KENYA ACCREDITATION SERVICE
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ISO 15189 CHECKLISTS
MEDICAL LABORATORY ACCREDITATION SCHEME

Type of assessment	Preliminary/initial/renewal/surveillance/non-routine/verification	
Laboratory		
Address		
Tel/fax		
Name of persons in charge		
Field/discipline		
Dates of visit		
Technical assessor(s)		
Staff officer		
	Name……. …… **Signature**……	**Date**……

Clause no.	Description	Yes	No	N/A	Remarks
4.	**Management requirements**				
4.1	**Organization** Is the laboratory or organization i) Legally identifiable? ii) Certificate of registration available?				
4.1.2	Does the medical laboratory services, including appropriate interpretation and advisory services meet: i) The needs of the patients and all personnel responsible for patient care?				
4.1.3	Does the laboratory management system cover and meet the requirement of the standard for the work carried out in i) Permanent facilities? ii) Sites away from its permanent facilities iii) Associated temporary facilities? iv) Mobile facilities?				
4.1.4	If the laboratory is part of an organization performing activities other than testing: i) Are responsibilities of key personnel defined in order to identify potential conflict of interest?				
4.1.5	Is the management responsible for the design, implementation, maintenance and improvement of the quality system with regards to the following; - Management support to all personnel by providing the appropriate authority and resources to carry out their duties? - Have arrangements to ensure that its management and personnel are free from;				

	i) Any undue internal and external including but not limited to financial pressure that may adversely affect the quality of work. - Policies and procedures to ensure confidentiality of information? - Have policies and procedures to prevent involvement in any activities that would diminish confidence in its competence, judgment or operational integrity? - Define the organization and management structure of the laboratory: i) Its place in any parent organization? ii) Relationship between quality management, technical operations and supportive staff? iii) Its relationships to other associated organization (if any) Specify the: i) Responsibility? ii) Authority? iii) Interrelationships? iv) Of all personnel Provide adequate supervision of all testing staff by competent persons familiar with; i) Methods and procedures? ii) Purpose of each test and/ or calibration? iii) Assessment of the test results of the relevant examination procedures? iv) Is technical management available? Is a quality manager appointed?				

	i) With defined responsibility and authority? ii) Direct access to the highest level of management? Appoint deputies for key managerial personnel? *Note: (In smaller laboratories, staff may have more than one function and it may be impractical to appoint deputies for every function.)*				
4.2 4.2.1	**Quality Management System** Are policies and procedures including the requirements of the methods to be used i) Defined? ii) Documented? iii) Implemented iv) Understood?				
4.2.2	Does the quality system includes, but not limited to? i) Internal quality control? ii) Participation in inter-laboratory comparisons? iii) External proficiency programmes?				
4.2.3	Is the quality policy statement containing: i) Defined under the authority of the laboratory director? ii) Documented in the quality manual? iii) Concise & readily available to all personnel? iv) And containing the following:				

	a) The scope of service the laboratory intends to provide? b) The management's statement of the laboratory's standard of service? c) Objectives of the quality system? d) A requirement that all staff within the laboratory familiarize themselves with the quality documentation and implement the policies and procedure in their work? e) Is the laboratory committed to good professional practice, the quality of its examination, and compliance with the quality management system? f) Laboratory management's commitment to compliance with ISO 15189?				
4.2.4	Does the laboratory; i) Outline the structure of the documentation used in the quality manual? ii) Define the roles and responsibilities of the technical management and quality manager? iii) Are personnel instructed on the use and application of the quality manual references, supporting procedures including technical procedures?				
4.2.5	a) Does the laboratory establish and implement programme that regularly monitors and demonstrates proper calibration and function of; i) Instruments? ii) Reagents? iii) Analytical systems?				

	b) Are documentation of programme for preventive maintenance and calibration available? c) Does the calibration interval follow manufacturer's recommendations?				
4.3	**Document control**				
4.3.1	a).Has the laboratory established and maintained procedures to control all documents that form part of its quality system? b). Is a copy of these controlled documents i. Archived for later reference? ii. Retention period defined? *Note:* *(Document refers to any information including policy statements, textbooks, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, documents of external origin such as regulations, standards, and examination procedures. These may be maintained on any appropriate medium, which may or may not include paper)*				
4.3.2	Are procedures adopted to ensure that: - Documents issued to personnel are reviewed and approved for use prior to issue? - A master list or an equivalent document control procedure is available to identify the current revision status and distribution of				

4.3.3	documents? - Current authorized versions of appropriate documents are available at all appropriate locations? - Documents are periodically reviewed, revised where necessary and approved by authorized personnel? - Invalid or obsolete documents are promptly removed from all points use? - Retained obsolete documents are appropriately identified to prevent unintended use? - If Laboratory's documentation control system allows for the amendment of documentations by hand pending the re-issues of the documents: i) Are the procedures for such amendments defined? ii) Are the authorities for such amendments defined? iii) Are these amendments clearly? iv) Marked, initial and dated? Changes in documents maintained on computerized systems are made and controlled? Is the quality system documents generate by the laboratory uniquely identified?				

