|  |
| --- |
| **DETAILS OF ASSESSMENT** |
| **ORGANISATION** |  |
| **ADDRESS** |  |
| **LABORATORY REFERENCE NUMBER** |  |
| **ACCOMPANYING LABORATORY REPRESENTATIVE** |  |
| **DOCUMENTATION**  | **Quality Manual Procedures Manual** **Work Instructions Standard Operating Procedures****Records** |
| **ASSESSOR/TECHNICAL EXPERT WITH MAURITAS STAFF**  |  |
| **SIGNATURE** |  |
| **TYPE OF ASSESSMENT** | **Preliminary Visit Initial Assessment Assessment** **Extension Extraordinary visit Re-assessment** |
| **DATE OF REVIEW** |  |
| **DATE OF VISIT** |  |

**2. MAURITAS R DOCUMENTS REQUIREMENTS**

***Assessors need to check conformance of the laboratory with respect to the requirements of MAURITAS R1, R2, R3 and R4 Regulations:***

**MAURITAS R3 – Traceability of measurement**

|  |  |  |  |
| --- | --- | --- | --- |
| **CLAUSE** | **MAURITAS R3 REQUIREMENT** | **C/NC/NA** | **EVIDENCE CHECKED** |
| **6.1-6.2** | Assessor/MS to check whether:(i) calibrations are performed by an NMI covered by the CIPM MRA; |  |  |
| or (ii) an accredited calibration laboratory covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC; |  |  |
| or (iii) an accredited NMI |  |  |
| **6.3** | Assessor/MS to check whether:1. CRMs are produced by NMIs using a service that is included in the BIPM KCDB;
 |  |  |
|  | 1. CRMs are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC or

Where CRMs are produced by non-accredited RMPs, Accredited/applicant laboratories shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use |  |  |
|  | 1. The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.
 |  |  |
| **6.4** | Assessor to check whether laboratory performs in-house calibrations. |  |  |

**MAURITAS R4 – Conditions for the Use of MAURITAS accreditation symbol**

|  |  |  |  |
| --- | --- | --- | --- |
| **CLAUSE** | **MAURITAS R4 REQUIREMENT** | **C/NC/NA** | **EVIDENCE CHECKED** |
| **5 & 6** | Assessor/MS to check the use of MAURITAS symbol/disclaimer on test report; |  |  |
| **6.10.2.3** | Assessor/MS to check the use of disclaimers when the laboratory makes use of opinions and interpretations. |  |  |

| **CLAUSE** | **REQUIREMENTS** | **C/NC/NA** | **EVIDENCE CHECKED** |
| --- | --- | --- | --- |
| **6** | **Resource requirements** |  |  |
| **6.1** | **General** |  |  |
|  | Does the laboratory have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities? |  |  |
| **6.2** | **Personnel** |  |  |
| **6.2.1** | **General** |  |  |
|  | Does the laboratory have access to a sufficient number of competent persons to perform its activities? |  |  |
| **b)** | Do all personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially and ethically?Are they competent and work in accordance with the laboratory’s management system? |  |  |
| **c)** | Does the laboratory communicate to laboratory personnel the importance of meeting the needs and requirements of users as well as the requirements of this document? |  |  |
| **d)** | Does the laboratory have a programme to introduce personnel to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services? |  |  |
| **6.2.2** | **Competence requirements** |  |  |
|  | Does the laboratory specify the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience? |  |  |
|  | Does the laboratory ensure that all personnel have the competence to perform laboratory activities for which they are responsible?  |  |  |
|  | Does the laboratory have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment? |  |  |
|  | Does the laboratory have documented information demonstrating competence of its personnel? |  |  |
| **6.2.3** | **Authorization** |  |  |
|  | Has the laboratory authorized personnel to perform specific laboratory activities, including but not limited to, the following: 1. selection, development, modification, validation and verification of methods;
 |  |  |
|  | 1. Review, release, and reporting of results;
 |  |  |
|  | 1. Use of laboratory information systems, in particular: accessing patient data and information, entering patient data and examination results, changing patient data or examination results?
 |  |  |
| **6.2.4** | **Continuing education and professional development** |  |  |
|  | Is a continuing education programme available to personnel who participate in managerial and technical processes?Do all personnel participate in continuing education and regular professional development, or other professional liaison activities?Is the suitability of the programmes and activities periodically reviewed? |  |  |
| **6.2.5** | **Personnel records** |  |  |
|  | Does the laboratory have procedures and retain records for: 1. determining the competence requirements specified in 6.2.2 a)
 |  |  |
|  | 1. position descriptions;
 |  |  |
|  | 1. training and re-training;
 |  |  |
|  | 1. authorization of personnel;
 |  |  |
|  | 1. monitoring competence of personnel?
