate compliance with requirements.		
5.1.2 Personnel qualification	The laboratory management shall document document personnel qualification for each position. - The qualification shall reflect appropriate education, training, experience and demonstrated skills needed, and be appropriate for the tasks performed. - The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.		
5.1.3 Job description	The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.		
5.1.4 Personnel introduction to the organizational environment	The laboratory shall have programme to introduce new staff to the organisation, 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	The laboratory shall provide training for all personnel in 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 contamination of the effects of adverse incidents e) Ethics f) Confidentiality of patient information		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	Personnel undergoing training shall be supervised. The effectiveness of the training programme shall be periodically reviewed.		
5.1.6 Competence assessment	The laboratory shall assess the competence of each trained person to perform assigned managerial or technical tasks according to established criteria. Reassessment shall take place at regular interval. Retraining shall be provided, when necessary. Competency of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment: a) direct observation of routine work processes and procedures, including all applicable safety practices b) direct observation of equipment maintenance and function checks c) monitoring the recording and reporting of examination results d) review of work records e) assessment of problem solving skills f) examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples)		
5.1.7 Review of staff performance	Does the laboratory consider the needs of the laboratory and of the individual during the reviews of staff performance in order to maintain or improve the quality of service and encourage productive working relationships?		
5.1.8 Continuing education and professional development	Continuing education program shall be available for personnel participating in managerial and technical processes. Personnel shall take part in continuing education. Effectiveness of the continuing education programme shall be		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	periodically reviewed. Personnel shall take part in regular professional development or other professional liaison activities.		
5.1.9 Personnel records	The laboratory shall maintain the following records: a) educational and professional qualifications b) copy of certification or license, when applicable, c) references from previous employment, d) job descriptions, e) orientation records f) training in current job tasks g) competency assessments h) records of continuing education and achievements, i) reviews of staff performance j) records of accidents and exposure to occupational hazards k) records of immunization status (when relevant to assigned duties)		
5.2	**Accommodation and environmental conditions**		
5.2.1 General	The laboratory workplace shall be adequate to carry out quality work, quality control procedures, and safety of personnel and patient care services. Is there evidence that the laboratory director determined the adequacy of the laboratory's space? The laboratory resources shall be maintained in a functional and reliable condition Are provisions made for appropriate primary sample collection and examinations sites, which are different from permanent laboratory facility?		
5.2.2 Laboratory and office facilities	The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met: a) access to laboratory/facility controlled; b) medical information, patient samples, and laboratory resources safeguarded from unauthorized access;		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	c) laboratory/facility for examination allow correct performance of examinations? Example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions. d) communication systems within the laboratory appropriate to the size and complexity of the facility to allow effective transfer of information; e) safety facilities and devices provided and functioning regularly verified.		
5.2.3 Storage facilities	Storage space and conditions shall be provided to ensure continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results. Are clinical samples and materials stored in a manner to prevent cross contaminations? Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials and as specified by applicable requirements?		
5.2.4 Staff facilities	The laboratory shall have adequate access to washrooms, supply of drinking water and facilities for storage of personal protective equipment and clothing.		
5.2.5 Patient sample collection facilities	Do the patient sample collection facilities have separate reception/ waiting and collection areas? Are considerations made for accommodating patient disabilities, comfort, and privacy when primary sample collection facilities are provided? Is the environment in which the primary sample collection procedures are performed suitable so that it does not invalidate the results or adversely affect the quality of the examination? Are appropriate first aid materials		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	available and maintained for both patient and staff at sample collection facilities?		
5.2.6 Facility maintenance and environmental conditions	The laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained. The laboratory/facility shall monitor, control and record environment conditions as required by relevant specification or where they may influence the quality of sample, results and/or the health of staff. (Due attention shall be paid to light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels, and workflow logistics, as appropriate to the activities concerned so as not to invalidate the results or adversely affect the required quality of examination) There shall be effective separation between neighbouring areas where incompatible activities are performed. Appropriate measures shall be taken to prevent cross-contamination where examination procedures pose a hazard or where the work may be affected or influenced by not being separated (e.g. nucleic acid amplifications). The laboratory shall provide a quiet and uninterrupted work environment where it is needed.		
