DOCUMENT REVIEW REPORT FOR MEDICAL LABORATORIES – ISO 15189:2022

Initial Assessment ☐ Scope Extension ☐ Reassessment ☐ Other(Specify) ☐

NAME OF FACILITY	
REFERENCE NUMBER	
DOCUMENTS RECEIVED BY ASSESSMENT TEAM (Enter Date)	
DOCUMENT REVIEW CONDUCTED BY: *(List Names of Team Leader and Assessors/Technical Experts conducting the Document Review)*	
DATE OF SUBMISSION OF DOCUMENT REVIEW REPORT TO SADCAS BY TEAM LEADER	

SECTION 1: INTRODUCTION

The supplied documents were reviewed against the ISO 15189:2022 standard requirements, SADCAS requirements, ILAC P9 – Policy on Participating in Proficiency Testing Activities, ILAC P10 - Policy on Metrological Traceability of Measurement Results and ILAC P 14 - Policy for Measurement Uncertainty in Calibrations.

SECTION 2: REVIEW AGAINST F 43 (c) - APPLICATION FOR ACCREDITATION OF MEDICAL LABORATORYORATORY

Part 1- General Information
Part 2- Information regarding the organization
Part 3: Information on Senior Staff
Part 4- Scope of application

Part 5: Declaration

ISO 15189:2022 **MEDICAL LABORATORIES** **DOCUMENT REVIEW REPORT**	Organisation's SADCAS No/s:

Date/s of evaluation	
Name of Organisation	
Organisation Representative	
Area/Field of Operation	
Assessor/s & Observers	

REQUIREMENTS & COMMENTS.

NOTE 1: *For* ***CAB's comments****: Please add in this column* ***ONLY*** *the following information with respect to your management system documentation manual or procedures:*

- *Document name/number where this clause is referenced;*
- *Page number where this clause is referenced; and*
- *Paragraph number (if applicable) where this clause is referenced.*

NOTE 2: *For* ***Assessor's Comments****: The Assessor must provide information on the CAB's conformity with the requirements*

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
1.	Does the scope of accredited tests include only the tests that are performed by the Laboratory?		To be evaluated during the initial assessment.
2.	Do the relevant staff have access to SADCAS documentation?		
3.	Is a current list of approved signatories for each discipline within the laboratory available?		
4.	Where the laboratory is authorised to use the SADCAS accreditation symbol and/or Combine Mark, is this done in compliance with SADCAS R04?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
4. GENERAL REQUIREMENTS			
4.1 Impartiality			
a)	Are laboratory activities undertaken impartially? How is the laboratory structured and managed to safeguard impartiality?		
b)	What evidence is available to show management's commitment to impartiality?		
c)	What measures are in place to ensure that the laboratory takes responsibility for the impartiality of its activities and does not allow commercial, financial or other pressures to compromise impartiality?		
d)	Does the laboratory monitor its activities and relationships to identify threats to its impartiality? Does this monitoring include relationships of its personnel? *NOTE: A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts,*		

e)	*marketing & branding, payment of sales commission or other inducement for the referral of new laboratory users, etc? Such relationships do not necessarily present the laboratory with a threat to impartiality.* If a threat to impartiality is identified, how does the laboratory mitigate such threats to ensure the effect is eliminated or minimised so that the impartiality is not compromised?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
4.2	**Confidentiality**		
4.2.1	**Management of Information** Is the laboratory responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities? Does the management of patient information include privacy and confidentiality? Does the laboratory inform the user and/or the patient in advance, of the information it intends to place in the public domain? Except for information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g., for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?		
4.2.2	**Release of information** When the laboratory is required by law or authorized by contractual arrangements to release confidential information, does the laboratory notify the patient concerned of the information released, unless prohibited by law? Does the laboratory keep information about the patient from a source other than the patient (e.g., complainant, regulator) confidential? Does the laboratory keep the identity of the source confidential and not share it with the patient, unless agreed by the source?		

4.2.3	**Personnel responsibility** Do personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities?		

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4.3	**Requirements regarding patients**		
	Does the laboratory management ensure that patients' well-being, safety and rights are the primary considerations? Has the laboratory established and implemented the following processes:		
a)	opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results;		
b)	provision of patients and users with publicly available information about the examination process, including costs when applicable, and when to expect results;		
c)	periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary;		
d)	where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;		
e)	treatment of patients, samples, or remains, with due care and respect;		
f)	obtaining informed consent when required;		
g)	ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;		
h)	making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;		

i)	upholding the rights of patients to care that is free from discrimination?		
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5. STRUCTURAL AND GOVERNANCE REQUIREMENTS			
5.1	**Legal Entity**		
	Is the laboratory or the organization of which the laboratory is a part an entity that can be held legally responsible for its activities? *NOTE: A government laboratory is deemed to be a legal entity on the basis of its government status.*		
5.2	**Laboratory Director**		
5.2.1	**Laboratory director competence** Is the laboratory directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document?		
5.2.2	**Laboratory director responsibilities** Is the laboratory director responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed? Are the duties and responsibilities of the laboratory director documented?		
5.2.3	**Delegation of duties**		

	Has the laboratory director delegated either selected duties or responsibilities, or both, to qualified and competent personnel and is such delegation documented? However, does the laboratory director maintain the ultimate responsibility for the overall operation of the laboratory?		