	And do such identification include: i) Title? ii) Date of issue? iii) Revision identification/revision number? iv) Page numbering? /the total number of pages or a mark to signify the end of the document? v) The issuing authority (ies)? vi) Source identification?				
4.4 4.4.1.	**Review of contracts** Procedures established and maintained for review of contracts? Do policies and procedures for these reviews ensure that: - The requirements, including the methods to be used are: i) Defined? ii) Documented? iii) Understood? - Does capability and resources meet the following requirements? i) Physical? ii) Personnel? iii) Information resources?				
4.4.2	Appropriate methods selected and capable of meeting the contract requirements and clinical needs?				
4.4.3	Are records of these reviews and any significant changes maintained?				
4.4.4	Does the review cover any work referred by the laboratory?				
4.4.5	Is the client (e.g. Clinicians, health care bodies, health insurance companies, pharmaceutical				

	companies) informed of any deviation from the contracted work? If the contract needs to be amended after the work commerce: i) Is the same contract review process repeated? ii) Are any amendments communicated to all affected parties?				
4.5 4.5.1	**Examination by referral laboratories** Are documented procedures available to evaluate and select i) Referral laboratories? ii) Consultants who provide second opinions for histopathology, cytology, and related* disciplines?				
4.5.2	When referral laboratories or consultants are used, i) Are the clients consulted, where appropriate? ii) Is laboratory management responsible for selecting and monitoring the quality of referral laboratories and consultants? iii) Does the laboratory ensure that the referral laboratory or consultant is competent to perform the requested examinations? Are arrangements with referral laboratories and consults periodically reviewed to ensure that:				
4.5.3	The requirements, including the pre-examination and post- examination procedures are adequately i) Defined? ii) Documented? iii) Understood? The referral laboratory's capability to meet the requirements and there are no conflict of				

	interest? Selection of examination procedures is appropriate for the intended use? *Note: records of such reviews shall be maintained to national or regional/ International requirements)*				
4.5.4	The responsibilities for the interpretation of examination results are clearly defined? Does the laboratory maintain i) A register of all referral laboratories? ii) A register of all samples that have been referred to another lab? • Are names and address of referral laboratory given to the user? • Is duplicate laboratory report retained in both the patient record and permanent file of the lab?				
4.5.5	Is the referring laboratory, and not the **referral laboratory,** responsible to ensure that examination results and findings are provided to clinician making the request? Does the report have all the essential elements of the results if it is reported by the referral laboratory, without alterations that could affect any clinical interpretations? *Note: (The referring laboratory director may elect to provide additional interpretative remarks to those, if any, of the referral laboratory, in the context of the patient and the local medical environment. The author of such added remarks should be clearly identified)*				
4.6 4.6.1	**External services and supplies** i) Are policy and procedure(s) available for: - Selection? - Purchasing of services, equipment, and				

	consumable supplies it uses? ii) That affects the quality of the tests and/or calibrations. iii) Do the purchased items consistently meet the laboratory's quality requirements?				
4.6.2	iv) Do procedures exists for the: - Inspections? - Acceptance/rejection? - Storage?				
4.6.3	Are purchased equipment/ supplies/ reagents/ consumable materials inspected for compliance with standard specifications before use? *Note :(This may be accomplished by examining quality control samples and verifying that supplier's conformance to its quality system may also be used for verification.)*				
4.6.4	i) Is there an inventory control system for all supplies? ii) Are records maintained for - External services? - Supplies Purchased products established and maintain for a period of time?				
4.7	(iii) Are these quality records reviewed during the management review? Does the laboratory evaluate: - Suppliers of critical consumables? - Supplies and services which affects the quality of testing? - Maintain approved list and records of evaluation?				

4.8 **4.9** 4.9.1	**Advisory services** Are laboratories' professional staff approved to provide advice on - Choice of examination? - Use of services? - Repeat frequency? - Required sample? - Interpretation of test results, where appropriate? *Note: (There should be regular documented meetings of professional staff with the clinical staff regarding the use of laboratory services and for the purpose of consultation on scientific matters. The professional staff should participate in clinical rounds, enabling advice on effectiveness in general as well as in individual cases.)* **Resolution of complaints** i) Are policy and procedures available for resolution of compliants or other feedback from clinicians, patients or other parties? ii) Are records of compliants, investigations and corrective actions taken maintained by the laboratory? *Note: (Laboratories are encouraged to obtain feedback from their users, preferably in a systematic way (e.g. surveys). Both positive and negative feedback should be included).* **Identification and control of non-conformities** Ensure policy and procedures are implemented when the results do not conform to its own procedures or the agreed requirements of the				

	requested tests of the clinician? These shall ensure that:				
4.9.2	- Personnel responsible for corrective actions are defined? - Actions to be taken are defined?				
4.9.3	- The medical significance of the non – conformity tests is considered and requesting clinician informed where appropriate?				
4.10 4.10.1	- The examinations are halted and reports withheld as necessary? - Corrective actions and decisions taken immediately? - Non-conforming test results and examinations already released are recalled?				
4.10.2	- The responsibility for authorization of the resumption of work is defined?				
4.10.3	- Details of the non-conformity is documented and recorded and reviewed at regular specified intervals to detect trends and initiate preventive actions?				
4.11 4.11.1	*Note: (Non-conforming examinations or activities occur in many different ways. These include clinician complaints, quality control indications, instrument calibrations checking of consumable material, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.)*				
4.11.2	If evaluation of the non-conformity determine and recurrence, are procedures established and implemented to:- - Identify?				
4.12	- Document and Eliminate the root				