5.3	**Laboratory Equipment**		
	Note: Instruments, reference materials, consumables, reagents, and analytical systems are included as laboratory equipment, as applicable.		
5.3.1.1 General	Does the laboratory has documented procedure for selection, purchasing and management of equipment? Is the laboratory/facility furnished with all the items of equipment required for		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	its services (including primary sample collection, sample preparation and processing, examination and storage)? Where the laboratory/facility needs to use equipment outside its permanent control, does the laboratory management ensure that the requirements of ISO 15189 are met? The laboratory shall replace equipment as needed to ensure its quality of examination results.		
5.3.1.2 Equipment acceptance testing	The equipment shall be verified upon installation and before use to shown its capability to achieve the necessary performance and compliance with requirements relevant to any examinations concerned. Each item of equipment shall be uniquely labelled, marked or otherwise identified.		
5.3.1.3 Equipment instructions use	The equipment shall be operated by trained and authorized personnel at all times. Are current instructions, issued by manufacturer, on the use, safety and maintenance of equipment, including relevant manuals and directions for use, readily available? The laboratory shall have procedures for safe handling, transport, storage and use of equipment to prevent its contamination and deterioration.		
5.3.1.4 Equipment calibration and metrological traceability	The laboratory shall have documented procedure for the calibration of equipment that directly or indirectly affects examination results The procedure includes: a) reference to conditions of use and manufacturer's instructions; b) recording of the metrological traceability of the calibration standard and traceable calibration of the item of equipment; c) verification of the required measurement accuracy and function of the measuring system at defined intervals;		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	d) recording of the calibration status and date of recalibration; e) ensuring that calibration factors are correctly updated after calibration; f) safeguards to prevent adjustments or tampering that might invalidate examination results. Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available. Where this is not possible or relevant, does the laboratory use other means for providing confidence in the results such as (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	Is there documented programme of preventive maintenance which, at a minimum, following the recommendation from the manufacturer? Are equipment maintained in safe working condition and in working order? Are procedures in place to ensure examination of electrical safety, emergency stop devices, and safe handling and disposal of chemical, radioactive and biological materials by authorized persons? Manufacturer's specifications or instructions or both shall be used, as appropriate. Is defective equipment taken out of service, clearly labeled and not used until it has been repaired and shown by verification to meet specified acceptance criteria? Is the effect of this defect on previous examinations examined and institute		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	immediate action or corrective action? Are reasonable measures taken to decontaminate equipment prior to service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment? When equipment goes outside the direct control of the laboratory/facility, does the laboratory ensure its performance is verified before the equipment is returned to service?		
5.3.1.6 Equipment adverse incident reporting	Are adverse incidents and accidents that can be attributed to specific equipment investigated and reported to manufacturer and appropriate authorities, as required?		
5.3.1.7 Equipment records	Are the following records of each item of equipment contributing to the performance of examinations maintained: a) identity of the equipment, b) manufacturer's name, model, and serial number or other unique identification, c) manufacturer's/ supplier's contact information, d) date received and date of entered 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 it 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. Does the performance records referred in j) include copies of		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	reports/certificates of all calibrations and/or verifications including dates, time and results, adjustments, acceptance criteria and due date of next calibration and/or verification, to fulfil part or this entire requirement? Are the records maintained and readily available for the life span of the equipment or for any time period required by national, regional and local regulations?		
5.3.2	**Reagents and consumables**		
5.3.2.1 General	Does the laboratory has documented procedure for reception, storage, acceptance testing and inventory management of reagents and consumables?		
5.3.2.2 Reagent and consumables-Reception and storage	Where the laboratory is not the receiving facility, does the laboratory verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration? Is the storage of received reagents and consumables in accordance to manufacturer's specification?		
5.3.2.3 Reagent and consumables-Acceptance testing	Is new formulation of examination kits with changes in reagents or procedure, or new lot or shipment verified 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 Reagent and consumables-Inventory management	Does the laboratory establish an inventory control system for reagents and consumables? Does the inventory control system segregate uninspected and unacceptable reagents and consumables for those that have been accepted for use?		