 |  |  |
| **6.3** | **Facilities and environmental conditions** |  |  |
| **6.3.1** | **General** |  |  |
|  | Are the facilities and environmental conditions suitable for the laboratory activities? |  |  |
|  | Does the laboratory ensure that the validity of results, or the safety of patients, visitors, laboratory users, and personnel are not adversely affected? |  |  |
|  | Does this include pre-examination related facilities and sites other than the main laboratory premises where examinations are performed, as well as POCT? |  |  |
|  | Are the requirements for facilities and environmental conditions that are necessary for the performance of the laboratory activities specified, monitored and recorded? |  |  |
| **6.3.2** | **Facility controls** |  |  |
|  | Are facility controls implemented, recorded, monitored, periodically reviewed and include: 1. control of access, taking into consideration safety, confidentiality, quality and safeguarding medical information and patient samples;
 |  |  |
|  | 1. prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal;
 |  |  |
|  | 1. prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation;
 |  |  |
|  | 1. provision of safety facilities and devices, where applicable and regularly verifying their functioning;
 |  |  |
|  | 1. maintenance of laboratory facilities in a functional and reliable condition?
 |  |  |
| **6.3.3** | **Storage facilities** |  |  |
| a) | Are storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records provided? |  |  |
| 1. b)
 | Are patient samples and materials used in examination processes stored in a manner that prevent cross contamination and deterioration? |  |  |
| 1. c)
 | Are storage and disposal facilities for hazardous materials and biological waste appropriate to the classification of the materials in the context of any statutory or regulatory requirements? |  |  |
| **6.3.4** | **Personnel facilities** |  |  |
|  | Is there adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing? |  |  |
|  | Is space for personnel activities, such as meetings, quiet study and a rest area, provided? |  |  |
| **6.3.5** | **Sample collection facilities** |  |  |
|  | Do sample collection facilities: 1. enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations;
 |  |  |
|  | 1. consider privacy, comfort and needs (e.g. disabled access, toilet facility) of patients and accommodation of accompanying persons (e.g. guardian or interpreter) during collection;
 |  |  |
|  | 1. provide separate patient reception and collection areas;
 |  |  |
|  | 1. maintain first aid materials for both patients and personnel?
 |  |  |
| **6.4** | **Equipment** |  |  |
| **6.4.1** | **General** |  |  |
|  | Does the laboratory have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration? |  |  |
| **6.4.2** | **Equipment requirements** |  |  |
|  | Does the laboratory have access to equipment required for the correct performance of laboratory activities? |  |  |
|  | Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification, does the laboratory management ensure that the requirements of this document are met? |  |  |
|  | Are each item of equipment that can influence laboratory activities uniquely labelled, marked or otherwise identified and is a register maintained? |  |  |
|  | Does the laboratory maintain and replace equipment as needed to ensure the quality of examination results? |  |  |
| **6.4.3** | **Equipment acceptance procedure** |  |  |
|  | Does the laboratory verify that the equipment conforms to specified acceptability criteria before being placed or returned into service? |  |  |
|  | Are equipment used for measurement capable of achieving either the measurement accuracy or measurement uncertainty, or both, which is required to provide a valid result? (see 7.3.3 and 7.3.4 for details) |  |  |
| **6.4.4** | **Equipment instructions for use** |  |  |
|  | Does the laboratory have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results? |  |  |
|  | Are equipment operated by trained, authorized, and competent personnel? |  |  |
|  | Are instructions for the use of equipment, including those provided by the manufacturer, readily available? |  |  |
|  | Are the equipment used as specified by the manufacturer, unless validated by the laboratory (see 7.3.3)? |  |  |
| **6.4.5** | **Equipment maintenance and repair** |  |  |
|  | Does the laboratory have preventive maintenance programmes, based on manufacturer’s instructions?Are deviations from the manufacturer's schedules or instructions recorded? |  |  |
|  | Are equipment maintained in a safe working condition and working order?Does this include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorized personnel? |  |  |
|  | Is equipment that is defective or outside specified requirements, taken out of service?Is it clearly labelled or marked as being out of service, until it has been verified to perform correctly? Does the laboratory examine the effect of the defect or deviation from specified requirements and initiate actions when non-conforming work occurs (see 7.5)? |  |  |
|  | When applicable, does the laboratory decontaminate equipment before service, repair or decommissioning?Does the laboratory provide suitable space for repairs and appropriate personal protective equipment? |  |  |
| **6.4.6** | **Equipment adverse incident reporting** |  |  |
|  | Are adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required? |  |  |
|  | Does the laboratory have procedures for responding to any manufacturer’s recall or other notice, and taking actions recommended by the manufacturer? |  |  |
| **6.4.7** | **Equipment records** |  |  |
|  | Are records maintained for each item of equipment that influences the results of laboratory activities? |  |  |
|  | Do these records include the following, where relevant: 1. manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;
 |  |  |
|  | 1. dates of receipt, acceptance testing and entering into service;
 |  |  |
|  | 1. evidence that equipment conforms with specified acceptability criteria;
 |  |  |
|  | 1. the current location;
 |  |  |
|  | 1. condition when received (e.g. new, used or reconditioned);
 |  |  |
|  | 1. manufacturer's instructions;
 |  |  |
|  | 1. the programme for preventive maintenance;
 |  |  |
|  | 1. any maintenance activities performed by the laboratory or approved external service provider;
 |  |  |
|  | 1. damage to, malfunction, modification, or repair of the equipment;
 |  |  |
|  | 1. equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results;
 |  |  |
|  | 1. status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete?