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5.3	**Laboratory Activities**		
5.3.1	**General** Does the laboratory specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g., POCT, sample collection) for which it conforms with this document? Does the laboratory only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis?		
5.3.2	**Conformance with requirements** Does the laboratory carry out its activities in such a way as to meet the requirements of this document, the users, regulatory authorities and organizations providing recognition? Does this apply to the complete range of specified and documented laboratory activities, regardless of where the service is provided?		
5.3.3	**Advisory activities**		

	How does the laboratory management ensure that appropriate laboratory advice and interpretation are available, and does it meet the needs of patients and users? What arrangements has the laboratory established for communicating with laboratory users on the following when applicable: a) advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods~~,~~ and the frequency of requesting the examination; b) providing professional judgments on the interpretation of the results of examinations; c) promoting the effective utilization of laboratory examinations; d) advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria.		

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5.4	**Structure and Authority**		
5.4.1	**General** Has the laboratory: a) defined its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services? b) specified the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities? c) specified its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results?		
5.4.2	**Quality management** Does the laboratory have personnel who, irrespective of other		

	responsibilities, have the authority and resources needed to carry out their duties, including:		
a)	implementation, maintenance and improvement of the management system?		
b)	identification of deviations from the management system or from the procedures for performing laboratory activities?		
c)	initiation of actions to prevent or minimize such deviations?		
d)	reporting to laboratory management on the performance of the management system and any need for improvement?		
e)	ensuring the effectiveness of laboratory activities?		
	NOTE These responsibilities can be assigned to one or more persons.		

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5.5 Objectives and Policies			
a)	Has the laboratory management established, and do they maintain objectives and policies (see 8.2) to: 1) meet the needs and requirements of its patients and users; 2) commit to good professional practice; 3) provide examinations that fulfil their intended use; 4) conform to this document.		
b)	Are objectives measurable, and consistent with policies? How does the laboratory ensure that the objectives and policies are implemented at all levels of the laboratory organization?		

c)	How does the laboratory management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?		
d)	Has the laboratory established quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives? (see 8.8.2). *NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.*		

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5.6	**Risk Management**		
a)	Has laboratory management established, implemented, and maintained processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and have actions been developed to address both risks and opportunities for improvement? (see 8.5).		
b)	Does the laboratory director \ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective? *NOTE 1 ISO 22367 provides details for managing risk in medical laboratories.*		

	NOTE 2 ISO 35001 provides details for laboratory biorisk management.		

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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** a) 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, ethically, be competent and work in accordance with the laboratory's management system. NOTE ISO/TS 22583 provides guidance for supervisors and operators of POCT equipment. 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 requirement a) 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. b) Does the laboratory ensure all personnel have the competence to perform laboratory activities for which they are responsible. c) Does the laboratory have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment. d) Does the laboratory have documented information demonstrating competence of its personnel. NOTE Examples of competence assessment methods that can be used in any combination include: — direct observation of an activity, — monitoring the recording and reporting of examination results.- review of work records, — assessment of problem-solving skills, — examination of specially provided samples, e.g previously examined samples, interlaboratory comparison materials, or split samples.		
6.2.3.	**Authorization** a) Does the laboratory authorize personnel to perform specific laboratory activities, including but not limited to, the following: selection, development, modification, validation and verification of methods; b) review, release, and reporting of results; c) 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 shall be periodically reviewed.		

6.2.5.	**Personnel records** Does the laboratory have procedures and retain records for: **a)** determining the competence requirements specified in 6.2.2 a); **b)** position descriptions; **c)** training and re-training; **d)** authorization of personnel; **e)** monitoring competence of personnel.		
6.3.	**Facilities and environmental conditions**		
6.3.1.	**General** Are facilities and environmental conditions suitable for the laboratory activities to ensure the validity of results, or the safety of patients, visitors, laboratory users, and personnel. Are the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities specified, monitored, and recorded? NOTE 1 ISO 15190 provides details for facility and environmental conditions. NOTE 2 Environmental conditions that can adversely affect the validity of results include, but are not limited to: adventitious amplified nucleic acid, microbial contamination, dust, electromagnetic disturbances, radiation, lighting conditions (illumination), humidity, electrical supply, temperature, sound and vibration.		
6.3.2.	**Facility controls** Are facility controls implemented, recorded, monitored, periodically reviewed, and include: a) control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical		

	information and patient samples; b) prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal; c) prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation; d) provision of safety facilities and devices, where applicable and regularly verifying their functioning; EXAMPLES The operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers, accessibility of emergency showers, eyewash and resuscitation equipment. e) e) maintenance of laboratory facilities in a functional and reliable condition.		
6.3.3.	**Storage facilities** **a)** Storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records, are be provided. **b)** Patient samples and materials used in examination processes are stored in a manner that prevents cross contamination and deterioration. **c)** Storage and disposal facilities for hazardous materials and biological waste are 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 be provided?		
6.3.5.	**Sample collection facilities** Do sample collection facilities meet the following requirements? a) enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations; b) 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; c) provide separate patient reception and collection areas; d) maintain first aid materials for both patients and personnel. NOTE ISO 20658 provides details for sample collection facilities		
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. NOTE Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory		

	information systems, or any equipment that influences the results of laboratory activities, including sample transportation systems.		
6.4.2.	**Equipment requirements** a) Does the laboratory have access to equipment required for the correct performance of laboratory activities. b) 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. c) Is each item of equipment that can influence laboratory activities uniquely labelled, marked or otherwise identified and a register maintained. d) 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. Equipment used for measurement shall be capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result (see 7.3.3 and 7.3.4 for details). NOTE 1 This includes equipment used in the laboratory, equipment on loan, or equipment used in point of care settings, or in associated or mobile facilities, authorized by the laboratory.		