4.12.1	cause(s)? Are procedures defined and implemented for the release of results in the case of non-conformities including review of such results and are these documented? **Corrective Action**				
4.12.2	i) Do the procedures for corrective actions include an investigation process to determine underlying causes of the problem?				
4.12.3	ii) The findings, where appropriate, shall lead preventative actions.				
4.12.4	*Note:(Corrective actions shall be appropriate to the magnitude and the risk of the problem)* Does the management document and implement any changes required to its operational procedures resulting from corrective action investigations?				
4.12.5					
4.13					
4.13.1	Are the results of corrective actions monitored to ensure the effectiveness in overcoming the problem? i) Are the appropriate areas of activity audited in accordance with 4.14 when there is a doubt(s) on the laboratory's compliance?				
4.13.2	ii) Are the results for corrective actions submitted for laboratory management review? **Preventive actions** Are the needed improvements and potential sources of non-conformances identified?				
4.13.3	If preventive actions are required, are action plans.				

	- Developed? - Implemented? - Monitored for effectiveness? Are procedures for preventive actions effective? **Continual improvement** Are potential sources of non-conformances or other opportunities for improvement in the quality management system or technical practices identified through review at regular intervals, as defined by the management? If improvement is required, are actions plans: - Developed? - Documented? - Implemented? To take advantage of the opportunities for improvement. Is the effectiveness of the actions evaluated through a review or audit of the area concerned? Are the results of actions resulting from the review submitted to management for review and implementation of any needed changes?				
4.14 4.14.1 4.14.2	Are quality indicators implemented: - To systematically monitor and evaluate the lab's contribution to patient care? - When improvements are identified, and are these issues addressed regardless of where they occur? - To ensure participation in quality improvement activities that deal with relevant areas and outcomes of patient care. Are suitable training opportunities for all lab personnel and relevant users of the laboratory				

4.14.3	provided? **Quality and technical records**				
4.15 4.15.1	Does the laboratory establish and maintain procedures for: - Identification - Collection - Indexing - Access - Filling - storage - Maintenance - Safe disposal of quality and technical records? Are all records - Legible? - Appropriately stored and easily retrievable? - To prevent damage, deterioration, prevent loss, prevent unauthorized access?				
4.15.2	*(Records may be stored on any appropriate medium subject to local, national or regional legal requirements.)* Is retention time established? Is the retention time for test results defined by the nature of test and some records in accordance with statutory authority? Does the laboratory for the defined period retain records of but not limited to the following: - Request forms (including the patient chart or medical record only if used as				

	the request form, - Examination results and reports, - Instrument printouts, - Examination procedures - Laboratory work books or sheets, - Accession records, - Calibration functions and conversion factors, - Quality control records, - Complaints and action taken, - Records of internal and external audits - External quality assessment records/interlaboratory comparisons, - Lot documentation certificates of supplies and package inserts and Incident/accident records and action taken Staff training and competency records.				
4.15.3	- **Internal audits** i) Are internal audits conducted periodically to ensure compliance with QMS?				
4.15.4	ii) Are all elements of the quality management system, (both managerial and technical activities addressed especially, areas of critical importance to patience care?				
5.					
5.1	i) Are the IA* planned and organized/carried				

5.1.1	out by trained and qualified personnel who are, independent of the activity to be audited?				
5.1.2	ii) Do the procedures for internal audit define the types of audit frequencies methodologies and required documentation?				
	iii) When audit findings cast doubts does the laboratory have documented time frames for Corrective or Preventive action?				
	Are the results of internal audit submitted to the laboratory management for review?				
5.1.3	**Management review** Does the management review cover the following: - Laboratory's quality system? - All medical services including examination and advisory activities? - Continuing suitability and effectiveness in patient care? - Introduce any necessary changes or improvements?				
5.1.4	Are management reviews conducted periodically and in accordance with the predetermined schedule? *Note: (A typical period for conducting a management review is once every twelve months.)*				
	Is the review incorporated into a plan to include goal, objectives and action plans for the coming year? Does the review take account of: - Follow-up of previous management reviews? - Status of corrective actions taken and				

	required preventive action? - Reports from managerial and supervisory personnel? - The outcome of recent external audits? - Assessment by external bodies? - The outcome of external quality assessment and other forms of inter-laboratory comparison. - Any changes in the volume and type of work undertaken? - Feedback including complaints and other relevant factors, from clinicians, patients and other parties? - Quality indicators for monitoring the laboratory's contribution to patient care? - Non – conformities? - Monitoring of turnaround time? - Results of continuous improvement processes - Evaluation of suppliers *Note: It is recommended that more frequent intervals be adopted when a quality management system is being established. This will allow early action to be taken in response to areas identified as requiring amendment of the quality management system or other practices.)*				

	Are the quality management system and the appropriateness of the laboratory's contribution to patient care monitored and evaluated? Are findings and actions from management reviews recorded and carried out within an appropriate and agreed time frame? **Technical requirements** **Personnel** Does the laboratory management have an organizational plan, personnel policies and job description for all personnel? Does the management maintain records of relevant educational and professional qualifications, training, experience and competence of all personnel?				
5.1.5	Information may include: - Certification of license, if required. - References from previous employment. - Job descriptions - Records of continuing education and achievements. - Competency evaluations, and (inward inappropriate) Provision for inappropriate incident reports. *Note :(Other personnel records should include records of exposure to occupational hazards and records of immunization status.)*				
5.1.6	Does competent person with medical, scientific and technical background direct the laboratory?				