 |  |  |
|  | Are these records maintained and readily available for the lifespan of the equipment or longer, as specified in 8.4.3? |  |  |
| **6.5** | **Equipment calibration and metrological traceability** |  |  |
| **6.5.1** | **General** |  |  |
|  | Does the laboratory specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results?For quantitative methods of a measured analyte, do specifications include calibration and metrological traceability requirements? Do qualitative methods and quantitative methods that measure characteristics rather than discrete analytes specify:- the characteristic being assessed and - requirements necessary for reproducibility over time? |  |  |
| **6.5.2** | **Equipment calibration** |  |  |
|  | Does the laboratory have procedures for the calibration of equipment that directly or indirectly affects examination results?Do the procedures specify: 1. conditions of use and manufacturer’s instructions for calibration;
 |  |  |
|  | 1. recording of the metrological traceability;
 |  |  |
|  | 1. verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;
 |  |  |
|  | 1. recording the calibration status and date of re-calibration;
 |  |  |
|  | 1. ensuring that, where correction factors are used, these are updated and recorded when re-calibration occurs;
 |  |  |
|  | 1. handling of situations when calibration was out of control, to minimize risk to service operation and to patients?
 |  |  |
| **6.5.3** | **Metrological traceability of measurement results** |  |  |
| 1. a)
 | Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? |  |  |
| 1. b)
 | Does the laboratory ensure that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:* -Calibration provided by a competent laboratory; or
* -Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI?
 |  |  |
| 1. c)
 | Where it is not possible to provide traceability according to 6.5.3 a), are other means for providing confidence in the results applied, including but not limited to the following:* - Results of reference measurement procedures, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison;
* - Measurement of calibrator by another procedure?
 |  |  |
| 1. d)
 | For genetic examinations, is traceability to genetic reference sequences established? |  |  |
| 1. e)
 | For qualitative methods, is traceability demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction? |  |  |
| **6.6** | **Reagents and consumables**  |  |  |
| **6.6.1** | **General** |  |  |
|  | Does the laboratory have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables? |  |  |
| **6.6.2** | **Reagents and consumables – Receipt and storage** |  |  |
|  | Does the laboratory store reagents and consumables according to manufacturers’ specifications and monitor the environmental conditions where relevant? |  |  |
|  | When the laboratory is not the receiving facility, does it verify that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration? |  |  |
| **6.6.3** | **Reagents and consumables – Acceptance testing** |  |  |
|  | Is each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, verified for performance before placing into use, or before release of results, as appropriate?Are consumables that can affect the quality of examinations verified for performance before placing into use? |  |  |
| **6.6.4** | **Reagents and consumables – Inventory management** |  |  |
|  | Has the laboratory established an inventory management system for reagents and consumables? |  |  |
|  | Does the system for inventory management segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use? |  |  |
| **6.6.5** | **Reagents and consumables – Instructions for use** |  |  |
|  | Are instructions for the use of reagents and consumables, including those provided by the manufacturers, readily available?Are reagents and consumables used according to the manufacturer's specifications? If they are intended to be used for other purposes see 7.3.3. |  |  |
| **6.6.6** | **Reagents and consumables – Adverse incident reporting** |  |  |
|  | Are adverse incidents and accidents that can be attributed directly to specific reagents or consumables investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required?Does the laboratory have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer? |  |  |
| **6.6.7** | **Reagents and consumables - Records** |  |  |
|  | Are records maintained for each reagent and consumable that contributes to the performance of examinations?Do these records include, but not limited to, the following: 1. Identity of the reagent or consumable;
 |  |  |
|  | 1. manufacturer's information, including instructions, name and batch code or lot number;
 |  |  |
|  | 1. date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service;
 |  |  |
|  | 1. records that confirm the reagent's or consumable's initial and ongoing acceptance for use?
 |  |  |
|  | Where the laboratory uses reagents prepared, resuspended or combined in-house, do the records include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry? |  |  |
| **7** | **Process requirements** |  |  |
| **7.1** | **General** |  |  |
|  | Does the laboratory identify potential risks to patient care in the pre-examination, examination and post-examination processes?Are these risks assessed and mitigated to the extent possible?Is the residual risk communicated to users as appropriate? |  |  |
|  | Are the identified risks and effectiveness of the mitigation processed monitored and evaluated according to the potential harm to the patient? |  |  |
|  | Does the laboratory also identify opportunities to improve patient care and develop a framework to manage these opportunities? (see 8.5) |  |  |
| **7.2** | **Pre-examination processes** |  |  |
| **7.2.1** | **General** |  |  |
|  | Does the laboratory have procedures for all pre-examination activities and make them accessible to relevant personnel? |  |  |
| **7.2.2** | **Laboratory information for patients and users** |  |  |
|  | Does the laboratory have appropriate information available for its users and patients?Is the information sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory’s scope of activities and requirements? |  |  |
|  | Does the information include as appropriate:1. the location(s) of the laboratory, operating hours and contact information;
 |  |  |
|  | 1. the procedures for requesting and the collection of samples;
 |  |  |
|  | 1. the scope of laboratory activities and time for expected availability of results;
 |  |  |
|  | 1. the availability of advisory services;
 |  |  |
|  | 1. requirements for patient consent;
 |  |  |
|  | 1. factors known to significantly impact the performance of the examination or the interpretation of the results;
 |  |  |
|  | 1. the laboratory complaint process?
 |  |  |
| **7.2.3** | **Requests for providing laboratory examination** |  |  |
| **7.2.3.1** | **General** |  |  |
|  | Is each request accepted by the laboratory for examination(s) considered as an agreement? |  |  |
|  | Does the examination request provide sufficient information to ensure:* unequivocal traceability of the patient to the request and sample;
* identity and contact information of requester;
* identification of the examination(s) requested;
* informed clinical and technical advice, and clinical interpretation can be provided?
 |  |  |
|  | Is the examination request information provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user? |  |  |
|  | Where necessary for patient care, does the laboratory communicate with users or their representatives, to clarify the user’s request? |  |  |
| **7.2.3.2** | **Oral requests** |  |  |
|  | Does the laboratory have a procedure for managing oral requests for examinations, if applicable, that includes the provision of documented confirmation of the examination request to the laboratory, within a given time? |  |  |
| **7.2.4** | **Primary sample collection and handling** |  |  |
| **7.2.4.1** | **General** |  |  |
|  | Does the laboratory have procedures for the collection and handling of primary samples?Is information available to those responsible for sample collection? |  |  |
|  | Is deviation from the established collection procedures clearly recorded?Are the potential risk and impact on the patient outcome of acceptance or rejection of the sample assessed, recorded and communicated to the appropriate personnel? |  |  |
|  | Does the laboratory periodically review requirements for sample volume, collection device and preservatives for all sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte? |  |  |
| **7.2.4.2** | **Information for pre-collection activities** |  |  |
|  | Does the laboratory provide information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised? |  |  |
|  | Does this include:1. preparation of the patient (e.g. instructions to caregivers, sample collectors and patients);
 |  |  |
|  | 1. type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives, and when relevant the order of collecting samples;
 |  |  |
|  | 1. special timing of collection, where relevant;
 |  |  |
|  | 1. provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs);
 |  |  |
|  | 1. sample labelling for unequivocal identification of the patient, as well as source and site of sample,

and labelling, when several samples from the same patient are to be collected, including multiple pieces of tissue or slides; |  |  |
|  | 1. the laboratory’s criteria for acceptance and rejection of samples specific to the examinations requested?