	NOTE 2 The verification of equipment acceptance testing can be, where relevant, based on the calibration certificate of the returned equipment.		
6.4.4.	**Equipment instructions for use** **a)** Does the laboratory have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results. **b)** Are equipment operated by trained, authorized, and competent personnel. **c)** Are instructions for the use of equipment, including those provided by the manufacturer, readily available. **d)** Are equipment used as specified by the manufacturer, unless validated by the laboratory (see 7.3.3).		
6.4.5.	**Equipment maintenance and repair** a) Does the laboratory have preventive maintenance programmes, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions shall be recorded. b) 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. c) 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). d) When applicable, does the laboratory		

	decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.		
6.4.6.	**Equipment adverse incident reporting** Adverse incidents and accidents that can be attributed directly to specific equipment are 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** Records are maintained for each item of equipment that influences the results of laboratory activities. These records include the following, where relevant: a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware; b) dates of receipt, acceptance testing and entering into service; c) evidence that equipment conforms with specified acceptability criteria; d) the current location; e) condition when received (e.g. new, used or reconditioned); f) manufacturer's instructions; g) the programme for preventive maintenance; h) any maintenance activities performed by the laboratory or approved external service provider; i) damage to, malfunction, modification, or repair of the equipment;		

	j) equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results; k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete. These records shall be maintained and shall be 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. Qualitative methods and quantitative methods that measure characteristics rather than discrete analytes specify the characteristic being assessed and such requirements necessary for reproducibility over time. NOTE Examples of qualitative methods and quantitative methods that may not allow metrological traceability include red cell antibody detection, antibiotic sensitivity assessment, genetic testing, erythrocyte sedimentation rate, flow cytometry marker staining, and tumour HER2 immunohistochemical staining		
6.5.2.	**Equipment calibration** Does the laboratory have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures specifies the following: a) conditions of use and manufacturer's instructions for calibration;		

	b) recording of the metrological traceability; c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals; d) recording the calibration status and date of re-calibration; e) ensuring that, where correction factors are used, these are updated and recorded when recalibration occurs; f) 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** 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. NOTE Information of traceability to a higher order reference material or reference procedure can be provided by an examination system manufacturer. Such documentation is acceptable only when the manufacturer's examination system and calibration procedures are used without modification. 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 NOTE 1 Calibration laboratories fulfilling the requirements of ISO/IEC 17025 are considered competent for performing		

	calibrations. — certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent. NOTE 3 Certified reference material fulfilling the requirements of ISO 15194 are considered suitable c) Where it is not possible to provide traceability according to 6.5.3 a), other means for providing confidence in the results are be 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. NOTE ISO 17511 provides further information on how to manage the compromises in the metrological traceability of measurands. d) For genetic examinations, traceability to genetic reference sequences shall be established. e) For qualitative methods, traceability may be 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. NOTE Reagents include substances which are commercially supplied or prepared in-house, reference materials (calibrators and QC materials), culture media; consumables include pipette tips, glass slides, POCT supplies etc		
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** Each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before placing into use, or before release of results, as appropriate. Consumables that can affect the quality of examinations are verified for performance before placing into use. ***NOTE 1*** *Comparative IQC performance of new reagent lots and that of previous lots can be used as evidence for acceptance (see 7.3.7.2). Patient samples are preferred when comparing different reagent lots to avoid issues with commutability of IQC materials.* **NOTE 2** *Verification can sometimes be based on the certificate of analysis of the reagent.*		

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 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** Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required. Does the laboratory shave 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 be limited, to the following: a) identity of the reagent or consumable; b) manufacturer's information, including instructions, name and batch code or lot number; c) 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; d) 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.		
6.7	**Service Agreements**		
6.7.1	**Agreements with laboratory users** Does the laboratory have a procedure to establish and periodically review agreements for providing laboratory activities? a) Does the procedure shall ensure: b) the requirements are adequately specified; c) the laboratory has the capability and resources to meet the requirements; and when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants? Does the laboratory inform users of any changes to an agreement that can affect examination results? Are records of reviews, including any significant changes retained?		

6.7.2	**Agreements with POCT operators** Do service agreements between the laboratory and other parts of the organization using laboratory supported POCT, ensure that respective responsibilities and authorities are specified and communicated? *Established multidisciplinary POCT committees can be used to manage such service agreements as described in Annex A of ISO 15189:2022*		

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6.8	**Externally provided products and services**		
6.8.1	**General** How does the laboratory ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are: a) intended for incorporation into the laboratory's own activities; b) provided, in part or in full, directly to the user by the laboratory, as received from the external provider; c) used to support the operation of the laboratory. *It can be necessary to collaborate with other organizational departments or functions to fulfil this requirement.* *NOTE Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programmes, referral laboratories and consultants.*		
6.8.2	**Referral laboratories and consultants** Does the laboratory communicate its requirements to referral		

	laboratories and consultants who provide interpretations and advice, for: a) the procedures, examinations, reports and consulting activities to be provided; b) management of critical results; c) any required personnel qualifications and demonstration of competence? Unless otherwise specified in the agreement, does the referring laboratory (and not the referral laboratory) maintain the responsible for ensuring that examination results of the referral laboratory are provided to the person making the request? Is a list of all referral laboratories and consultants maintained?		
CLAUSE	**ISO 15189:2022 REQUIREMENTS**	**CAB's COMMENTS (Refer to instructions on Pg. 1)**	**ASSESSOR's COMMENTS**
6.8.3	**Review and approval of externally provided products and services.** Does the laboratory have procedures and retain records for: a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services; b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers; c) referral of samples; d) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user; e) taking any actions arising from evaluations of the performance of external providers.		
7.0. Process Requirements			