5.1.7 5.1.8 5.1.9 5.1.10 5.1.11	*Note: (competence is understood as the produce of basic academic, postgraduate and continuing education, as well as training and experience of several years in medical laboratory)* Do the responsibilities of the director or designees include professional, scientific, consultative, advisory, organizational, administrative and educational matters? Does the laboratory director or designees for each task have the appropriate training and background to be able to discharge the following responsibilities? Provide advice to those requesting information about the choice of tests, the use of the laboratory service and the interpretation of laboratory data, Serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate. Relate and function effectively (including contractual arrangements, if necessary), with - Applicable accrediting and regulatory agencies, - Appropriate administrative officials, - The healthcare community and - The patient population served. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services, Implement the quality management system (the laboratory director and professional				

	laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable),				
5.2	Monitor all work performed in the laboratory to determine that reliable data are being generated,				
5.2.1	Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory,				
	Plan, set goals develop and allocate resources appropriate to the medical environment,				
	Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities,				
5.2.2	Provide educational programs for the medical and laboratory staff and participate in educational programs of the institution,				
	Plan and direct research and development appropriate to the facility,				
5.2.3	Select and monitor all referral laboratories for quality of service, Implement a safe laboratory environment in compliance with good practice and applicable regulations,				
5.2.4	Address any compliant, request or suggestion from the users of the laboratory, for ensuring that quality services are provided for patients.				
	Ensure good staff morale?				

	Note: *(The laboratory director need not perform all responsibilities personally. However, it is the laboratory director's responsibility for the overall operation and administration of the laboratory, for ensuring that quality Management Systems services are provided for patients.)* Are staff resources adequate to carry out all the functions of the quality management system? Are personnel trained specifically in quality assurance and management for services offered? Does the management authorize personnel to perform particular tasks such as - Sampling? - Examination? - Operating particular types of equipment, including use of computers in the lab information system? Are policies and procedures established to define who - Operates the computer system? - May access patient data only? - Is authorize to enter patient results? - Change results? - Correct billing? - Modify computer programs?				
5.2.5					
5.2.6					
5.2.7					
5.2.8	Is continuing education program available for all levels of staff? Are employees trained to prevent or contain the effects to adverse incidents?				
5.2.9					

5.2.10	Is the competency of the staff undergoing training assessed? Is it done periodically thereafter? i) Do the personnel making professional judgment with reference to test examination have theoretical and practical knowledge and recent experience? *Note: the professional judgment can be expressed as opinion interpretation, predictions, simulation & models and value.* ii) Do they take part in regular professional liaison? iv) Do all personnel maintain confidentiality of patient information?				
5.3 5.3.1	**Accommodation and environmental conditions** i) Is the laboratory workspace adequate to carry out quality work, quality control procedures and ensure safety of personnel and patient care services? ii) Is there evidence that the laboratory director determines the adequacy of the laboratory's space? iii) Are laboratory resources maintained in a functional and reliable condition? iv) Are provisions made for appropriate primary sample collection and examinations sites, which are different from permanent laboratory facilities? Is the laboratory designed - For efficiency of its operation?				

	- To optimize the comfort of its occupants? - To minimize the risk of injury and occupational hazard? Are considerations made for accommodating patient disabilities, comfort and privacy when primary sample collection facilities are provided?				
5.3.2	i) Is the laboratory design and environment suitable for the tasks carried out? ii) Is the environment in which the primary sample collection and/or examinations undertaken suitable and monitored so that it does not invalidate the results or adversely affect the required quality of any measurement *Note:* *(Laboratory facilities for examination should facilitate correct performance of examinations. These include but are not limited to energy sources, lighting, ventilation, water, waste and refuse disposal and environment does not adversely affect the performance of specimen collection and equipment.)*				
5.3.3	Does the laboratory monitor, control and record environment conditions as required by relevant specification or where they may influence the quality of results? *Note:* *(Due attention should be paid to sterility, dust, electromagnetic interference, radiation, humility, electrical, supply, temperature and sound and vibration levels as appropriate, to the technical activities concerned.)* i) Is there effective separation between				

	neighbouring areas where incompatible activities are performed? ii) Are appropriate measures taken to prevent cross contamination? Is the control of access specified? Are the communication systems within the laboratory efficient to the size and complexity of the facility and the efficient transfer of messages? Are relevant storage space and conditions provided to ensure but not limited to the following:- - Continuing integrity of samples - Slides - Histology blocks - Retained micro-organisms - Documents - Files - Manuals - Equipment - Reagents - Laboratory supplies - Records and results? etc. i) Is the work area kept clean and well maintained? ii) Are dangerous materials stored and disposed				
5.3.4	specified by relevant regulations? iii) Are measures taken to ensure good housekeeping in the laboratory? iv) Are special procedures and training for personnel provided when necessary? **Laboratory equipment**				

5.3.5	*Note:* *Instruments, reference materials, consumables, reagents, and analytical systems are included as laboratory equipment, as applicable.* i) Is the laboratory furnished with all the items of equipment required for its services (including primary sample collection, sample preparation and processing examination and storage)?				
5.3.6	ii) Where the laboratory needs to use equipment outside its permanent control, does the laboratory management ensure that the requirements of ISO 15189 are met? *Note:* *(When selecting equipment account should be taken of the use of energy and future disposal (care of environment.)*				
5.3.7	i) Is equipment shown to be capable of achieving the performance required and complies with specifications relevant to examinations concerned? ii) Is a programme established to regularly monitor and demonstrates proper calibration and function of instruments, reagents and analytical systems? iii) Is there documentation of preventive maintenance, at a minimum, following the recommendation from the manufacturer?				
5.3.8	*Note: manufacturer's instructions, operator's manual or other documentation may be used to establish requirements for compliance with relevant standards or to specify requirements for periodic calibration.*				

	Is each equipment uniquely labeled marked or otherwise identified? i) Are the following records of each items of equipment contributing to the performance of examinations maintained which include at least the following: - Identity of the equipment. - Manufacturer's name, type, identity and serial number or other unique identification - Manufacturer's contact person and telephone number as appropriate. - Date received and date placed in service, - Current location, where appropriate. - Condition when received e.g. (new, used or reconditioned) - Manufacturer's instructions if available or reference to their retention, - Equipment performance records that confirm equipment's suitability for use. *Note:* *the performance records referred above should include copies of reports and certificates of all calibrations and/or verifications including dates time and results adjustments, acceptance criteria and due date of next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration as appropriate to fulfill part or all of this requirement. Manufacturer's instructions as may be used to establish acceptance criteria, procedures and frequency of verification for maintenance or calibration of both, as appropriate, to fulfill parts or all of this requirement.)* Maintenance carried out and that planned for the future,				

	Damage to or malfunction, modification or Repair, of the equipment, i) Predicted replacement date, if possible. ii) Are the above records maintained and readily available for the life span of the equipment or for any time period required by law or regulation? i) Are the equipment operated by authorized personnel only? ii) Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) readily available?				
5.4 5.4.1	i) Are equipment maintained in safe working condition? ii) Are procedures in place to ensure examination of electrical safety, emergency stop devices, 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.)* i) Is defective equipment taken out of service, clearly labeled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria? ii) Is the effects of this defect on previous examinations examined and institute the procedure given to 4.9?				

	iii) Are reasonable measures taken to decontaminate equipment prior to service, repair or decommissioning? i) Is a list of the measures taken to reduce contamination given to the person working on the equipment? ii) Does the laboratory provide suitable space for repairs and appropriate personal protective equipment? iii) Are the equipment labeled or otherwise coded to indicate the status of calibration or verification and the date when recalibration or re-verification is due? iv) When equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of equipment are checked and shown to be				
5.4.2	satisfactory before the equipment is returned to service? v) Does the laboratory ensure the following when computers or automated examination equipment are used for collection, processing, recording, reporting, storage or retrieval of examination data?				
5.4.3	vi) Computers software (including that built into equipment) is documented and suitably validated as adequate for the use in the facility? vii) Procedures are established and implemented for protecting the integrity of data at all times? viii) Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating				

	conditions necessary for maintaining the integrity of data? ix) Computer programs and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons? x) Are the procedures available for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration? xi) Where calibrations gives rise to a set of correction factors, does the laboratory have procedures to ensure that copies of prior correction factors are correctly updated? xii) Are equipment including both hardware and software reference materials, consumables, reagents and analytical systems safeguarded from adjustments or tampering that might invalidate examination results? **Pre-examination procedures** Does the request form contain sufficient information to identify - The patient? - Authorized requester? - Provides pertinent clinical data? The request form or electronic equipment should allow space for the inclusion of but not limited to: Unique identification of the patient; Name or other unique identifier of physician or other person legally authorized to order				

5.4.4	examinations or use medical information together with the destination for the report. The requesting clinician's address should be provided as part of the request form information; Type of primary sample and the anatomic site of origin, where appropriate; Examination(s) requested; Clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes; Date and time of primary sample collection; and date and time of receipt of samples by the laboratory. *Note: The format of the request form (e.g. electronic or paper) and in the manner in which requests are to be communicated to the laboratory should be determined in discussion with the user of laboratory services.* Are specific instructions for the proper collection and handling of primary samples - Documented? - Implemented? - Made available to those responsible for primary sample collection Are these instructions contained in a primary sample collection manual? Does the primary sample collection manual include Copies of or references to: 1. List of laboratory examinations offered 2. Consent forms, where applicable? 3. Information and instruction provided to patients in relation to their own preparation before primary sample collection? Includes copies of: 4. Information for users of the laboratory services on medical indications and appropriate selection of available				

	procedures?				
5.4.5	Procedures for: 1. Preparation of the patient (e.g. instructions to caregivers and phlebotomists)? 2. Identifications of primary sample? 3. Primary sample collection (e.g., phlebotomy, skin puncture, blood, urine and other body fluids) with descriptions of the primary sample containers and any necessary additives?				
5.4.6	Instructions for : 1. Completion of request form or electronic request? 2. Type and amount of the primary sample to be collected. 3. Special timing of collection, if required? 4. Any special handling needs between time of collection and time received by the laboratory (e.g. transport requirements, refrigeration, warming, immediate delivery etc.?				
5.4.7	5. Labeling of primary samples? 6. Clinical information (e.g. history of administration of drugs.)? 7. Positive identification in details of the patient from whom a primary sample is collected? 8. Recording the identity of the person collecting the primary sample? 9. Safe disposal of materials used in the collection?				
5.4.8	Instructions for : 1. Storage of examined samples? 2. Time limits for requesting additional				

	examinations? 3. Allowed additional examinations? 4. Repeat examination due to analytical failure or further examinations of same primary sample?				
5.4.9	Is the primary sample collection manual part of the document control system?				
5.4.10	i) Are primary samples traceable to an identified individual normally by a request form? ii) Are primary samples lacking proper identification rejected by the laboratory?				
5.4.11 5.4.12 5.4.13	*Note:* *Where there is uncertainty in the identification of the primary sample or instability of the analytes in the primary sample (cerebro spinal fluid, biopsy etc.) and the primary sample is irreplaceable critical, the laboratory may choose initially to process the sample but not release the results until the requesting physician or person responsible for the primary sample collection takes responsibility for identifying and accepting the sample or providing proper information, In such instance, the signature of that person taking responsibility for the primary sample identification should be recorded on or traceable to the request form. If this requirement, for any reason, is not met, the responsible person should be identified in the report if the examination is carried out. Samples to be set aside for future examination (e.g. viral antibodies metabolites relevant to the clinical syndrome) should also be identifiable.*				
5.5	Does the laboratory monitor how the samples				

	are transported to the laboratory for the following;				
5.5.1	Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned? Within a temperature range specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples? In a manner that ensures safety for the carrier, the general public and the receiving laboratory? *Note:* *The procedures shall comply with regulatory requirements.*				
5.5.2	i) Are all the primary samples recorded in an accession book, worksheet, computer or other comparable system upon receipt? ii) Is date and time of receipt of samples and identity of the receiving officer recorded? i) Are criteria developed and documented for acceptance or rejection of primary samples? (ii) If compromised sample are accepted, does the final report indicate the nature of the problem and if applicable, is that caution required when interpreting the results? Does the laboratory periodically review its sample volume requirements for phlebotomy(and other sample such as cerebrospinal fluid) to ensure that - Neither insufficient nor excessive				

	amounts of sample are collected?				
5.5.3	Is there systematic review of requests and samples by the authorized personnel to decide which examinations are to be performed and the methods used to perform them? Is there a documented procedure for the receipt, labeling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent? Does the procedure include: - Details of special handing of request forms and primary samples - Mechanism of transfer of the primary sample to the examination area of the laboratory? - Any rapid processing mode to be used? - Any special reporting criteria to be followed? Are sample portions traceable to original primary sample? Are written policies available concerning verbal requests for sample examinations? Are samples stored for a specified time under conditions - Ensuring the stability of sample properties? - To enable repetition of the examinations after reporting of the result? - For additional examinations? **Examination procedures** *Note:* *Some of the following may not apply to all discipline in the scope of laboratory medicine.*				

5.5.4	i) Is the laboratory using appropriate examination procedure for: - Selecting or taking sample portions, - Meeting the needs of the users of the laboratory services? - Appropriate for the examinations? ii) Is the laboratory selecting appropriate methods published from: - Established/authoritative textbooks, - Peer-reviewed texts - Journals - International, regional, national guidelines? iii) If in-house procedures are used, are they - Appropriately validated for their intended use? - Fully documented? i) Are validated procedures used for confirming that the examination procedures are suitable for the intended use? ii) The validations shall be as extensive as necessary to meet the needs in the given application or fields of application. iii) Are results obtained and the procedure used for validation recorded? iv) Are the methods and procedures evaluated for satisfactory results before implementation? v) Does the laboratory director or designee review these procedures initially and at defined intervals (normally annual review)? vi) Are these reviews documented?				

	i) Are all documented test procedures available at the workstation? Is it available in a commonly understood language? ii) Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.				
5.5.5 5.5.6 5.5.7	- Is the procedure based in whole or in part on the instructions for use (e.g. package insert) written by the manufacturer, provided that they are in accordance with 5.5.1 and 5.5.2 and that they describe the procedure as it is performed in the laboratory and are written in the language commonly understood by the staff? - Are deviations reviewed and documented? - Is each new version of the examination kits with major changes in reagents or procedures checked for performance and suitability for intended use? - Are procedural changes dated and authorized as for other procedures?				
5.6	In addition to document control identifiers does documentation include, when applicable the following; - Purpose of examination, - Principle of the procedure used for examination, - Performance specification (e.g.				