 |  |  |
| **7.2.4.3** | **Patient consent** |  |  |
| a) | Does the laboratory obtain the informed consent of the patient for all procedures carried out on the patient? |  |  |
|  | Do special procedures, including more invasive procedures, or those with an increased risk ofcomplications to the procedure, need a more detailed explanation and, in some cases, recordedconsent? |  |  |
|  | If obtaining consent is not possible in emergency situations, does the laboratory carry out necessaryprocedures, provided they are in the patient’s best interest? |  |  |
| **7.2.4.4** | **Instructions for collection activities** |  |  |
|  | To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, does the laboratory provide instructions for: |  |  |
|  | 1. verification of the identity of the patient from whom a primary sample is collected;
 |  |  |
|  | 1. verification and when relevant, recording that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals];
 |  |  |
|  | 1. collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant;
 |  |  |
|  | 1. labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;
 |  |  |
|  | 1. recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time;
 |  |  |
|  | 1. requirements for separating or dividing the primary sample when necessary;
 |  |  |
|  | 1. stabilization and proper storage conditions before collected samples are delivered to the laboratory;
 |  |  |
|  | 1. safe disposal of materials used in the collection process?
 |  |  |
| **7.2.5** | **Sample transportation** |  |  |
|  | To ensure the timely and safe transportation of samples, does the laboratory provide instructions for:1. packaging of samples for transportation;
 |  |  |
|  | 1. ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations;
 |  |  |
|  | 1. maintaining the temperature interval specified for sample collection and handling;
 |  |  |
|  | 1. any specific requirements to ensure integrity of samples, e.g. use of designated preservatives?
 |  |  |
|  | If the integrity of a sample has been compromised and there is a health risk, is the organization responsible for the transport of the sample notified immediately and action taken to reduce the risk and to prevent recurrence? |  |  |
|  | Does the laboratory establish and periodically evaluate adequacy of sample transportation systems? |  |  |
| **7.2.6** | **Sample receipt** |  |  |
| **7.2.6.1** | **Sample receipt procedure** |  |  |
|  | Does the laboratory have a procedure for sample receipt that includes:1. the unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable the anatomical site;
 |  |  |
|  | 1. criteria for acceptance and rejection of samples;
 |  |  |
|  | 1. recording the date and time of receipt of the sample when relevant;
 |  |  |
|  | 1. recording the identity of the person receiving the sample, when relevant;
 |  |  |
|  | 1. evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s);
 |  |  |
|  | 1. instructions for samples specifically marked as urgent, which include details of special labelling, transport, any rapid processing method, turnaround times, and special reporting criteria to be followed;
 |  |  |
|  | 1. ensuring that all portions of the sample shall be unequivocally traceable to the original sample?
 |  |  |
| **7.2.6.2** | **Sample acceptance exceptions** |  |  |
|  | Does the laboratory have a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to1. incorrect patient or sample identification,
2. sample instability due to, for example, delay in transport,
3. incorrect storage or handling temperature,
4. inappropriate container(s), and
5. insufficient sample volume?
 |  |  |
|  | When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, does the final report indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected? |  |  |
| **7.2.7** | **Pre-examination handling, preparation, and storage** |  |  |
| **7.2.7.1** | **Sample protection** |  |  |
|  | Does the laboratory have procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during handling, preparation and storage? |  |  |
| **7.2.7.2** | **Criteria for additional examination requests** |  |  |
|  | Do laboratory procedures include time limits for requesting additional examinations on the same sample? |  |  |
| **7.2.7.3** | **Sample stability** |  |  |
|  | Considering the stability of the analyte in a primary sample, is the time between sample collection and performing the examination specified and monitored where relevant? |  |  |
| **7.3** | **Examination processes** |  |  |
| **7.3.1** | **General** |  |  |
|  | Does the laboratory select and use examination methods which have been validated for their intended use to assure the clinical accuracy of the examination for patient testing? |  |  |
|  | Do the performance specifications for each examination method relate to the intended use of that examination and its impact on patient care? |  |  |
|  | Are all procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and be readily available to personnel? |  |  |
|  | Do personnel follow established procedures and is the identity of persons performing significant activities in examination processes recorded, including POCT operators? |  |  |
|  | Do authorized personnel periodically evaluate the examination methods provided by the laboratory to ensure they are clinically appropriate for the requests received? |  |  |
| **7.3.2**  | **Verification of examination methods** |  |  |
|  | Does the laboratory have a procedure to verify that it can properly perform examination methods before introducing into use, by ensuring that the required performance, as specified by the manufacturer or method, can be achieved? |  |  |
|  | Are the performance specifications for the examination method confirmed during the verification process those relevant to the intended use of the examination results? |  |  |
|  | Does the laboratory ensure the extent of the verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making? |  |  |
|  | Do personnel with the appropriate authorization and competence review the verification results and record whether the results meet the specified requirements? |  |  |
|  | If a method is revised by the issuing body, does the laboratory repeat verification to the extent necessary? |  |  |
|  | Are the following records of verification retained:1. performance specifications to be achieved,
 |  |  |
|  | 2) results obtained, and |  |  |
|  | 1. a statement of whether the performance specifications were achieved and if not, action taken?