7.1.	**General** Does the laboratory identify potential risks to patient care in the pre-examination, examination and post-examination processes. These risks are assessed and mitigated to the extent possible. The residual risk is communicated to users as appropriate. The identified risks and effectiveness of the mitigation processes are 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. NOTE 1 The pre-examination processes can influence the outcome of the intended examination. NOTE 2 ISO 20658 provides detailed information for sample collection and transport. NOTE 3 ISO 20186-1, ISO 20186-2, ISO 20186-3, ISO 20166 (all parts), ISO 20184 (all parts), ISO 23118 and ISO 4307 provide detailed information for samples from particular sources and for specific analytes.		
7.2.2.	**Laboratory information for patient 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 shall include as appropriate: a) the location(s) of the laboratory, operating hours and contact information; b) the procedures for requesting and the collection of samples; c) the scope of laboratory activities and time for expected availability of results; d) the availability of advisory services; e) requirements for patient consent; f) factors known to significantly impact the performance of the examination or the interpretation of the results; g) the laboratory complaint process.		
7.2.3.	**Requests for providing laboratory examinations.** a) Each request accepted by the laboratory for examination(s) is considered an agreement. b) The examination request provides 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. c) The examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user. **d)** Where necessary for patient care, the laboratory communicates with users or their representatives, to clarify the user's request.		
7.2.3.1	**General**		

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 the information available to those responsible for sample collection? Is any deviation from the established collection procedures clearly recorded? Is 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?		
CLAUSE	**ISO 15189:2022 REQUIREMENTS**	**CAB's COMMENTS (Refer to instructions on Pg. 1)**	**ASSESSOR's COMMENTS**
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:		

a)	preparation of the patient (e.g., instructions to caregivers, sample collectors and patients);		
b)	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;		
c)	special timing of collection, where relevant;		
d)	provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g., history of administration of drugs);		
e)	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;		
f)	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? *NOTE For most routine laboratory procedures, consent can be inferred when the patient willingly submits to the sample collecting procedure, for example, venipuncture.*		
b)	Are special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, provide a more detailed explanation and, in some cases, recorded consent?		
c)	If obtaining consent is not possible in emergency situations, can the laboratory carry out necessary procedures, provided they are in the patient's best interest?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
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:		
a)	verification of the identity of the patient from whom a primary sample is collected;		
b)	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;		
c)	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;		
d)	labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;		
e)	recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time;		
f)	requirements for separating or dividing the primary sample when necessary;		
g)	stabilization and proper storage conditions before collected samples are delivered to the laboratory;		
h)	safe disposal of materials used in the collection process.		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.2.5	**Sample transportation**		
a)	To ensure the timely and safe transportation of samples, does the laboratory provide instructions for: 1) packaging of samples for transportation; 2) ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations; 3) maintaining the temperature interval specified for sample		

	collection and handling; 4) any specific requirements to ensure integrity of samples, e.g.? use of designated preservatives.		
b)	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?		
c)	Does the laboratory establish and periodically evaluate adequacy of sample transportation systems?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.2.6	**Sample receipt**		
7.2.6.1	**Sample receipt procedure** Does the laboratory have a procedure for sample receipt that includes:		
a)	the unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable, the anatomical site;		
b)	criteria for acceptance and rejection of samples;		
c)	recording the date and time of receipt of the sample, when relevant;		
d)	recording the identity of the person receiving the sample, when relevant;		
e)	evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s);		
f)	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;		
g)	ensuring that all portions of the sample shall be unequivocally traceable to the original sample?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.2.6.2 a) b)	**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 to: 1) 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 **7.2.7.1**	**Pre-examination handling, preparation, and storage** **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?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.3 EXAMINATION PROCESSES			
7.3.1	**General** a) 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. NOTE Preferred methods are those specified in the instructions for use of in vitro diagnostic medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts, or journals, or in international and national consensus standards or guidelines, or national or regional regulations. b) Do performance specifications for each examination method relate to the intended use of that examination and its impact on patient care. c) 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 (see 8.3). d) Do personnel follow established procedures and the identity of persons performing significant activities in examination processes recorded, including POCT operators. e) 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** a) 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. b) Are the performance specifications for the examination method confirmed during the verification process those relevant to the intended use of the examination results. c) Did the laboratory ensure the extent of the verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making. d) Do personnel with the appropriate authorization and competence review the verification results and record whether the results meet the specified requirements. e) If a method is revised by the issuing body, does the laboratory repeat verification to the extent necessary. f) Are the following records of verification retained: 1) performance specifications to be achieved, 2) results obtained, and 3) a statement of whether the performance specifications were achieved and if not, action taken.		
7.3.3.	**Validation of examination methods** **a)** Does the laboratory validate examination methods derived from the following sources: **1)** laboratory designed or developed methods; **2)** 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 are available**);**		

	3) validated methods subsequently modified. b) Is the validation extensive as is necessary and confirm, 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. c) Personnel with the appropriate authorization and competence review the validation results and record whether the results meet the specified requirements. d) When changes are proposed to a validated examination method, is the clinical impact shall reviewed, and a decision made as to whether to implement the modified method. e) Are the following records of validation retained: 1) the validation procedure used; 2) specific requirements for the intended use; 3) determination of the performance specifications of the method; **4)** results obtained; 5) a statement on the validity of the method, detailing its fitness for the intended use		
7.3.4.	**Evaluation of measurement uncertainty (MU)** a) The MUs of measured quantity values are evaluated and maintained for its intended use, where relevant. The MU is be compared against performance specifications and documented. NOTE ISO/TS 20914 provides details on these activities together with examples. b) MU evaluations are regularly reviewed. c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation shall be documented. d) MU information is made available to laboratory users on request. e) When users have inquiries on MU, the laboratory's response takes into account other sources of uncertainty, such as, but not limited to biological variation.		