5.6.1	linearity, precision, accuracy as expressed as uncertainty of measurement. Detection limits, measuring interval, trueness of measurement, sensitivity, and specificity) - Primary sample system (e.g. plasma, serum, urine) - Type of container and additive. - Required equipment and reagents. - Calibration procedures. - Procedural steps. - Quality control procedures. - Interference (e.g. lipaemia haemolysis				
5.6.2	bilirubinemia) and cross reaction. - Principle of procedure for calculating results including measurement uncertainty. - Biological reference intervals. - Reportable interval of patient examination results. - Alert/critical values, where appropriate. - Laboratory interpretations. - Safety precautions. - Potential sources of variability *Note:* *(Electronic manuals are acceptable provided that the information described above is included. The same requirements for document control should also apply to electronic manuals*				
5.6.3	*The laboratory director is responsible for ensuring that the contents of examination procedures are complete, current and has been thoroughly reviewed.)* i) Does the performance specifications for each procedure used in an examination)relate to the intended use of that procedure? ii) Are the biological reference intervals				

	periodically reviewed? iii) Does the laboratory undertake investigations if the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population? Are necessary follow-ups made as corrective action? Are biological reference intervals also reviewed, if appropriate, when the laboratory changes an examination procedure or pre-examination procedure?				
5.6.4	Does the laboratory make a list of its current examination procedures, including primary sample requirements and relevant performance specifications and its requirements available to laboratory users upon request? When the laboratory changes an examination procedure so that results or their interpretations may be significantly different, are: The implications explained to users in writing prior to the introduction of the change? *Note:* *This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include; directed mailings, laboratory newsletters, or part of the examination report itself.*				
5.6.5	**Assuring quality of examination procedures** Does the laboratory design internal quality control systems that verify the attainment of the intended quality of a result?)				

5.6.6	*Note:* *It is important that the control system provides staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples requests, examinations, reports etc.*				
5.6.7	i) Does the laboratory determine the uncertainty of its measurements, where relevant and possible? ii) Are the uncertainty components which are of importance taken into account?				
5.7 5.7.1 5.7.2 5.7.3	*Note:* *Sources that may contribute to the uncertainty may include but not limited to:-* - *Sample preparation,* - *Sample portion selection,* - *Calibrators,* - *Reference materials,* - *Input quantities,* - *Equipment used,* - *The environmental conditions,* - *The conditions of the sample* - *Changes in the operator, etc.*				
5.8 5.8.1 5.8.2	i) Is a programme designed for calibration of measuring systems and verification of trueness designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference? ii) Where the laboratory is using external calibration services, is traceability of measurement assured of these external calibration laboratories? iii)Where none of these are possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:-				

5.8.3 5.8.4	- Participation in a suitable programme of inter laboratory comparisons, - The use of suitable reference materials certified to indicate the characterization of the material, - Examination or calibration by another procedure. - Ratio or reciprocity type measurements, - Mutual consent standards or methods which are clearly established specified, characterized and mutual agreed upon by all parties concerned. - Documentation of statements regarding reagents, procedures or examination system when traceability is provided by the supplier or manufacturer. i) Does the laboratory participate in inter-laboratory comparisons such as those organized by external quality assessment schemes? ii)Does the laboratory - Monitor the results of external quality assessment? - Participate in the implementation of corrective actions when control criteria are not fulfilled? *Note:* *External quality assessment programmes should as far as possible provide clinically relevant challenges the checking the entire examination process including pre- and post – examination procedures.* i) When proficiency or inter-laboratory comparison programmes are not available, does the laboratory develop mechanism for deciding the acceptability of procedures not otherwise evaluated?				

	Note: *Wherever possible mechanism shall utilize externally derived challenge materials such as exchange of sample with other laboratories.*				
5.8.5	ii) Does the laboratory monitor the results in the above programmes and participate in the implementation and recording of corrective actions? For tests and examination performed using - Different procedures - Different equipment, or - Different sites				
5.8.6	i) Is there a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals? ii) Are such verifications performed at defined periods of time appropriate to the characteristics of the procedure or instruments?				
5.8.7	i) Does the laboratory document, record the results appropriately				
5.8.8	ii) Does the laboratory expeditiously act upon results from the above comparisons? iii) Are the problems or deficiencies identified, rectified and records of actions retained?				
5.8.9	**Post-examination procedures.** Do authorized personnel systematically review the results of examinations and evaluate them in conformity to clinical information available regarding the patient and authorize the release of the results? Are primary samples and other laboratory				

5.8.10	samples stored in accordance with approved policy? Are samples that are no longer required for examination disposed safely and in accordance with regulations or recommendations for waste management? **Reporting of Results**				
5.8.11	Is the laboratory responsible for formatting reports? *Note: the format of the report form (e.g. electronic or paper) and how it is to be communicated from the laboratory should be determined in discussion with the laboratory users.*				
5.8.12	i) Does the laboratory management share responsibility with the requester to ensure that the reports are received by the appropriate individual within the agreed upon time interval?				
5.8.13	ii) Are the test results - Legible? - Without mistakes in transcription? - Reported to person authorized to receive and use medical information?				
5.8.14	The report should include but not limited to : - Clear unambiguous identification of the examination including where appropriate, the measurement procedure? - The identification of the laboratory that issued the report? - Unique identification and location of the patient, where possible and				

	destination of the report? - Name or other unique identity of the requester and the requesters address. - Date and time of primary sample collection, where available and relevant to patient care, and the time of receipt by the laboratory?				
5.8.15	- Date and time of release of report, if not on the report, shall be readily accessible when needed?				
5.8.16	- Source and system (primary sample type), - Results of the examination including SI units or units traceable to SI units, where applicable? - Biological reference intervals, where applicable?				
5.8.17	- (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.) - Interpretations of results, where appropriate? - Other comments (e.g. quality or adequacy of primary sample, which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure)? - (The report should identify examinations undertaken as part of a development programme and for which no specific claims on measurement performance are made) Where applicable, information on detection limit and uncertainty of measurement should be provided upon request.) Identification of the person authorizing the				

	release of the report? If relevant, original and corrected results? Signature or authorization of the person checking or releasing the report, where possible? As appropriate, the description of examinations performed and their results should follow the vocabulary and syntax recommended by one or more of the following organizations: - International council for standardization in haematology (ICSH), - International society of haematology, - International federation of clinical chemistry and laboratory medicine (IFCC), - International union of pure and applied chemistry (IUPAC) - International society of thrombosis and haematostasis (ISTH) - European committee for standardization (CEN) As appropriate, the description and results should follow the nomenclature recommended by one or more of the follow organizations. - International union of biochemistry and molecular biology(IUBMB) - International union of microbiological societies (IUIS) - International union of Immunological societies (IUIS) - SNOMED International (college of American Pathologists), - World Health Organization(WHO) If the quality of the primary sample received was unsuitable for examination or could have compromised the result, are these indicated in				

	the report? Are copies or files of reported results retained by the laboratory such that prompt retrieval of the information is possible? Are reported results retained for a period as long as medically relevant or as required by the National Regional and International regulations requirements? i) Does the laboratory have procedures for immediate notification of physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alerts” or “critical” intervals? ii) Does the above also include sample sent to referral laboratories for examination? Does the laboratory determine the critical properties and their “alert/critical” intervals in agreement with the clinicians who use the laboratory? Do the above apply to all examinations including both normal and ordinal properties? For results transmitted as an immediate interim Report, is the original report always forwarded to the requester? i) Are records maintained of actions taken in response to results in the critical intervals? ii)Do these records include - Date? - Time? - Responsible laboratory staff member?				

	- Person notified? - Examination results? - Any difficulty encountered in meeting this requirement? iii) Are such records reviewed during the audits? i) Does the laboratory in consultation with the requesters, establish turnaround times for each Of its examinations? ii) Does the turnaround time reflect the clinical needs? iii) Is there a policy available for notifying requester when an examination is delayed? Are the turnaround times as well as any feedback from clinicians regarding turnaround times - Monitored? - Recorded? - Reviewed? - Where necessary, identify corrective actions to address any problems? *Note:* *(This does not mean that the clinical personnel are to be notified of all delays in examination, but only in those situations where the delay may compromise patient care. This procedure should be developed in collaboration between clinical and laboratory personnel.)* When examination results from referral laboratory need to be transcribed by the referring laboratory, are there procedures available to verify the correctness of all transcriptions? i) Does the laboratory have clearly documented procedures for release of examination results including details of who may release results and				

	to whom? ii) Do the procedures also include guidelines for the release of results directly to patients? i) Do the laboratories establish policies and practices to ensure that the results distributed by telephone or other electronic means only reach authorized receivers? ii) Are results provided verbally followed by a properly recorded report? i) Does the laboratory have written policies and procedure regarding the alteration of reports? ii) Does altered reports indicate the - Time? - Dates? and - Names of person responsible for the change? iii) Are original entries legible when alterations are made? iv) Are original electronic records retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration? i) Are results used for clinical decision making revised and retained in subsequent. ii) Cumulative reports and clearly identified as having been revised? iii) If the reporting system does not capture amendments, a change, or alterations, is an audit log used?				
KENAS- Requirements					
A 1.	**Key Personnel** Do the key personnel still occupy appropriate				

2.	positions in the staff structure to be responsible for the adequacy of test results? Do the key personnel still retain sufficient contact time with testing procedures to maintain the ability for critical evaluation of results?				
B.	**KENAS Endorsed reports and use KENAS of mark** Does the laboratory comply with the terms and conditions for use of accreditation Mark				
C.	Does the laboratory immediately notify KENAS of: i) Any change in its legal, commercial or organizational status; ii)Any change in policies and procedures, where appropriate; iii) Any change in organization and management e.g. Key personnel, authorized representative; iv) Changes of duties of key personnel; v) Significant changes in laboratory environment, equipment, facilities and/or other resource; vi) Changes of premises, where the laboratory will be subjected to a re-assessment which will cover the full scope of accreditation and the laboratory has responsibility to Inform KENAS at least 3 months in advance vi) Any lawsuit or criminal investigation of the laboratory staff				
Follow up on last assessment's findings					
Other Observation and Comments Safety					