 |  |  |
| **7.3.3** | **Validation of examination methods** |  |  |
|  | Does the laboratory validate examination methods derived from the following sources:1. laboratory designed or developed methods;
 |  |  |
|  | 1. methods used outside their originally intended scope (i.e. outside of the manufacturer's instructions for use, or original validated measurement range, third party reagents used on instruments other than intended instruments and where no validation data is available);
 |  |  |
|  | 1. validated methods subsequently modified?
 |  |  |
|  | Is the validation as extensive as is necessary and confirmed, through the provision of objective evidence in the form of performance specifications, that the specific requirements for the intended use of the examination have been fulfilled?Does the laboratory ensure that the extent of validation of an examination method is sufficient to ensure the validity of results pertinent to clinical decision making? |  |  |
|  | Do personnel with the appropriate authorization and competence review the validation results and record whether the results meet the specified requirements? |  |  |
|  | When changes are proposed to a validated examination method, is the clinical impact reviewed, and a decision made as to whether to implement the modified method? |  |  |
|  | Are the following records of validation retained:1. the validation procedure used;
 |  |  |
|  | 1. specific requirements for the intended use;
 |  |  |
|  | 1. determination of the performance specifications of the method;
 |  |  |
|  | 1. results obtained;
 |  |  |
|  | 1. a statement on the validity of the method, detailing its fitness for the intended use?
 |  |  |
| **7.3.4** | **Evaluation of measurement uncertainty (MU)** |  |  |
|  | Are the MU of measured quantity values evaluated and maintained for its intended use, where relevant?Is the MU compared against performance specifications and documented? |  |  |
|  | Are MU evaluations regularly reviewed? |  |  |
|  | For examination procedures where evaluation of MU is not possible or relevant, is the rationale for exclusion from MU estimation documented? |  |  |
|  | Is MU information made available to laboratory users on request? |  |  |
|  | When users have inquiries on MU, does the laboratory’s response take into account other sources of uncertainty, such as, but not limited to biological variation? |  |  |
|  | If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, is MU in the output quantity estimated using representative positive and negative samples? |  |  |
|  | For examination with qualitative results, are MU in intermediate measurement steps or IQC results which produce quantitative data also considered for key (high risk) parts of the process? |  |  |
|  | Is MU taken into consideration when performing verification or validation of a method, when relevant? |  |  |
| **7.3.5** | **Biological reference intervals and clinical decision limits** |  |  |
|  | Are biological reference intervals and clinical decision limits, when needed for interpretation of examination results, defined and communicated to users? |  |  |
|  | Are biological reference intervals and clinical decision limits defined, and their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients? |  |  |
|  | Are biological reference intervals and clinical decision limits periodically reviewed, and any changes communicated to users? |  |  |
|  | When changes are made to an examination or pre-examination method, does the laboratory review the impact on associated biological reference intervals and clinical decision limits and communicate to the users when applicable? |  |  |
|  | For examinations that identify presence or absence of a characteristic, is the biological reference interval the characteristic to be identified, e.g. genetic examinations? |  |  |
| **7.3.6** | **Documentation of examination procedures** |  |  |
|  | Does the laboratory document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results? |  |  |
|  | Are procedures written in a language understood by laboratory personnel and available in appropriate locations? |  |  |
|  | Does any abbreviated document content correspond to the procedure? |  |  |
|  | Can information from product instructions for use, that contain sufficient information, be incorporated into procedures by reference? |  |  |
|  | When the laboratory makes a validated change to an examination procedure which could affect interpretation of results, are the implications of this explained to users? |  |  |
|  | Are all documents associated with the examination process subjected to document control? (see 8.3) |  |  |
| **7.3.7** | **Ensuring the validity of examination results** |  |  |
| **7.3.7.1** | **General** |  |  |
|  | Does the laboratory have a procedure for monitoring the validity of results?Are the resulting data recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques are applied to review the results?Is this monitoring planned and reviewed? |  |  |
| **7.3.7.2** | **Internal quality control (IQC)** |  |  |
|  | Does the laboratory have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making? |  |  |
| 1. Is the intended clinical application of the examination considered, as the performance specifications for the same measurand can differ in different clinical settings?
 |  |  |
| 1. Does the procedure also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method?

To enable this, does the laboratory procedure avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both? |  |  |
| 1. Is the use of third-party IQC material considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer?
 |  |  |
|  | Does the laboratory select IQC material that is fit for its intended purpose?When selecting IQC material, do factors to be considered include: |  |  |
| 1. stability with regard to the properties of interest;
 |  |  |
| 1. the matrix is as close as possible to that of patient samples;
 |  |  |
| 1. the IQC material reacts to the examination method if a manner as close as possible to patient samples;
 |  |  |
|  | 1. the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method?
 |  |  |
|  | If appropriate IQC material is not available, does the laboratory consider the use of other methods for IQC? Does examples of such other methods include: |  |  |
|  | 1. trend analysis of patient results, e.g. with moving average of patient results, or percentage of samples with results below or above certain values or associated with a diagnosis;
 |  |  |
|  | 1. comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references as specified in ISO 17511;
 |  |  |
|  | 1. retesting of retained patient samples?
 |  |  |
|  | Is IQC performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result? |  |  |
|  | Is the resulting data recorded in such a way that trends and shifts are detectable and, where applicable, are statistical techniques applied to review the results? |  |  |
|  | Is IQC data reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance? |  |  |
|  | Does the laboratory prevent the release of patient results in the event that IQC fails the defined acceptability criteria? |  |  |
|  | 1. When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, are the results rejected and relevant patient samples re-examined after the error has been corrected? (see 7.5)
 |  |  |
|  | 1. Are the results from patient samples that were examined after the last successful IQC event evaluated?
 |  |  |
| **7.3.7.3** | **External quality assessment (EQA)** |  |  |
|  | Does the laboratory monitor its performance of examination methods, by comparison with results of other laboratories?Does this include participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods? |  |  |
|  | Has the laboratory established a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available? |  |  |
|  | Are EQA samples processed by personnel who routinely perform pre-examination, examination, and post-examination procedures? |  |  |
|  | Do the EQA programme(s) selected by the laboratory, to the extent possible:1. have the effect of checking pre-examination, examination, and post-examination processes;
 |  |  |
|  | 1. provide samples that mimic patient samples for clinically relevant challenges;
 |  |  |
|  | 1. fulfill ISO/IEC 17043 requirements?
 |  |  |
|  | When selecting EQA programme(s), does the laboratory consider the type of target value offered?Target values are:1. independently set by a reference method, or
2. set by overall consensus data, and/or
3. set by method peer group consensus data, or
4. set by a panel of experts.
 |  |  |
|  | When an EQA programme is either not available, or not considered suitable, does the laboratory use alternative methodologies to monitor examination method performance?Does the laboratory justify the rationale for the chosen alternative and provide evidence of its effectiveness? |  |  |
|  | Is EQA data reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance? |  |  |
|  | Where EQA results fall outside specified acceptability criteria, is appropriate action taken (see 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples? |  |  |
|  | Where it is determined that the impact is clinically significant, is a review of patient results that could have been affected and the need for amendment considered and are users advised as appropriate? |  |  |
| **7.3.7.4** | **Comparability of examination results** |  |  |
|  | When either different methods of equipment, or both, are used for an examination, and/or the examination is performed at different sites, is a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals specified? |  |  |
|  | Does the laboratory record the results of comparability performed and its acceptability? |  |  |
|  | Does the laboratory periodically review the comparability of results? |  |  |
|  | Where differences are identified, is the impact of those differences on biological reference intervals and clinical decision limits evaluated and acted upon? |  |  |
|  | Does the laboratory inform users of any clinically significant differences in comparability of results? |  |  |
| **7.4**  | **Post-examination processes** |  |  |
| **7.4.1** | **Reporting of results** |  |  |
| **7.4.1.1** | **General** |  |  |
|  | Are examination results reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure?Does the report include all available information necessary for the interpretation of the results? |  |  |
|  | Does the laboratory have a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient? |  |  |
|  | Is all information associated with issued reports retained in accordance with management system requirements? (see 8.4) |  |  |
| **7.4.1.2** | **Result review and release** |  |  |
|  | Are results reviewed and authorized prior to release? |  |  |
|  | Does the laboratory ensure that authorized personnel review the results of examinations and evaluate them against IQC and, as appropriate, available clinical information and previous examination results? |  |  |
|  | Are responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, specified? |  |  |
| **7.4.1.3** | **Critical result reports** |  |  |
|  | When examination results fall within established critical decision limits:1. Is the user or other authorized person notified as soon as relevant, based on clinical information available?
 |  |  |
|  | 1. Are actions taken documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification?
 |  |  |
|  | 1. Does the laboratory have an escalation procedure for laboratory personnel when a responsible person cannot be contacted?