	f) 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, MU in the output quantity is estimated using representative positive and negative samples. g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data are also be considered for key (high risk) parts of the process. h) MU is taken into consideration when performing verification or validation of a method, when relevant.		
7.3.5	Biological reference intervals and clinical decision limits Biological reference intervals and clinical decision limits, when needed for interpretation of examination results, are defined and communicated to users. **a)** Biological reference intervals and clinical decision limits are defined, and their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients. NOTE Biological reference values, provided by the manufacturer can be used by the laboratory, if the population base of these values is verified and deemed acceptable by the laboratory. b) Biological reference intervals and clinical decision limits are periodically reviewed, and any changes communicated to users. c) When changes are made to an examination or pre-examination method, the laboratory reviews the impact on associated biological reference intervals and clinical decision limits and communicate to the users when applicable. d) For examinations that identify presence or absence of a characteristic, the biological reference interval is the characteristic to be identified, e.g. genetic examinations.		
7.3.6.	**Documentation of examination procedures.** a) The laboratory has documented its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of		

	its results. b) Procedures are written in a language understood by laboratory personnel and be available in appropriate locations. c) Any abbreviated document content corresponds to the procedure. NOTE Working instructions, flow process diagrams or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a full procedure is available for reference and that the summarized information is updated as needed, concurrently with the full procedure update. d) Information from product instructions for use, that contain sufficient information, has been incorporated into procedures by reference. e) When the laboratory makes a validated change to an examination procedure which could affect interpretation of results, the implications of this is explained to users. f) All documents associated with the examination process are be subject to document control (see 8.3).		
7.3.7	**Ensuring the validity of examination results.**		
7.3.7.1	**General** The laboratory shall has a procedure for monitoring the validity of results. The resulting data is be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed.		
7.3.7.2	**Internal quality control (IQC)** a) The laboratory has 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) The intended clinical application of the examination is considered, as the performance specifications for the same measurand can differ in different clinical settings. 2) The procedure allows for the detection of		

	either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure avoids lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both. 3) The use of third-party IQC material has been considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer. NOTE Monitoring of interpretations and opinions can be achieved through regular peer review of examination results. b) The laboratory selected IQC material that is fit for its intended purpose. When selecting IQC material, factors to be considered shall include: 1) stability with regard to the properties of interest; 2) the matrix is as close as possible to that of patient samples; 3) the IQC material reacts to the examination method in a manner as close as possible to patient samples; 4) 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 c) If appropriate IQC material is not available, the laboratory considers the use of other methods for IQC. Examples of such other methods may 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; 2) 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; 3) retesting of retained patient samples. d) IQC shall be 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. e) The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results. f) IQC data shall be reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance. g) The laboratory shall 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, the results shall be rejected and relevant patient samples re-examined after the error has been corrected (see 7.5). 2) The results from patient samples that were examined after the last successful IQC event shall be evaluated.		
7.3.7.3	**External quality assessment (EQA)** a) Does the laboratory monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods. b) Has the laboratory established a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available. c) Are EQA samples processed personnel who routinely perform pre-examination, examination, and post-examination procedures. d) Do the EQA programme(s) selected by the laboratory		

	meet the following to the extent possible: 1) have the effect of checking pre-examination, examination, and post-examination processes; 2) provide samples that mimic patient samples for clinically relevant challenges; 3) fulfill ISO/IEC 17043 requirements. e) When selecting EQA programme(s), 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. NOTE 1 When method-independent target values are not available, consensus values can be used to determine whether deviations are laboratory- or method-specific. NOTE 2 Where lack of commutability of EQA materials can hamper comparison between some methods, it can still be useful for comparisons to be made between methods for which it is commutable, rather than relying only on within-method comparisons. f) When an EQA programme is either not available, or not considered suitable, the laboratory uses alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness. NOTE Acceptable alternatives include: — participation in sample exchanges with other laboratories; — interlaboratory comparisons of the results of the examination of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material; — analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material; — analysis of microbiological organisms using split/ blind		

	testing of the same sample by at least two persons, or on at least two analyzers, or by at least two methods; — analysis of reference materials considered to be commutable with patient samples; — analysis of patient samples from clinical correlation studies; — analysis of materials from cell and tissue repositories. g) Is EQA data reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance. h) 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. **i)** Where it is determined that the impact is clinically significant, does the laboratory review patient results that could have been affected and consider the need for amendment and users advised as appropriate.		
7.3.7.4	**Comparability of examination results** a) When either different methods or equipment, or both, are used for an examination, and/or the examination is performed at different sites, does the lab specify a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals. NOTE The use of patient samples when comparing different examination methods can avoid the difficulties linked to the limited commutability of IQC materials. When patient samples are either not available or impractical, see all options described for IQC and EQA. b) Does the laboratory record the results of comparability performed and its acceptability. c) Does the laboratory periodically review the comparability of results. d) Where differences are identified, the impact of those differences on biological reference intervals and clinical decision limits are evaluated and acted upon. e) Does the laboratory inform users of any clinically significant differences in comparability of results.		