5.3.2.5 Reagent and consumables-Instruction for	Are instructions for use of reagents and consumables, including those provided by the manufacturers, readily available?		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
use			
5.3.2.6 Reagent and consumables-Adverse incident reporting	Are adverse incidents and accidents that can be attributed to specific reagents or consumables investigated and reported to manufacturer and appropriate authorities, as required?		
5.3.2.7 Reagent and consumables-Records	Are the following records (but not limited to) of each reagents and consumables contributing to the performance of examinations maintained: a) Identity of the reagent or consumable b) manufacturer's name, and batch code/ lot number, c) manufacturer's/ supplier's contact information, d) date received, expiry date, and date of entering into service and, where applicable, the date the material was taken out of service, e) condition when received (e.g. accepted or damaged), f) manufacturer's instructions, g) records that confirmed the reagent's or consumable's initial acceptability for use, h) performance records that confirm the reagent's or consumable's ongoing acceptance of use. Where the laboratory uses reagents prepared or completed in-house, does the records also include reference to the persons or persons undertaking their preparation and the date of preparation?		
5.4	**Pre-examination Process**		
5.4.1 General	Does the laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations?		
5.4.2 Information for patients and users	Are the following information available for patients and users of the laboratory services: a) 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) examinations offered by the		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	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) Instruction for completion of request form f) Instruction for preparation of the patient g) Instruction for patient-collected samples h) Instruction for transportation of samples, including any special handling needs, i) any requirement 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 examination or the interpretation of the results l) availability of clinical advice on ordering of examinations and on interpretation of examination results, m) the laboratory's policy on protection of personal information, n) the laboratory's complaint procedure Is information that includes an explanation of the clinical procedure to be performed available for patients and users to enable informed consent? Are 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 from information	The request form or electronic equivalent shall allow space for the inclusion of, but not limited to:		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	a) patient identification, gender, date of birth, location/contact details of the patient and unique identification of the patient; b) name or other unique identifier of physician or other person legally authorised to order examinations or use medical information together with the destination for the report. If the requesting clinician's address provided as part of the request form information; c) type of primary sample and the anatomic site of origin, where relevant; 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; and g) date and time of receipt of samples by the laboratory. The laboratory shall have documented procedure to handle verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time. The laboratory shall be willing to cooperate with users or their representatives in clarifying the user's request.		
5.4.4	**Primary sample collection and handling**		
5.4.4.1 General	The laboratory shall have documented procedures for proper collection and handling of primary samples. The procedure(s) shall be available to those responsible for primary sample collection regardless if the collectors are laboratory staff. Where the user requires deviations, exclusions from or additions to, the documented collection procedure, are the deviations recorded and included in all documents containing		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	examination results and communicated to the appropriate personnel? In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures; provided they are in patient's best interest.		
5.4.4.2 Instructions for pre-collection activities	Does the laboratory have instructions to include the following: a) completion of request form or electronic requests; b) preparation of the patient (e.g. instructions to caregivers and phlebotomists)? c) type and amount of primary sample to be collected (e.g., phlebotomy, skin puncture, blood, urine and other body fluids) with descriptions of the primary sample containers and any necessary additives? d) special timing of collection, if required? e) clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs)?		
5.4.4.3 Instructions for collection activities	Does the instructions for collection activities include the following: a) positive identification in detail of the patient from whom a primary sample is collected? b) verification that patient meets pre-examination requirements [e.g. fasting status, medication status, 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) where primary sample is collected as part of clinical practice, determination and communication to appropriate clinical staff on the information and instructions for primary sample containers, any necessary additives and sample transport conditions?		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	e) instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected. f) identification of the collector and collection date, and when needed, recording of the collection time g) instructions for proper storage conditions before collected samples are delivered to the laboratory h) safe disposal of materials used in the collection allowed additional examinations?		
5.4.5 Sample transportation	Do the laboratory's instructions for post-collection activities include packaging of samples for transportation? Does the laboratory monitor how the samples are transported to the laboratory for the following: a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned? b) within a temperature range specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples? c) in a manner that ensures the integrity of the samples and safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements?		
5.4.6 Sample reception	The laboratory's procedure for sample reception shall ensure that the following conditions are met: a) Samples unequivocally traceable, by request and labelling, to an identified patient or site. b) Laboratory-developed and documented criteria for acceptance or rejection of samples applied. c) Where there is uncertainty in the identification of the primary sample, or sample instability due		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	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, does the final report indicate the nature of the problem, and where applicable, that caution is required when interpreting the result? d) All sample received are recorded in an accession book, worksheet, computer or other comparable system and include: - date and time of receipt and/ or registration of samples - identity of person receiving the sample, whenever possible e) Authorised personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination. f) Where relevant, are there instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent? Do the instructions include: - details of special handling of the request form and the primary sample? - mechanism of transfer of the primary sample to be examination area of the laboratory? - any rapid processing mode to be used? - any special reporting criteria to be followed? All portions of the primary sample shall be unequivocally traceable to the original primary sample.		
5.4.7 Pre-examination handling, preparation and storage	The laboratory shall have procedures and appropriate facilities to : - secure patient samples - prevent deterioration, loss or damage during pre-examination activities, and during handling, preparation and storage		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	The laboratory procedure shall include time limits for request of additional examinations or further examinations on the same primary sample.		
5.5	**Examination Process**		
5.5.1	**Selection, verification and validation of examination procedure**		
5.5.1.1 General	The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded. Does the specified requirements (performance specifications) for each examination procedure relate to the intended use of that examination.		
5.5.1.2 Verification of examination procedures	Validated examination procedures used without modifications shall be subject to independent verification by the laboratory before being introduced in routine use. The laboratory shall obtain information from the manufacturer/ method developer for confirming the performance characteristics of the procedure. Does the independent verification by the laboratory, through obtaining of objective evidence, confirm that the performance claims for the examination procedure have been met and relevant to the intended use? Is there documented verification procedure? Is the result obtained recorded? Are the verification results reviewed by appropriate authority and is the review documented?		
5.5.1.3 Validation of examination procedures	The laboratory shall validate the examination procedures derived from: a) non-standard methods, b) laboratory designed or developed methods c) standard methods used outside their intended scope		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	d) validated methods subsequently modified The validations shall be as extensive as necessary and confirm, through provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled. Is there documented validation procedure? Is the result obtained recorded? Are the validation results reviewed by appropriate authority and is the review documented? When changes are made to a validated examination procedure, are the impact of the changes documented and, when appropriate, a new validation shall be carried out.		
5.5.1.4 Measurement uncertainty of measured quantity values	The laboratory shall determine measurement uncertainty for each measurement procedure used to report measured quantity values on patient's samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty. The laboratory shall consider measurement uncertainty when interpreting measured quantity values. Upon request, does the laboratory make its estimation of measurement uncertainty available to laboratory users? Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
5.5.2 Biological reference intervals or clinical decision values	The laboratory shall define the biological reference intervals or clinical decision values, document the basis for reference intervals or decision values and communicate this information to users. Are appropriate changes made, when a particular biological reference interval or decision value is no longer relevant for the population served? Are the changes communicated to the users? When the laboratory changes an examination procedure or pre-examination procedure, are the associated reference intervals and clinical decision values reviewed?		
5.5.3 Documentation of examination procedures	Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory. It shall be available in appropriate locations. Any condensed document format (e.g. card files or similar used systems) shall correspond to the documented procedure. Are all documents associated with the performance of examinations, including procedures, summary documents, condensed documents format and product instructions for use, subjected to document control? In addition to document control identifiers, does documentation include, when applicable, the following: a) purpose of the examination b) principle and method of the procedure used for examinations c) performance characteristics d) type of sample (e.g. plasma, serum, urine) e) patient preparation f) type of container and additive		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	g) required equipment and reagents h) environmental and safety controls i) calibration procedures (metrological traceability) j) procedural steps k) quality control procedures l) interferences (e.g., lipaemia, haemolysis, bilirubinemia) and cross reaction m) principle of procedure for calculating results, including, where relevant, measurement uncertainty of measured quantity values n) biological reference intervals or clinical decision values o) reportable interval of examination results p) instructions for determining quantitative results when results is not within the measurement interval q) alert/critical values, where appropriate r) laboratory clinical interpretation s) potential sources of variation t) references If the laboratory intends to change to an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure.		
5.6	**Ensuring quality of examination results**		
5.6.1 General	The laboratory shall ensure that quality of examinations by performing them under defined conditions. Appropriate pre- and post- examination processes shall be implemented. The laboratory shall not fabricate any results.		
5.6.2	**Quality control**		
5.6.2.1 General	The laboratory/facility shall design internal quality control procedures that verify the attainment of the intended quality of results.		
5.6.2.2 Quality control materials	The laboratory shall use quality control materials that react to the examination system in a manner as close as possible to patient samples.		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	The quality control materials shall be 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	The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall evaluate the results from patient samples that were examined after the last successful quality control event. The quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. The preventive actions taken shall be recorded when such trends are noted.		
5.6.3	**Interlaboratory Comparison**		
5.6.3.1 Participation	The laboratory shall participate in inter-laboratory comparison programme(s) appropriate to the examination and interpretations of examination results. The laboratory shall: - monitor the results of the interlaboratory comparison programme(s) - participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled. The laboratory shall establish a documented procedure for interlaboratory comparison participation that include: - defined responsibilities and instructions for participation?		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	- performance criteria that differs from the criteria used in the interlaboratory comparison programme? Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process including pre- and post-examination procedures, where possible.		
5.6.3.2 Alternative approaches	Whenever interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results. Wherever possible, this mechanism shall utilise appropriate materials. Examples of such materials may include: - certified reference materials - samples previously examined; - material from cell or tissue repositories; - exchange of samples with other laboratories - control materials that are tested daily in interlaboratory comparison programs.		
5.6.3.3 Analysis of interlaboratory comparison samples	The laboratory shall integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. The laboratory shall ensure that: - interlaboratory comparison samples are examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples. - no communication with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data.		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	- interlaboratory comparison samples are not sent for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.		
5.6.3.4 Evaluation of laboratory performance	The performance in interlaboratory comparisons shall be reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled, does the laboratory: - involved the staff in the implementation and recording of corrective actions? - monitored the effectiveness of the corrective action? - evaluated the returned results for trends that indicate potential nonconformities and take appropriate preventive action?		
5.6.4 Comparability of examination results	There shall be defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these. (In the particular case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable). The laboratory shall notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand and when examination methods are changed. The laboratory shall document, record and as appropriate, expeditiously act upon results from the above comparisons.		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	Problems or deficiencies identified shall be acted upon and records of actions retained.		
5.7	**Post-examination process**		
5.7.1 Review of results	The laboratory shall have procedure to ensure that authorised personnel systematically review the results of examinations and evaluate them in conformity of the clinical information available regarding the patient and authorise the release of the results. Review criteria shall be established, approved and documented for procedure that involves automatic selection and reporting.		
5.7.2 Storage, retention and disposal of clinical samples	The laboratory shall have a documented procedure for: - identification - collection - retention - indexing - access - storage - maintenance - safe disposal of clinical samples The laboratory shall define the retention time of clinical samples. Retention time shall be defined by: - nature of sample - the examination - any applicable requirements/ regulation Safe disposal of samples shall be carried out in accordance with local regulations or recommendations for waste management.		
5.8	**Reporting of Results**		
5.8.1 General	The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. The laboratory shall define the format and medium of the report (electronic or paper) and the manner in which it is to be communicated from the laboratory. The laboratory shall have procedures in place to ensure correctness of		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	transcription of laboratory results. The reports shall have the necessary information for the interpretation of the examination results. The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.		
5.8.2 Report attributes	The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet 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 and d) interpretative comments on results, where applicable, which may include the verification of the interpretation or automatically selected and reported results in the final report are effectively communicated and meet the users' needs.		
5.8.3 Report content	The report should include but not limited to: a) clear unambiguous identification of the examination including, where appropriate, the examination procedure; b) the identification of the laboratory/facility that issued the report; c) Identification of all examinations that have been performed by a referral laboratory; d) identification and location of the patient 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 where available and relevant to patient care; g) source and system (or primary		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	sample type), h) measurement procedure, where appropriate; i) results of the examination including SI units or 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. (Under some circumstances, it may be appropriate to distribute lists or tables of biological reference intervals to all users and sites where reports are received). k) interpretations of results, where appropriate; l) other comments such as cautionary or explanatory notes (e.g., quality or adequacy of 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 authorising the release of the report (if not contained in the report, readily available when needed); o) date and time of release of report, if not on the report, shall be readily accessible when needed; p) page number to total number of pages (e.g. “Page 1 of 5”)		
5.9	**Release of Results**		
5.9.1 General	The laboratory/facility shall have documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure the following conditions are met:		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	a) When quality of the primary sample received is unsuitable for examination, or could have compromised the result, it is indicated in the report. b) When examination results fall within established "alert" or "critical" intervals, - immediate notification of physician (or other clinical personnel responsible for patient care) including referral laboratories' results. - records of actions taken are maintained including ✓ date and time ✓ responsible laboratory staff member ✓ person notified ✓ examination results conveyed ✓ any difficulty encountered in meeting this requirement c) results are legible, without mistakes in transcription, and reported to persons authorised 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. Reports provided orally shall be followed by a written report. There shall be records of all oral results provided.		
5.9.2 Automated selection and reporting of results	If the laboratory implements a system for automated selection and reporting of results, it shall establish documented procedure to ensure that : a) criteria for automated selection and reporting are defined, approved, readily available and understood by the staff? b) criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning? c) a process is in place to indicate the presence of sample interferences		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	(e.g. haemolysis, iceterus, lipaemia) that may alter the results of the examination; d) a process to incorporate analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate; e) results selected for automated reporting are identifiable at the time of review before release and that date and time of selection are included; f) a process for rapid suspension of automated selection and reporting is in place.		
5.9.3 Revised reports	There shall be written instructions regarding the revision of reports. So that: a) Revised report is clearly identified as revision and includes reference to the date and patient's identity in the original report. b) user regarding is made aware of the revision; c) the revised record shows the time and date of change and the name of person responsible for the change; d) the original report entries in the record when revisions are made. Results used for clinical decision-making revised shall be retained in subsequent cumulative reports and clearly identified as having been revised. When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.		
5.10	Laboratory Information Management		
5.10.1 General	The laboratory/facility shall have access to the data and information needed to provide a service which meets the needs and requirements of the users. The laboratory shall have documented procedure to ensure confidentiality of patient information is maintained at all times.		
5.10.2	The laboratory shall ensure that the		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
Authorities and responsibilities	authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care. The laboratory shall define 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 to release examination results and reports.		
5.10.3 Information system management	The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be: a) validated by supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorised, documented and verified before implementation? b) documented to include day to day functioning of the system and be readily available to authorised users? c) protected from unauthorised access d) safeguarded against tampering or loss e) operated in an environment that complies with supplier specifications or provides conditions which safeguard the accuracy of manual recording and transcription; f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions, g) in compliance with national or		

Clause	Requirements of Accreditation/ Description	Reference to Laboratory Document (To be completed by the laboratory)	PAB Remarks
	international requirements regarding data protection. The laboratory shall verify 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. clinics' computer systems, fax machines, e-mail, personal web devices or websites.) When new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory. The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information system that affects the laboratory's ability to provide service. When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, the laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.		

PAB Supplementary Requirements	
LA/SR08 (Supplementary Requirements for the Accreditation of Medical Testing Laboratory)	

PAB Supplementary Requirements	
LA/SR 09 (Supplementary Requirements for Participation to Proficiency Testing)	
LA/SR 10 (Supplementary Requirements on Traceability of Measurement)	
LA/SR 11 (Supplementary Requirements on the Use of PAB Laboratory and Inspection Body Accreditation Symbol)	