 |  |  |
| **7.4.1.4** | **Special considerations for results** |  |  |
|  | When agreed with the user, are the results reported in s simplified way?Is any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user readily available? |  |  |
|  | When results are transmitted as a preliminary report, is the final report always forwarded to the user? |  |  |
|  | Are records kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b)?Are such results always followed by a report? |  |  |
|  | Is special counselling needed for examination results with serious implications for the patient (e.g. for genetic or certain infectious diseases)?Does laboratory management ensure that these results are not communicated to the patient without the opportunity for adequate counselling? |  |  |
|  | Are results of laboratory examinations that have been anonymized used for such purposes as epidemiology, demography, or other statistical analyses, provided that all risks to patient privacy and confidentiality are mitigated and in accordance with any either legal or regulatory requirements, or both? |  |  |
| **7.4.1.5** | **Automated selection, review, release and reporting of results** |  |  |
|  | When the laboratory implements a system for automated selection, review, release and reporting of results, has a procedure been established to ensure that: |  |  |
|  | 1. the criteria for automated selection, review and release are specified, approved, readily available and understood by personnel responsible for authorizing the release of results;
 |  |  |
|  | 1. the criteria are validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning and place patients care at risks;
 |  |  |
|  | 1. results selected by an automated reporting system for manual review are identifiable; and as appropriate, date and time of selection and review, as well as identity of the reviewer are retrievable;
 |  |  |
|  | 1. when necessary, rapid suspension of automated selection, review, release and reporting is applied?
 |  |  |
| **7.4.1.6** | **Requirements for reports** |  |  |
|  | Does each report include the following information, unless the laboratory has documented reasons for omitting any items: |  |  |
|  | 1. unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report;
 |  |  |
|  | 1. identification of the laboratory issuing the report;
 |  |  |
|  | 1. name or other unique identifier of the user;
 |  |  |
|  | 1. type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description);
 |  |  |
|  | 1. clear, unambiguous identification of the examinations performed;
 |  |  |
|  | 1. identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle;
 |  |  |
|  | 1. examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units;
 |  |  |
|  | 1. biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary;
 |  |  |
|  | 1. identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;
 |  |  |
|  | 1. identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);
 |  |  |
|  | 1. identification of any results that need to be considered as preliminary;
 |  |  |
|  | 1. indications of any critical results;
 |  |  |
|  | 1. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end (e.g. page number total number of pages)?
 |  |  |
| **7.4.1.7** | **Additional information for reports** |  |  |
|  | When necessary for patient care, is the time of primary sample collection included? |  |  |
|  | Is time of report release, if not contained in the report, readily available when needed? |  |  |
|  | Does the report identify all examinations or parts of examinations performed by a referral laboratory, including information provided by consultants, without alteration, as well as the name of the laboratory performing the examinations? |  |  |
|  | When applicable, does a report include interpretation of results and comments on:1. sample quality and suitability that can compromise the clinical value of examination results;
 |  |  |
|  | 1. discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;
 |  |  |
|  | 1. possible risk of misinterpretation when different units of measurement are in use regionally or nationally;
 |  |  |
|  | 1. result trends or significant changes over time?
 |  |  |
| **7.4.1.8** | **Amendments to reported results** |  |  |
|  | Do procedures for the issue of amended or revised results ensure that:1. the reason for change is recorded and included in the revised report, when relevant?
 |  |  |
|  | 1. revised results are delivered only in the form of an additional document or data transfer, and clearly identified as having been revised, and the date and patient’s identity in the original report indicated?
 |  |  |
|  | 1. the user is made aware of the revision?
 |  |  |
|  | 1. when it is necessary to issue a completely new report, this is uniquely identified and contain a reference and traceability to the original report that it replaces?
 |  |  |
|  | 1. when the reporting system cannot capture revisions, a record of such is kept?
 |  |  |
| **7.4.2** | **Post-examination handling of samples** |  |  |
|  | Does the laboratory specify the length of time samples are to be retained following examination and the conditions under which samples are to be stored? |  |  |
|  | Does the laboratory ensure that after the examination, the1. patient and source identification of the sample are maintained,
 |  |  |
|  | 1. suitability of the sample for additional examination is known,
 |  |  |
|  | 1. sample is stored in a manner that optimally preserves suitability for additional examination,
 |  |  |
|  | 1. sample can be located and retrieved, and
 |  |  |
|  | 1. sample is discarded appropriately?
 |  |  |

🗆**The Assessor/MS has performed review of the documentation of the laboratory prior to the assessment.**

**Verified by: Name:………………………………………. Signature:………………………………….. Date:…………………**