7.4			
7.4.1.	**Result reporting**		
7.4.1.1.	**General** a) Are Examination results reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure. The report shall include all available information necessary for the interpretation of the results. b) Does the laboratory have a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient. c) Is all information associated with issued reports retained in accordance with management system requirements (see 8.4). NOTE For the purposes of this document, reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.		
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. Responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, are specified.		
7.4.1.3.	**Critical result reports** When examination results fall within established critical decision limits:		

	a) the user or other authorized person is notified as soon as relevant, based on clinical information available; b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification; c) the laboratory has an escalation procedure for laboratory personnel when a responsible person cannot be contacted.		
7.4.1.4.	**Special considerations for reports** a) When agreed with the user, the results may be reported in a simplified way. Any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user shall be readily available. **b)** When results are transmitted as a preliminary report, the final report is always forwarded to the user**.** **c)** Records are kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b). Such results shall always be followed by a report. **d)** Special counselling may be needed for examination results with serious implications for the patient (e.g. for genetic or certain infectious diseases). Laboratory management should ensure that these results are not communicated to the patient without the opportunity for adequate counselling. **e)** Results of laboratory examinations that have been anonymized may be 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, and release and reporting of results.** When the laboratory implements a system for automated selection, review, release and reporting of results, does it establish a procedure to ensure that: a) the criteria for automated selection, review and release are specified, approved, readily available and understood		

	by personnel responsible for authorizing the release of results; b) 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 patient care at risk; c) 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; d) 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: a. unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report; b. identification of the laboratory issuing the report; c. name or other unique identifier of the user; d. type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description); e. clear, unambiguous identification of the examinations performed; f. identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle; NOTE Logical Observation Identifiers Names and Codes (LOINC) and Nomenclature for Properties and Units (NPU, NGC) and SNOMED CT are examples of electronic identification. g. examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units; h. biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms		

	supporting clinical decision limits as necessary; NOTE Lists or tables of biological reference intervals can be distributed to users of the laboratory. i. identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available; j. 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); k. identification of any results that need to be considered as preliminary; l. indications of any critical results; **m.** 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 to total number of pages).		
7.4.1.7	**Additional information for reports** a) When necessary for patient care, the time of primary sample collection is included. b) Time of report release, if not contained in the report, is readily available when needed. c) Identification of 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. d) When applicable, a report includes interpretation of results and comments on: 1) sample quality and suitability that can compromise the clinical value of examination results; 2) discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations; 3) possible risk of misinterpretation when different units of measurement are in use regionally or nationally; 4) 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: a) The reason for the change is recorded and included in the revised report, when relevant. b) Revised results shall be 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 shall be indicated. c) The user is made aware of the revision. d) When it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference and traceability to the original report that it replaces. e) When the reporting system cannot capture revisions, a record of such shall be 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, the a) patient and source identification of the sample are maintained, b) suitability of the sample for additional examination is known, c) sample is stored in a manner that optimally preserves suitability for additional examination, d) sample can be located and retrieved, and		
7.5	**Nonconforming Work**		

	Does the laboratory have a process for when any aspect of its laboratory activities or examination results do not conform to its own procedures, quality specifications, or the user requirements (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)?		
a)	Does the process ensure that:		
b)	the responsibilities and authorities for the management of nonconforming work are specified;		
c)	immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;		
d)	examinations are halted, and reports withheld when there is a risk of harm to patients;		
e)	an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance;		
f)	a decision is made on the acceptability of the nonconforming work;		
g)	when necessary, examination results are revised, and the user is notified;		
	the responsibility for authorizing the resumption of work is specified.		
	Does the laboratory implement corrective action commensurate with the risk of recurrence of the nonconforming work? (see 8.7).		
	Does the laboratory retain records of nonconforming work and actions as specified in 7.5 a) to g)?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.6	**Control of data and information management**		
7.6.1	**General** Does the laboratory have access to the data and information needed to perform laboratory activities? *NOTE 1 In this document, "laboratory information systems" includes the management of data and information contained in both computer and non-computerized systems? Some of the requirements can be more applicable to computer systems than to non-computerized systems.* *NOTE 2 Risks associated with computerized laboratory information systems are discussed in ISO 22367:2020, A.13.* *NOTE 3 The information security controls, strategies and best practices to ensure the preservation of confidentiality, integrity and availability of information, are listed in ISO/IEC 27001:2022, Annex A Information security controls reference.*		

7.6.2	**Authorities and responsibilities for information management** Does the laboratory ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information systems that can affect patient care? Is the laboratory ultimately responsible for the laboratory information systems?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.6.3	**Information systems management** Are the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information:		
a)	validated by the supplier and verified for functionality by the laboratory before introduction? Any changes to the system, including laboratory software configuration or modifications to commercial off-the-shelf software, shall be authorized, documented and validated before implementation? *NOTE 1 Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as laboratory equipment, hospital patient administration systems and systems in primary care.* *NOTE 2 Commercial off-the-shelf software used within its designed application range can be considered sufficiently validated (e.g., word processing and spreadsheet software, and quality management software programs).*		
b)	documented, and the documentation readily available to authorized users, including that for day-to-day functioning of the system?		
c)	implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss?		
d)	operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription?		
e)	maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions?		

	Are calculations and data transfers checked in an appropriate and systematic manner?		
CLAUSE	**ISO 15189:2022 REQUIREMENTS**	**CAB's COMMENTS (Refer to instructions on Pg. 1)**	**ASSESSOR's COMMENTS**
7.6.4	**Downtime plans** Does the laboratory have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities? Does this include automated selection and reporting of results?		
7.6.5	**Off site management** When the laboratory information system(s) are managed and maintained off-site or through an external provider, how does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document?		
7.7	**Complaints**		
7.7.1	Does the laboratory have a process for handling complaints that shall include at least the following:		
a)	a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response; *NOTE The resolution of complaints can lead to implementation of corrective actions (see 8.7) or be used as input into the improvement process (see 8.6).*		
b)	tracking and recording the complaint, including the actions undertaken to resolve it;		
c)	ensuring appropriate action is taken.		

