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| **5** **TECHNICAL REQUIREMENTS**   1. **Accommodation and environmental conditions** 2. **General**   Is the laboratory/facility workspace adequate to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of the laboratory personnel, patient and visitors?  Is there evidence that the laboratory/facility director determined the adequacy of the laboratory’s space?  Where applicable, are similar provisions made for primary sample collection and examinations at sites other than the main laboratory premises, for example POCT under the management of the laboratory?   1. **Does the laboratory and associated office facilities meet the following conditions:** 2. Is access to laboratory/facility controlled? 3. Are medical information, patient samples, and laboratory resources safeguarded from unauthorized access? 4. Does the laboratory/facility for examination allow correct performance of examinations?   Example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.   1. Are the communication systems within the laboratory appropriate to the size and complexity of the facility to allow effective transfer of information? 2. Are safety facilities and devices provided and functioning regularly verified? 3. **Storage facilities**   Are storage space and conditions 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 material s 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?   1. **Staff facilities**   Does the laboratory have adequate access to washrooms, supply of drinking water and facilities for storage of personal protective equipment and clothing?  (When possible, the laboratory should provide space for staff activities such as meeting and quiet study and rest area).   1. **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 available and maintained for both patient and staff at sample collection facilities?**   1. **Facility maintenance and environmental conditions**   Is the laboratory maintained in a functional and reliable condition?  Is the work areas clean and well maintained?  Does the laboratory/facility 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)  Is there effective separation between neighbouring areas where incompatible activities are performed?  Are appropriate measures 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)?  Does the laboratory provide an environment conducive to quiet and uninterrupted work where it is needed? (e.g. cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutation results)   1. **Laboratory Equipment, reagents and consumables**   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  Management of equipment?  Is the laboratory/facility furnished with all the items of equipment required for 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?  **Does the laboratory replace equipment as needed to ensure its quality of examination results?**  **5.3.1.2 Equipment acceptance testing**  Is equipment verified upon installation and before use to shown its capability to achieve the necessary performance and compliance with requirements relevant to any examinations concerned?  (this requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory).  Is each item of equipment uniquely labeled, marked or otherwise identified?  **5.3.1.3 Equipment instructions for use**  Are equipment 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?  Does the laboratory 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**  Does the laboratory have documented procedure for the calibration of equipment that directly or indirectly affects examination results?  Does the procedure includes:   1. Reference to conditions of use and manufacturer’s instructions? 2. Recording of the metrological traceability of the calibration standard and traceable calibration of the item of equipment? 3. verification of the required measurement accuracy and function of the measuring system at defined intervals 4. recording of the calibration status and date of recalibration 5. ensuring that calibration factors are correctly updated after calibration 6. 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.  (Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer.  Such documentation is acceptable as long as the manufacturer’s examination system and calibration procedures are used without modification).  Where this is not possible or relevant, 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 al parties concerned?  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 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:   1. identity of the equipment, 2. manufacturer’s name, model, and serial number or other unique identification, 3. manufacturer’s/ supplier’s contact information, 4. date received and date of entered into service, 5. location, 6. condition when received (e.g. new, used or reconditioned), 7. manufacturer’s instructions, 8. records that confirmed the equipment’s initial acceptability for use when it is incorporated in the laboratory, 9. maintenance carried out and the schedule for preventive maintenance, 10. equipment performance records that confirm the equipment’s ongoing acceptability for use, 11. Damage to, or malfunction, modification or repair, of the equipment.   Does the performance records referred in j) include copies of 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?   * 1. **Reagents and consumables**  1. **.1 General**   Does the laboratory has documented procedure for   * + reception   + storage   + acceptance testing   + inventory management of reagents and consumables   **5.3.2.2 Reagents and consumables – reception and storage**  **Where the laboratory is not the receiving facility, does 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 Reagents 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 **Reagents 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 **Reagents and consumables – Instructions for** **use**  **Are instructions for use of reagents and consumables, including those provided by the manufacturers, readily available?**  5.3.2.6 **Reagents and consumables – Adverse incident reporting**  Are adverse incidents and accidents that can be attributed to specific reagents or consumables investigated and reported to manufacturer and appropriate authorities, as  Required?  **5.3.2.7 Reagents and consumables – Records**  Are the following records (but not limited to) of each reagents and consumables contributing to the performance of examinations maintained   1. Identity of the reagent or consumable 2. manufacturer’s name, and batch code/ lot number, 3. manufacturer’s/ supplier’s contact information, 4. date received, expiry date, and date of entering into service and, where applicable, the date the material was taken out of service, 5. condition when received (e.g. accepted or damaged), 6. manufacturer’s instructions, 7. records that confirmed the reagent’s or consumable’s initial acceptability for use, 8. 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?**   1. **Pre-examination Process** 2. **General**   **Does the laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations?**   1. **Information for patients and users**   Are the following information available for patients and users of the laboratory services:   1. location of the laboratory 2. types of clinical services offered by the laboratory including examinations referred to other laboratories 3. opening hours of the laboratory 4. examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values, 5. Instruction for completion of request form 6. Instruction for preparation of the patient 7. Instruction for patient-collected samples 8. Instruction for transportation of samples, including any special handling needs, 9. any requirement for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed 10. the laboratory’s criteria for accepting and rejecting samples, 11. a list of factors known to significantly affect the performance of examination or the interpretation of the results 12. availability of clinical advice on ordering of examinations and on interpretation of examination results, 13. the laboratory’s policy on protection of personal information, 14. 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?   1. **Request form information**   Does the request form or electronic equivalent allow space for the inclusion of, but not limited to:   1. unique identification of the patient; 2. 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; 3. type of primary sample and the anatomic site of origin, where relevant; 4. examinations requested; 5. clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes; 6. date and time of primary sample collection; and 7. Date and time of receipt of samples by the laboratory.   The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the user of laboratory services.  Does the laboratory has a documented procedure to handle verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time?  **Is the laboratory willing to cooperate with users or their representatives in clarifying the user’s request?**  **5.4.4 Primary sample collection and handling**  **5.4.4.1 General**  Does the laboratory have documented procedures for proper collection and handling of primary samples?  Is the procedure(s) 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 examination results and communicated to the appropriate personnel?**  (**All procedures carried out on a patient need** **the informed consent of the patient**)  (**Special procedures, including more invasive** **procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent**).  **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**.  (Note: Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected).  **5.4.4.2 Instructions for pre-collection activities**  Does the laboratory have instructions to include the following:   1. completion of request form or electronic requests; 2. Preparation of the patient (e.g. instructions to caregivers and phlebotomists)?   Identifications of primary sample?   1. 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? 2. Special timing of collection, if required? 3. 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:   1. Positive identification in detail of the patient from whom a primary sample is collected? 2. Verification that patient meets pre-examination requirements [e.g. fasting status, medication status, sample collection at predetermined time or time intervals, etc]? 3. Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives? 4. **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?** 5. Instructions for labeling of primary samples in a manner that provides an uniequivocal link with the patients from whom they are collected. 6. identification of the collector and collection date, and when needed, recording of the collection time 7. instructions for proper storage conditions before collected samples are delivered to the laboratory 8. safe disposal of materials used in the collection allowed additional examinations? 9. **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:   1. Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned? 2. Within a temperature range specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples? 3. 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?   (A laboratory which is not involved in primary sample collection and transportation is considered to have satisfied clause 5.4.5c) above when, upon receipt of a sample whose integrity was compromised or which could have jeopardized the safety of the carrier or the general public, the sender is contacted immediately and informed about measures to be taken to eliminate recurrence).   1. **Sample reception**   Does the laboratory’s procedure for sample reception ensure that the following conditions are met:  Is the primary sample collection manual part of the document control system?   1. Are primary samples unequivocally traceable, by request and labeling, to an identified patient or site? 2. Are laboratory-developed and documented criteria for acceptance or rejection of samples applied? 3. Where there is uncertainty in the identification of the primary sample, or sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the   Laboratory chooses to process the sample, does the final report indicate the nature of the problem, and where applicable, that caution is required when interpreting the result?   1. Are all sample received 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   1. Are received samples evaluated by the authorised personnel to ensure that they meet the acceptance criteria relevant for the requested examination? 2. 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?   Are all portions of the primary sample unequivocally traceable to the original primary sample?   1. **Pre-examination handling, preparation and storage**   Does the laboratory have procedures and appropriate facilities to :   * + secure patient samples   + prevent deterioration, loss or damage during pre-examination activities, and during handling, preparation and storage   Is time limits established for request of additional examinations or further examinations on the same primary sample?   1. **Examination procedures**     1. **Selection, verification and validation of examination procedures** 2. **.1 General**   Does the laboratory select examination procedures which have been validated for their intended use?  Is the identity of persons performing activities in examination processes recorded?  Does the specified requirements (performance specifications) for each examination procedure relate to the intended use of that examination.  (Preferred procedures are those specified in the instructions of use of *in vitro* medical devices or those published in established/ authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines or regional and national regulations).  **5.5.1.2** **Verification of examination procedures**  Does the laboratory performed independent verification for validated examination procedures before being introduced into routine use?  **Is information from the manufacturer/ method developer obtained 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?  Are the verification procedure and results obtained documented?  Are the verification results reviewed by appropriate authority and is the review documented?  **5.5.1.3 Does the laboratory validate the examination procedures derived from:**   1. non-standard methods, 2. laboratory designed or developed methods 3. standard methods used outside their intended scope 4. 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.  (Performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy,  measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substance, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and sensitivity).  **Are the validation procedure and results obtained documented?**  **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**  **Does the laboratory determine measurement uncertainty for each measurement procedure used to report measured quantity values on patient’s samples?**  **Is the performance requirements for the measurement uncertainty of each measurement procedure defined regularly reviewed?**  **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.**   1. **Biological reference intervals or clinical decision values**   Are the biological reference intervals or clinical decision values, defined and basis of which, documented and communicated 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 pr pre-examination procedure, are the associated reference intervals and clinical decision values reviewed?   1. **Documentation of examination procedures**   Are examination procedures documented and written in a language commonly understood by the staff in the laboratory? Ire they available in appropriate locations?  Any condensed document format (e.g. card files or similar used systems) shall correspond to the documented procedure.  (Information from product instructions for use may be incorporated into examination procedures by reference).  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:   1. purpose of the examination 2. principle and method of the procedure used for examinations 3. performance characteristics ( see 5.5.1.2 and 5.5.1.3) 4. type of sample (e.g. plasma, serum, urine) 5. patient preparation 6. type of container and additive 7. required equipment and reagents 8. environmental and safety controls 9. calibration procedures (metrological traceability) 10. procedural steps 11. quality control procedures 12. interferences (e.g., lipaemia, haemolysis, bilirubinemia) and cross reaction 13. principle of procedure for calculating results, including, where relevant, measurement uncertainty of measured quantity values 14. biological reference intervals or clinical decision values 15. reportable interval of examination results 16. instructions for determining quantitative results when results is not within the measurement interval 17. alert/critical values, where appropriate 18. laboratory clinical interpretation 19. potential sources of variation     1. 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.  This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory/facility newsletters, or part of the examination report itself.   1. **Ensuring quality of examination results**     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** (see 4.14.7, 5.4, 5.7 and 5.8).  **The laboratory shall not fabricate any results.**   * 1. **Quality control**  1. **.1 General**   Does the laboratory/facility design internal quality control systems that verify the attainment of the intended quality of results?  **5.6.2.2 Quality control material**  **Does the laboratory use quality control materials that react to the examination system in a manner as close as possible to patient samples?**  **Are quality control materials periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result?**  he laboratory should choose concentration of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made).  (Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer).  **5.6.2.3 Quality control data**  **Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure?**  **When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified.**  **Does the laboratory evaluate the results from patient samples that were examined after the last successful quality control event?**  **Are quality control data reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system?**  **Are preventive actions taken when such trends are noted and the actions recorded?**   * 1. **Interlaboratory comparisons**  1. **.1 Participation**   Does the laboratory participate in inter-laboratory comparison programme(s) appropriate to the examination and interpretations of examination results?  Does the laboratory   * Monitor the results of the interlaboratory comparison programme(s)? * Participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled?   **Is there a documented procedure for interlaboratory comparison participation that include:**   * **Defined responsibilities and instructions for participation?** * **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, does the laboratory develop other approaches and provide objective evidence for determining the acceptability of examination results?  Wherever possible, this mechanism shall utilise appropriate materials.  **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.  Does the laboratory 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.   + interlaboratory comparison samples are not sent for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.  1. **.4 Evaluation of laboratory performance**   **Is the performance in interlaboratory comparisons 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?  1. **Comparability of examination results**   Is there a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals?  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).  **Does the laboratory notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand and when examination methods are changed?**  Does the laboratory document, record and as appropriate, expeditiously act upon results from the above comparisons?  Are the problems or deficiencies identified and rectified and records of actions retained?   1. **Post-examination process** 2. **Review of results**   Do authorised personnel review the results of examinations and evaluate them against internal quality control, available clinical information and previous examination results before the release of the results?  **Are review criteria established, approved and documented for procedure that involves automatic selection and reporting** (see 5.9.1)?   1. **Storage, retention and disposal of clinical samples**   Does the laboratory have a documented procedure for   * + identification   + collection   + retention   + indexing   + access   + storage   + maintenance   + safe disposal of clinical samples   **Does the laboratory define the retention time of clinical samples?** Does the retention timetake into consideration:   * + nature of sample   + the examination   + Any applicable requirements/ regulation?   Are samples that are no longer required for examination disposed safely and in accordance with regulations or recommendations for waste management? |  |  |  |