	Is a description of the process for handling complaints made publicly available?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.7.2	**Receipt of complaint**		
a)	Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, does it resolve the complaint? (see 8.7.1)?		
b)	Is the laboratory receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated?		
c)	Whenever possible does the laboratory acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports?		
7.7.3	**Resolution of complaint**		
	Does investigation and resolution of complaints result in any discriminatory actions?		
	Is the resolution of complaints made by, or reviewed and approved by, persons not involved in the subject of the complaint in question?		

	Where resources do not permit this, does the laboratory ensure that any alternative approach does not compromise impartiality?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
7.8	**Continuity and Emergency preparedness planning**		
	Does the laboratory ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption? Are plans periodically tested and the planned response capability exercised, where practicable? Does the laboratory:		
a)	establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel?		
b)	provide information and training as appropriate to relevant laboratory personnel?		
c)	respond to actual emergency situations;		

d)	take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.	**MANAGEMENT SYSTEM REQUIREMENTS**		
8.1	**General Requirements**		
8.1.1	Does the laboratory establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document? As a minimum, does the management system of the laboratory include the following: — responsibilities (8.1) — objectives and policies (8.2) — documented information (8.2, 8.3 and 8.4) — actions to address risks and opportunities for improvement (8.5) — continual improvement (8.6) — corrective actions (8.7) — evaluations and internal audits (8.8) — management reviews (8.9)		
8.1.2	**Fulfilment of management system requirements** The laboratory may meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g.? in accordance with the requirements of ISO 9001) (see Table B.1)? This quality management system shall support and demonstrate the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.		

8.1.3	**Management system awareness** Does the laboratory ensure that persons doing work under the laboratory's control are aware of: a) relevant objectives and policies; b) their contribution to the effectiveness of the management system, including the benefits of improved performance; c) the consequences of not conforming with the management system requirements.		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.2	**Management System Documentation**		
8.2.1	**General** Did laboratory management establish, document, and maintain objectives and policies for the fulfilment of the purposes of this document and did they ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization? *NOTE The management system documents can, but are not required to, be contained in a quality manual.*		
8.2.2	**Competence and quality** Do the objectives and policies address the competence, quality and consistent operation of the laboratory?		
8.2.3	**Evidence of commitment** How does laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?		
8.2.4	**Documentation** Are all documentation, processes, systems, and records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system?		

8.2.5	**Personnel access** Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.3	**Controls of Management System Documents**		
8.3.1	**General** Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document? *NOTE In this context, "document" can be policy statements, procedures and related job aids, flow charts, instructions for use, specifications, manufacturer's instructions, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as laws, regulations, standards and textbooks from which examination methods are taken, documents describing personnel qualifications (such as job descriptions), etc? These can be in any form or type of medium, such as hard copy or digital.*		✓
CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS

8.3.2	**Control of documents** Does the laboratory ensure that: a) documents are uniquely identified; b) documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy; c) documents are periodically reviewed and updated as necessary; d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; changes and the current revision status of documents are identified; e) documents are protected from unauthorized changes and any deletion or removal; f) documents are protected from unauthorized access; g) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose; h) at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements. i) j)		
8.4	**Control of Records**		
8.4.1	**Creation of records** Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements of this document? Are records created at the time each activity that affects the quality of an examination is performed? *NOTE Records can be in any form or type of medium.*		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to	ASSESSOR's COMMENTS

		instructions on Pg. 1)	
8.4.2	**Amendment of records** Does the laboratory ensure that amendments to records can be traced to previous versions or to original observations? Are both the original and amended data and files kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations?		
8.4.3	**Retention of records**		
a)	Does the laboratory implement the procedures needed for the identification, storage, protection from unauthorized access and changes, back-up, archive, retrieval, retention time, and disposal of its records?		
b)	Are the retention times for records specified? *NOTE 1 In addition to requirements, retention times can be chosen based on identified risks*.		
c)	Are reported examination results retrievable for as long as necessary or as required?		
d)	Are all records accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review (see 8.9)? *NOTE 2 Legal liability concerns regarding certain types of procedures (e.g.? histology examinations, genetic examinations, pediatric examinations) can require the retention of certain records for much longer times than for other records.*		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.5	**Actions to address risks and opportunities for improvement**		
8.5.1	**Identification of risks and opportunities for improvement** Does the laboratory identify risks and opportunities for improvement associated with the laboratory activities to: a) prevent or reduce undesired impacts and potential failures in the laboratory activities; b) achieve improvement, by acting on opportunities; c) assure that the management system achieves its intended results; d) mitigate risks to patient care; and e) help achieve the purpose and objectives of the laboratory?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.5.2	**Acting on risks and opportunities for improvement** Does the laboratory prioritize and act on identified risks? Are actions taken to address risks proportional to the potential impact on laboratory examination results, as well as patient and personnel safety? Does the laboratory record decisions made and actions taken on risks and opportunities? Does the laboratory integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness? *NOTE 1 Options to address risks can include identifying and avoiding threats, eliminating a risk source, reducing the likelihood or consequences of a risk, transferring a risk, taking a risk in order to pursue an opportunity for improvement, or accepting risk by informed decision.* *NOTE 2 Although this document requires that the laboratory identifies and addresses risks, there is no requirement for any particular risk management method? Laboratories can use ISO 22367 and ISO 35001 for guidance.* *NOTE 3 Opportunities for improvement can lead to expanding the scope of the laboratory activities, applying new technology, or creating other possibilities to fulfil patient and user needs.*		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.6	**Improvement**		

8.6.1	**Continual improvement**		
a)	Does the laboratory continually improve the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies?		
b)	Does the laboratory identify and select opportunities for improvement and develop, document, and implement any necessary actions? Are improvement activities directed at areas of highest priority based on risk assessments and the opportunities identified (see 8.5)? *NOTE Opportunities for improvement can be identified through risk assessment, use of the policies, review of the operational procedures, overall objectives, external evaluation reports, internal audit findings, complaints, corrective actions, management reviews, suggestions from personnel, suggestions or feedback from patients and users, analysis of data and EQA results.*		
c)	Does the laboratory evaluate the effectiveness of the actions taken? Does laboratory management ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care?		
d)	Does laboratory management communicate to personnel its improvement plans and related goals?		
e)			
8.6.2	**Laboratory patients, user, and personnel feedback** Does the laboratory seek feedback from its patients, users, and personnel? Is the feedback analysed and used to improve the management system, laboratory activities and services to users? Are records of feedback maintained including the actions taken? Is communication provided to personnel on actions taken arising from their feedback?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to	ASSESSOR's COMMENTS

		instructions on Pg. 1)	
8.7	**Nonconformities and corrective actions**		
8.7.1	**Actions when nonconformity occurs** When a nonconformity occurs, does the laboratory: a) Respond to the nonconformity and, as applicable: 1) take immediate action to control and correct the nonconformity; 2) address the consequences, with a particular focus on patient safety including escalation to the appropriate person. b) Determine the cause(s) of the nonconformity? c) Evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by: 1) reviewing and analyzing the nonconformity; 2) determining whether similar nonconformities exist, or could potentially occur; 3) assessing the potential risk(s) and effect(s) if the nonconformity recurs? d) Implement any action needed? e) Review and evaluate the effectiveness of any corrective action taken? f) Update risks and opportunities for improvement, as needed? g) Make changes to the management system, if necessary?		
8.7.2	**Corrective action effectiveness**		

	Are corrective actions appropriate to the effects of the nonconformities encountered and shall mitigate the identified cause(s)?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.7.3	**Records of nonconformities and corrective actions** Does the laboratory retain records as evidence of the: a) nature of the nonconformities, cause(s) and any subsequent actions taken, and b) evaluation of the effectiveness of any corrective action?		
8.8	**Evaluations**		
8.8.1	**General** Does the laboratory conduct evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document?		
8.8.2	**Quality indicators** Is the process of monitoring quality indicators [see 5.5 d)] planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring? Are the indicators periodically reviewed, to ensure continued appropriateness?		

8.8.3	**Internal audits**		
8.8.3.1	Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system:		
a)	conforms to the laboratory's own requirements for its management system, including the laboratory activities,		
b)	conforms to the requirements of this document, and is		
c)	effectively implemented and maintained?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.8.3.2	Does the laboratory plan, establish, implement and maintain an internal audit programme that includes:		
a)	priority given to risk to patients from laboratory activities?		
b)	a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities?		
c)	specified audit objectives, criteria and scope for each audit?		
d)	selection of auditors who are trained, qualified and authorized to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited?		
e)	ensuring objectivity and impartiality of the audit process?		
f)	ensuring that the results of the audits are reported to relevant personnel?		
g)	implementation of appropriate correction and corrective actions without undue delay?		
h)	retention of records as evidence of the implementation of the audit programme and audit results?		
	NOTE ISO 19011 provides guidance for auditing management systems.		
8.9	**Management Reviews**		
8.9.1	**General** Does laboratory management review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
8.9.2	**Review input** Are the inputs to management review recorded and does it include evaluations of at least the following: a) status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources; b) fulfilment of objectives and suitability of policies and procedures; c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies; d) patient, user and personnel feedback and complaints; quality assurance of result validity; e) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement; f) performance of external providers; g) results of participation in interlaboratory comparison programmes; h) evaluation of POCT activities; i) other relevant factors, such as monitoring activities and training. j)		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS

8.9.3	**Review output** Is the output from the management review a record of decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; c) provision of required resources; d) improvement of services to patients and users; any e) need for change. Does laboratory management ensure that actions arising from management review are completed within a specified time frame? Are conclusions and actions arising from management reviews communicated to laboratory personnel?		
Additional requirements for Point-of-Care Testing (POCT)			
A.2	**Governance** Is the governing body of the organization ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organization? Do service agreements between the laboratory and all locations using laboratory supported POCT ensure that respective responsibilities and authorities are specified and communicated within the organization? Do these agreements have clinical approval, and where applicable, financial approval? Are these service agreements with POCT areas and can they be managed via a health professional grouping (e.g. medical advisory committee)?		

CLAUSE	ISO 15189:2022 REQUIREMENTS	CAB's COMMENTS (Refer to instructions on Pg. 1)	ASSESSOR's COMMENTS
A.3	**Quality assurance programme** Did the laboratory appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT?		
A.4	**Training programme** Is a person with appropriate training and experience appointed to manage training and competency assessment of personnel performing POCT? Does the trainer develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel?		

Additional / General Comments *This space may also be used to expand on comments in specific sections*

GENERAL COMMENTS:

RECOMMENDATION

Signed: Team Leader		**Date:**	

REVIEW OF ADDITIONAL DOCUMENTS
Reviewer Name: Date: Review Signature: