Hong Kong Laboratory Accreditation Scheme

HOKLAS 016-A2

Management System Checklist

(for ISO 15189:2022)

The applicant / accredited laboratory must complete the following checklist for an initial application and when there has been a significant change to the management system.

This checklist consists of questions based on the requirements of ISO 15189:2022, HKAS PD002, HKAS 002, HKAS SC-06 and HOKLAS SC-33. For further information, please refer to the corresponding document and clause listed in the second column.

The laboratory should indicate in the “Management System” column, for every question, the part(s) of the management system documents which cover the requirement.

	Clause	Y	N	NA	Management system	Remarks (for internal use)
ISO 15189:2022						
General requirements	**4**					
Impartiality						
Are laboratory activities undertaken impartially? Is your laboratory structured and managed in a way to safeguard impartiality?	4.1 a	☐	☐	☐		
Is your laboratory management committed to impartiality?	4.1 b	☐	☐	☐		
Is your laboratory responsible for the impartiality of the laboratory activities?	4.1 c	☐	☐	☐		
Does your laboratory allow commercial, financial or other pressures to compromise impartiality?	4.1 c	☐	☐	☐		
Does your laboratory monitor the activities and relationships (including personnel) to identify threats to impartiality?	4.1 d	☐	☐	☐		
If a threat is identified, does your laboratory eliminate or minimize the threat so that the impartiality is not compromised?	4.1 e	☐	☐	☐		
Confidentiality						
Does your laboratory have legally enforceable arrangements for the management of all patient information obtained or created during the performance of laboratory activities?	4.2.1	☐	☐	☐		
Does your laboratory inform the user and/or patient in advance, of the information your laboratory intends to place in the public domain?	4.2.1	☐	☐	☐		
When the laboratory is required by law or authorized by contractual arrangements to release confidential information, has the patient concerned been notified of the information released, unless prohibited by law.	4.2.2	☐	☐	☐		
Does the laboratory keep information about the patient from a source other than the patient (e.g. complainant, regulator) confidential?	4.2.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory keep confidential the identity of the source and not share with the patient, unless agreed by the source.	4.2.2	☐	☐	☐		
Do all kinds of personnel, including committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf keep all information confidential?	4.2.3	☐	☐	☐		
Requirements regarding patients						
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;	4.3 a)	☐	☐	☐		
b) provision of patients and users which publicly available information about the examination processes, including costs when applicable, and when to expect results;	4.3 b)	☐	☐	☐		
c) periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary;	4.3 c)	☐	☐	☐		
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;	4.3 d)	☐	☐	☐		
e) treatment of patients, samples, or remains, with due care and respect;	4.3 e)	☐	☐	☐		
f) obtaining informed consent when required;	4.3 f)	☐	☐	☐		
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;	4.3 g)	☐	☐	☐		
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;	4.3 h)	☐	☐	☐		
i) upholding the rights of patietns to care that is free from discrimination.	4.3 i)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Stuctural requirements and governance requirements	**5**					
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?	5.1	☐	☐	☐		
Laboratory director						
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 ISO 15189:2022?	5.2.1	☐	☐	☐		
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 systemically identified and addressed?	5.2.2	☐	☐	☐		
Are the duties and responsibilities of the laboratory director documented?	5.2.2	☐	☐	☐		
Delegation of duties						
Are selected duties or responsibilities, or both, delegated to qualified and competent personnel?	5.2.3	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is the delegation documented?	5.2.3	☐	☐	☐		
Does the laboratory director maintain the ultimate responsibility for the overall operation of the laboratory?	5.2.3	☐	☐	☐		
Laboratory activities						
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 ISO 15189:2022?	5.3.1	☐	☐	☐		
Does the laboratory only claim conformity with ISO 15189:2022 for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis?	5.3.1	☐	☐	☐		
Conformance with requirements						
Are laboratory activities carried out in such a way as to meet the requirements of ISO 15189:2022?	5.3.2	☐	☐	☐		
Advisory activities						
Does laboratory management ensure that appropriate laboratory advice and interpretation are available and meet the nees of patients and users?	5.3.3					
Does the laboratory establish arrangements 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;	5.3.3 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) providing professional judgments on the interpretation of results of examinations;	5.3.3 b)	☐	☐	☐		
c) promoting the effective utilization of laboratory examinations;	5.3.3 c)	☐	☐	☐		
d) advising on scientific and logistical matters such as instanceds of failure of sample(s) to meet acceptability criteria.	5.3.3 d)	☐	☐	☐		
Structure and authority						
General						
Does the laboratory:						
a) define its organization and management structure, its place in any parent organization, and the relationship between management, technical operations and support services;	5.4.1 a)	☐	☐	☐		
b) specify the responsibility, authority, lines of communicaton and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;	5.4.1 b)	☐	☐	☐		
c) specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validty of results.	5.4.1 c)	☐	☐	☐		
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;	5.4.2 a)	☐	☐	☐		
b) identification of deviations from the management system or from the procedures for performing laboratory activities;	5.4.2 b)	☐	☐	☐		
c) initation of actions to prevent or minimize such deviations;	5.4.2 c)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
d) reporting to laboratory management on the performance of the management system and any need for improvement;	5.4.2 d)	☐	☐	☐		
e) ensuring the effectiveness of laboratory activities.	5.4.2 e)	☐	☐	☐		
Objectives and policies						
a) Does the laboratory establish and maintain objectives and policies to:	5.5 a)	☐	☐	☐		
1) meet the needs an drequirements of its patients and user;						
2) commit to good professional practice;						
3) provide examinations that fulfil their intended use;						
4) conform to ISO 15189:2022.						
b) Are objectives measurable, and consistent with policies? Does the laboratory ensure that the objectives and policies are implemented at all levels of the laboratory organisation?	5.5 b)	☐	☐	☐		
c) Does laboratory management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?	5.5 c)	☐	☐	☐		
d) Does the laboratory establish quality indicators to evaluated performance throughout key aspects of pre-examination, examination and post-examination processes and monitor performance in relation to objectives?	5.5 d)	☐	☐	☐		
Risk management						
Does laboratory management establish, implement, and maintain proceses for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement?	5.6 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory director ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective?	5.6 b)	☐	☐	☐		
Resource requirements	**6**					
General						
Does the laboratory have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities?	6.1	☐	☐	☐		
Personnel						
General						
a) Does the laboratory have access to a sufficient number of competent persons to perform its activities?	6.2.1 a)	☐	☐	☐		
b) Do all personnel of the laboratory, either internal or external, that could influence the laboratory's activities act impartially, ethically, be competent and work in accordance with the laboratory's management system?	6.2.1 b)	☐	☐	☐		
c) Does the laboratory communicate to laboratory personnel the importance of meeting the needs and requirements of users as well as the requirements of ISO 15189:2022?	6.2.1 c)	☐	☐	☐		
d) Does the laboratory have a programme to introduce personnel to the organisation, the department or area in which the person will work, the terms and conditions of employment, staff factilities, health and safety requirements, and occupational health services?	6.2.1 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Competence requirements						
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?	6.2.2 a)	☐	☐	☐		
b) Does the laboratory ensure all personnel have the competence to perform laboratory activities for which are responsible?	6.2.2 b)	☐	☐	☐		
c) Does the laboratory have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment?	6.2.2 c)	☐	☐	☐		
d) Does the laboratory have documented information demonstrating competence of its personnel?	6.2.2 d)	☐	☐	☐		
Authorisation						
Does the laboratory authorize personnel to perform specific laboratory activities, including but not limited to the following:						
a) selection, development, modification, validation and verification of methods;	6.2.3 a)	☐	☐	☐		
b) review, release and reporting of results;	6.2.3 b)	☐	☐	☐		
c) user of laboratory information systems, in particular, accessing patient data and information, entering patient dat and examination results, changing patient data or examinations.	6.2.3 c)	☐	☐	☐		
Continuing education and professional development						
Is a continuing education programme available to personnel who participate in managerial and technical processes?	6.2.4	☐	☐	☐		
Do all personnel participate in continuing education and regular professional development, or other professional liaison activities?	6.2.4	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Personnel records						
Does the laboratory have procedures and retain records for:						
a) determining the competence requirements specified in 6.2.2 a)	6.2.5 a)	☐	☐	☐		
b) position descriptions;	6.2.5 b)	☐	☐	☐		
c) training and re-training;	6.2.5 c)	☐	☐	☐		
d) authorization of personnel;	6.2.5 d)	☐	☐	☐		
e) monitoring competence of personnel.	6.2.5 e)	☐	☐	☐		
Facilities and environmental conditions						
General						
Are the facilities and environmental conditions suitable for the laboratory activities and not adversely affect the validty of results, or the safety of patients, visitors, laboratory users, and personnel?	6.3.1	☐	☐	☐		
Are the requirements for facilities and environmental conditions necessary for the performance of the laboratory specified, monitored and recorded?	6.3.1	☐	☐	☐		
Facility controls						
Are facility controls implemented, recorded, monitored periodically reviewed, and include:						
a) control of acess, taking into consideration safety confidentiality, quality, and safeguarding medical information and patient samples;	6.3.2 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) prevention of cross-contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste diposal;	6.3.2 b)	☐	☐	☐		
c) prevention of cross-contamination, where examination procedures pose a risk, or where work can be affectged or influenced by lack of separation;	6.3.2 c)	☐	☐	☐		
d) provision of safety facilities and devices, where applicable and regularly verifying their functioning;	6.3.2 d)	☐	☐	☐		
e) maintenance of laboratory facilities in a functional and reliable condition.	6.3.2 e)	☐	☐	☐		
Storage facilities						
a) Are storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records, provided?	6.3.3 a)	☐	☐	☐		
b) Are patient samples and materials used in examination processes stored in a manner that prevents corss contamination and deterioration?	6.3.3 b)	☐	☐	☐		
c) Are storage and disposal facilities for hazardous materials and biological waste appropriate to the classification of the materials in the context of any statuory or regaulatory requirements?	6.3.3 c)	☐	☐	☐		
Personnel facilities						
Are there adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing?	6.3.4	☐	☐	☐		
Are space for personnel activities, such as meetings, quiet study and a rest area provided?	6.3.4	☐	☐	☐		
Sample collection facilities						
Do sample collection facilities:						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
a) enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations?	6.3.5 a)	☐	☐	☐		
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?	6.3.5 b)	☐	☐	☐		
c) provide separate patient reception and collection areas?	6.3.5 c)	☐	☐	☐		
d) maintain first aid materials for both patients and personnel?	6.3.5 d)	☐	☐	☐		
Equipment						
General						
Does the laboratory have proceses for the selection, procurement, installation, acceptance testing (including acceptiblity criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration?	6.4.1	☐	☐	☐		
Equipment requirements						
a) Does the laboratory have access to equipment required for the correct performance of laboratory activities?	6.4.2 a)	☐	☐	☐		
b) Where the equipment is used outside the laboratory's permanent control or equipment manufacturer's functional specification, does laboratory management ensure that the requirements of ISO 15189:2022 are met?	6.4.2 b)	☐	☐	☐		
c) Is each item of equipment that can influence laboratory activities uniquely labelled, marked or otherwise identified and a register maintained?	6.4.2 c)	☐	☐	☐		
d) Does the laboratory maintain and replace equipment as needed to ensure the quality of examination results?	6.4.2 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Equipment acceptance procedure						
Does the laboratory verify that equipment conforms to specified acceptability criteria before being placed or returned into service?	6.4.3	☐	☐	☐		
Is equipment used for measurement capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result?	6.4.3	☐	☐	☐		
Equipment instructions for use						
a) Does the laboratory have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results?	6.4.4 a)	☐	☐	☐		
b) Is equipment operated by trained, authorized, and competent personnel?	6.4.4 b)	☐	☐	☐		
c) Are instructions for use of equipment, including those provided by the manufacturer, readily available?	6.4.4 c)	☐	☐	☐		
d) Is the equipment used as specified by the manufacturer, unless validated by the laboratory?	6.4.4 d)	☐	☐	☐		
Equipment maintenance and repair						
a) Does the laboratory have preventive maintenance programmes, based on manufacturer's instructions? Are deviations from the manufacturer's schedules or instructions recorded?	6.4.5 a)	☐	☐	☐		
b) Is equipment maintained in a safe working condition and working order?	6.4.5 b)	☐	☐	☐		
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 intiate actions when non-conforming work occurs?	6.4.5 c)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
d) Where applicable, does the laboratory decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment?	6.4.5 d)	☐	☐	☐		
Equipment adverse incident reporting						
Are adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required?	6.4.6	☐	☐	☐		
Does the laboratory have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer?	6.4.6	☐	☐	☐		
Equipment records						
Are records maintained for each item of equipment that influences the results of laboratory activities?	6.4.7	☐	☐	☐		
Does these records including the following, where relevant:						
a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;	6.4.7 a)	☐	☐	☐		
b) dates of receipt, acceptance testing and entering into service;	6.4.7 b)	☐	☐	☐		
c) evidence that equipment conforms with specified acceptability criteria;	6.4.7 c)	☐	☐	☐		
d) the current location;	6.4.7 d)	☐	☐	☐		
e) condition when received (e.g. new, used or reconditioned);	6.4.7 e)	☐	☐	☐		
f) manufacturer's instructions;	6.4.7 f)	☐	☐	☐		
g) the programme for preventive maintenance;	6.4.7 g)	☐	☐	☐		
h) any maintenance activities performed by the laboratory or approved external service provider;	6.4.7 h)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
i) damage to, malfunction, modification or repair of equipment;	6.4.7 i)	☐	☐	☐		
j) equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results;	6.4.7 j)	☐	☐	☐		
k) status of equipment such as active or in-service, out-of-service, quarantined, retired or obsolete/	6.4.7 k)	☐	☐	☐		
Are these records maintained and readily available for the lifespan of the equipment or longer, as specified in 8.4.3.	6.4.7	☐	☐	☐		
Equipment calibration and metrological traceability						
General						
Does the laboratory specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results?	6.5.1	☐	☐	☐		
For quantitative methods of a measured analyte, do specificiations include calibration and metrological traceability requirements?	6.5.1	☐	☐	☐		
Do qualitative methods and quantitative methods that measure characteristics rather than discreate analytes specify the characteristic being assessed and such requiremetns necessary for reproducibility over time?	6.5.1	☐	☐	☐		
Equipment calibration						
Does the laboratory have procedures for the calibration of equipment that directly or indirectly affects examination results?	6.5.2	☐	☐	☐		
Do the procedures specify:						
a) conditions of use and manufacturer’s instructions for calibration?	6.5.2 a)	☐	☐	☐		
b) recording of the metrological traceability?	6.5.2 b)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals?	6.5.2 c)	☐	☐	☐		
d) recording the calibration status and date of re-calibration?	6.5.2 d)	☐	☐	☐		
e) ensuring that, where correction factors are used, these are updated and recorded when recalibration occurs?	6.5.2 e)	☐	☐	☐		
f) handling of situations when calibration was out of control, to minimize risk to service operation and to patients?	6.5.2 f)	☐	☐	☐		
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 meansurement uncertainty, linking them to an appropriate reference?	6.5.3 a)	☐	☐	☐		
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:	6.5.3 b)	☐	☐	☐		
- calibration provided by a competent laboratory?						
- certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI?						
c) Where it is not possible to provide traceability according to 6.5.3 a), are other means for providing confidence in the results applied, including but not limited to the following:	6.5.3 c)	☐	☐	☐		
- 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?						
d) For genetic examiantions, are traceability to genetic reference sequences established?	6.5.3 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
e) For qualitative methods, may traceability be demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction?	6.5.3 e)	☐	☐	☐		
Reagents and consumables						
General						
Does the laboratory have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables?	6.6.1	☐	☐	☐		
Reagents and consumables – Receipt and storage						
Does the laboratory store reagents and consumables according to manufacturer's specifications and monitor the environmental conditions where relevant?	6.6.2	☐	☐	☐		
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?	6.6.2	☐	☐	☐		
Reagents and consumables – Acceptance testing						
Is each reagent or new formulation of examinations kits with changes in reagents or procedures, or a new lot or shipment verified for performance before placing into use, or before release of results, as appropriate?	6.6.3	☐	☐	☐		
Are consumables that can affect the quality of examinations verified for performance before placing into use?	6.6.3	☐	☐	☐		
Reagents and consumables – Inventory management						
Does the laboratory establish an inventory management system for reagents and consumables?	6.6.4	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
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?	6.6.4	☐	☐	☐		
Reagents and consumables – Instructions for use						
Are instructions for the use of reagents and consumables, including those provided by the manufacturers readily available?	6.6.5	☐	☐	☐		
Are reagents and consumables used according to the manufacturer's specifications?	6.6.5	☐	☐	☐		
Reagents and consumables – Adverse incident reporting						
Are adverse incidents and accidents that can be attributed directly to specific reagents or consumables investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required?	6.6.6	☐	☐	☐		
Does the laboratory have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer?	6.6.6	☐	☐	☐		
Reagents and consumables – Records						
Are records maintained for each reagent and consumable that contributes to the performance of examinations?	6.6.7	☐	☐	☐		
Are these records include, but not be limited, to the following:						
a) identity of the reagent or consumable;	6.6.7 a)	☐	☐	☐		
b) manufacturer's information, including instructions, name and batch code or lot number;	6.6.7 b)	☐	☐	☐		
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;	6.6.7 c)	☐	☐	☐		
d) records that confirm the reagent's or consumable's initial and ongoing acceptance for use.	6.6.7 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Where the laboratory uses reagents prepared, resuspended or combined in-house, are 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?	6.6.7	☐	☐	☐		
Service agreements						
Agreements with laboratory users						
Does the laboratory have a procedure to establish and periodically review agreements for providing laboratory activities?	6.7.1	☐	☐	☐		
Does the procedure ensure:						
a) the requirements are adequately specified?	6.7.1 a)	☐	☐	☐		
b) the laboratory has the capability and resources to meet the requirements?	6.7.1 b)	☐	☐	☐		
c) when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants?	6.7.1 c)	☐	☐	☐		
Are laboratory users informed of any changes to an agreement that can affect examination results?	6.7.1	☐	☐	☐		
Are records of review, including any significant changes, retained?	6.7.1	☐	☐	☐		
Agreements with POCT operators						
Do service agreements between the laboratory and other parts of the organisation using laboratory supported POCT ensure that respective responsibilities and authorities are specified and communicated?	6.7.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Externally provided products and services						
General						
Does the laboratory ensure that externally provided products and services that affect laboratory activities are suitable when such products or services are:						
a) intended for incorporation into the laboratory's own activities?	6.8.1 a)	☐	☐	☐		
b) provided, in part or in full, directly to the users by the laboratory, as received from the external provider?	6.8.1 b)	☐	☐	☐		
c) used to support the operation of the laboratory?	6.8.1 c)	☐	☐	☐		
Referral laboratories and consultants						
Does the laboratory communicate its requirements to referral laboratories and consultatns who provide interpretation and advice, for:						
a) the procedures, examinations, reports and consulting activities to be provided?	6.8.2 a)	☐	☐	☐		
b) management of critical results?	6.8.2 b)	☐	☐	☐		
c) any required personnel qualifications and demonstration of competence?	6.8.2 c)	☐	☐	☐		
Unless otherwise specified in the agreement, is the referring laboratory (and not the referral laboratory) responsible for ensuring that examination results of the referral laboratory are provided to the person making the request?	6.8.2	☐	☐	☐		
Is a list of all referral laboratories and consultants maintained?	6.8.2	☐	☐	☐		
Review and approval of externally provided products and services						
Does the laboratory have procedures and retain records for:						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services?	6.8.3 a)	☐	☐	☐		
b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers?	6.8.3 b)	☐	☐	☐		
c) referral of samples?	6.8.3 c)	☐	☐	☐		
d) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of ISO 15189:2022, before they are used or directly provided to the user?	6.8.3 d)	☐	☐	☐		
e) taking any actions arising from evaluations of the performance of external provider?	6.8.3 e)	☐	☐	☐		
Process requirements	**7**					
General						
Does the laboratory identify potential risks to patient care in the pre-examination, examination and post-examination processes?	7.1	☐	☐	☐		
Are these risk assessed and mitigated to the extent possible?	7.1	☐	☐	☐		
Is residual risk communicated to users as appropriate?	7.1	☐	☐	☐		
Are the identified risks and effectiveness of the mitigation processes monitored and evaluated according to the potential harm to patients?	7.1	☐	☐	☐		
Does the laboratory also identify opportunities to improve patient care and develop a framework to manage these opportunities?	7.1	☐	☐	☐		
Pre-examination processes						
General						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory have proceudres for all pre-examination activities and make them accessible to relevant personnel?	7.2.1	☐	☐	☐		
Laboratory information for patients and users						
Does the laboratory have appropriate information available for its users and patients?	7.2.2	☐	☐	☐		
Is the information sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements?						
Does the information include as appropriate:						
a) the location(s) of the laboratory, operating hours and contact information?	7.2.2 a)	☐	☐	☐		
b) the procedures for requesting and the collection of samples?	7.2.2 b)	☐	☐	☐		
c) the scope of laboratory activities and time for expected availability of results?	7.2.2 c)	☐	☐	☐		
d) the availability of advisory services?	7.2.2 d)	☐	☐	☐		
e) requirements for patient consent?	7.2.2 e)	☐	☐	☐		
f) factors known to significantly impact the performance of the examination or the interpretation of the results?	7.2.2 f)	☐	☐	☐		
g) the laboratory complaint process	7.2.2 g)	☐	☐	☐		
Requests for providing laboratory examinations						
General						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
a) Is each request accepted by the laboratory for examination(s) considered an agreement?	7.2.3.1 a)	☐	☐	☐		
b) Does the examination request provide sufficient information to ensure:	7.2.3.1 b)	☐	☐	☐		
- unequivocal traceability of the patient to the request and sample?						
- identity and contact information of requester?						
- informed clinical and technical advice, and clinical interpretation can be provided?						
c) Is the examination request information provided in a format or medium as deemed apprproriate by the laboratory and acceptable to the user?	7.2.3.1 c)	☐	☐	☐		
d) Where necessary for patient care, does the laboratory communicate with users or their representatives, to clarify the user's request?	7.2.3.1 d)	☐	☐	☐		
Oral requests						
Does the laboratory have a procedure for managing oral requests for examination, if applicable, that includes the providsion of documented confirmation of the examination request to the laboratory, within a given time?	7.2.3.2	☐	☐	☐		
Primary sample collection and handling						
Does the laboratory have procedures for the collection and handling of primary samples?	7.2.4.1	☐	☐	☐		
Is information available to those responsible for sample collection?	7.2.4.1	☐	☐	☐		
Is any deviation from the established collection procedures clearly recorded?	7.2.4.1	☐	☐	☐		
Is the potential risk and impace on the patient outcome of acceptance or rejection of the sample assessed, recorded and communicated to the appropriate personnel?	7.2.4.1	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory periodically review requirements for sample volume, collection device and preservatives for all samples, as applicable, to ensure that neither insufficeient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte?	7.2.4.1	☐	☐	☐		
Information for pre-collection activities						
Does the laboratory provide information an dinstructions for pre-collection activities with sufficient detail to ensure that integrity of the sample is not compromised?	7.2.4.2	☐	☐	☐		
Does this include:						
a) preparation of the patient (e.g. instructions to caregivers, sample collectors and patients)?	7.2.4.2 a)	☐	☐	☐		
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?	7.2.4.2 b)	☐	☐	☐		
c) special timing of collection, where relevant?	7.2.4.2 d)	☐	☐	☐		
d) provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs)?	7.2.4.2 d)	☐	☐	☐		
e) sample labelling for unequivocal identification of patient, as well as source and site of sample, and labelling, when several samples from the same patient are to to be collected, including multiple pieces of tissue or slides?	7.2.4.2 e)	☐	☐	☐		
f) the laboratory's criteria for acceptance and rejection of samples specific to the examinations requested?	7.2.4.2 f)	☐	☐	☐		
Patient consent						
a) Does the laboratory obtain the informed consent of the patient for all procedures carried out on the patients?	7.2.4.3 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) Does a more detailed explanation and, in some cases recorded consent needed for special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure?	7.2.4.3 b)	☐	☐	☐		
c) If obtaining consent in not possible in emergency situations, does the laboratory carry out necessary procedures, provided they are in the patient's interest?	7.2.4.3 c)	☐	☐	☐		
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?	7.2.4.4 a)	☐	☐	☐		
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]?	7.2.4.4 b)	☐	☐	☐		
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?	7.2.4.4 c)	☐	☐	☐		
d) labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected?	7.2.4.4 d)	☐	☐	☐		
e) recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time?	7.2.4.4 e)	☐	☐	☐		
f) requirements for separating or dividing the primary sample when necessary?	7.2.4.4 f)	☐	☐	☐		
g) stabilization and proper storage conditions before collected samples are delivered to the laboratory?	7.2.4.4 g)	☐	☐	☐		
h) Safe disposal of materials in the collection process?	7.2.4.4 h)	☐	☐	☐		
Sample transportation						
a) To ensure the timely and safe transportation of samples, does the laboratory provide instructions for the following?	7.2.5 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
1) packaging of samples for transportation; 2) ensuring the time between collection and receipt in the laboratory is appropriate for the requested examination; 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 organisation responsible for the transport of the sample notifed immediately and action taken to reduce the risk and to prevent recurrence?	7.2.5 b)	☐	☐	☐		
c) Does the laboratory establish and periodically evaluate adequacy of sample transportation systems?	7.2.5 c)	☐	☐	☐		
Sample receipt						
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?	7.2.6.1 a)	☐	☐	☐		
b) criteria for acceptance and rejection of samples?	7.2.6.1 b)	☐	☐	☐		
c) recroding the date and time of receipt of samples, when relevant?	7.2.6.1 c)	☐	☐	☐		
d) recording the identity of the persone receiving the sample, when relevant?	7.2.6.1 d)	☐	☐	☐		
e) evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s)?	7.2.6.1 e)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
f) instructions for samples specifically markes as urgent, which include details of special labelling, transport, any rapid processing method, turnaround times, and special reporting criteria to be followed?	7.2.6.1 f	☐	☐	☐		
g) ensuring that all portions of the samle shall be unequivocally traceable to the original sample?	7.2.6.1 g)	☐	☐	☐		
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	7.2.6.2 a)	☐	☐	☐		
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)?						
5) insufficient sample volume?						
When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to pateient safety, does the final report indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected?	7.2.6.2 b)	☐	☐	☐		
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?	7.2.7.1	☐	☐	☐		
Criteria for additional examination requests						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Do laboratory procedures include time limits for requesting additional examinations on the sample sample?	7.2.7.2	☐	☐	☐		
Sample stability						
Considering the stability of the analyte in a primary sample, is the time between sample collection and performing the examination specified and monitored where relevant?	7.2.7.3	☐	☐	☐		
Examination processes						
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?	7.3.1 a)	☐	☐	☐		
b) Do the performance specifications for each examination method relate to the intended use of that examination and its impace on patient care?	7.3.1 b)	☐	☐	☐		
c) Are all proceudres and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and readily available to personnel?	7.3.1 c)	☐	☐	☐		
d) Do personnel follow established procedures and the identity of persons performing significant activities in examination processes recorded, including POCT operators?	7.3.1 d)	☐	☐	☐		
e) Is authorized periodically evaluate the examination methods provided by the laboratory to ensure they are clinically appropriate fo the requests received?	7.3.1 e)	☐	☐	☐		
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 ensure that the required performance, as specified by the manufacturer or method, can be achieved?	7.3.2 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) Are the performance specifications for the examination method confirmed during the verification process those relevant to the intended use of the examination results?	7.3.2 b)	☐	☐	☐		
c) Does the laboratory ensure the extent of the verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making?	7.3.2 c)	☐	☐	☐		
d) Does personnel with the appropriate authorization and competence review the verification results and record whether the results meet the specified requirements?	7.3.2 d)	☐	☐	☐		
e) If a method is revised by the issuing body, does the laboratory repeat verification to the extent necessary?	7.3.2 e)	☐	☐	☐		
f) Are the following records of verification retained?	7.3.2 f)	☐	☐	☐		
1) performance specification to be achieved,						
2) results obtained, and						
3) a statement whether the performance specifications were achieved and if not, action taken.						
Validation of examination methods						
a) Does the laboratory validate examination methods derived from the following sources?	7.3.3 a)	☐	☐	☐		
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.						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) Is the validation as extensive as 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? Doest the laboratory ensure that the extent of validation of an examination method is sufficient to ensreu the validity of results pertinent to clinical decision making?	7.3.3 b)	☐	☐	☐		
c) Do personnel with the appropriate authorization and competence review the validation results and record whether the results meet the specified requirements?	7.3.3 c)	☐	☐	☐		
d) When changes are proposed to a validated examination method, is the clinical impace reviewed, and a decision made as to whether to implement the modified method?	7.3.3 d)	☐	☐	☐		
e) Are the following records of validation retained?	7.3.3 e)	☐	☐	☐		
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.						
Evaluation of measurement uncertainty (MU)						
a) Are the MU of measurement quantity values evaluated and maintained for its intended use, where relevant? Are the MU compared against performance specification and documented?	7.3.4 a)	☐	☐	☐		
b) Are MU evaluations regularly reviewed?	7.3.4 b)	☐	☐	☐		
c) For examination procedures where evaluation of MU is not poassible or relevant, is the rationale for exclusion from MU estimation documented?	7.3.4 c)	☐	☐	☐		
d) Is MU information made available to laboratory users on request?	7.3.4 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
e) When users have inquiries on MU, does the laboratory's reponse take into account other sources of uncertainty, such as but not limited to biological variation?	7.3.4 e)	☐	☐	☐		
f) If the qualitative results of an examination relies on a test which produces quanitative output data and is specified as positive or negative, based on a threshold, is MU in the output quantity estimated using representative positive and negative samples?	7.3.4 f)	☐	☐	☐		
g) For examinations with qualitative rsults, are MU in intermediate measurement steps or IQC results which produce quantitative data considered for key (high risk) parts of the process?	7.3.4 g)	☐	☐	☐		
h) Are MU take into considfation when performing verification or validation of a method, when relevant?	7.3.4 h)	☐	☐	☐		
Biological reference intervals and clinical decision limits						
Are biological reference intervals and clinical decision limits, when needed for interpretation of examination results, defined and communicated to users?	7.3.5	☐	☐	☐		
a) Are biological reference intervals and clinical decision limits defined, and their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients?	7.3.5 a)	☐	☐	☐		
b) Are biological reference intervals and clinical decision limits periodically reviewed, and any changes communicated to users?	7.3.5 b)	☐	☐	☐		
c) When changes are made to an examination or pre-examination method, does the laboratory review the impact on associated reference intervals and clinical decision limits and communicate to the users when applicable?	7.3.5 c)	☐	☐	☐		
d) For examinations that identify presence or absence of a characteristic, is the biological reference interval the characteristic to be identified, e.g. genetic examination?	7.3.5 d)	☐	☐	☐		
Documentation of examination procedures						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
a) Does the laboratory document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results?	7.3.6 a)	☐	☐	☐		
b) Are procedures written in a language understood by laboratory personnel and available in appropriate locations?	7.3.6 b)	☐	☐	☐		
c) Does any abbreviated document content correspond to the procedure?	7.3.6 c)	☐	☐	☐		
d) Is information from product instructions for use, that contain sufficient information, incorporated into procedures by reference?	7.3.6 d)	☐	☐	☐		
e) When the laboratory makes a validated change to an examination procedure which could affect interpretation of results, are the implications explained to users?	7.3.6 e)	☐	☐	☐		
f) Are all documents associated with the examination process subject to document control?	7.3.6 f)	☐	☐	☐		
Ensuring the validity of examination results						
General						
Does the laboratory have a procedure for monitoring the validity of results?	7.3.7.1	☐	☐	☐		
Are the resulting data recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques applied to review the results?	7.3.7.1	☐	☐	☐		
Is this monitoring planned and reviewed?	7.3.7.1	☐	☐	☐		
Internal quality control (IQC)						
a) Does the laboratory have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making?	7.3.7.2 a)	☐	☐	☐		
1) Is the intended clinical application of the examination considered, as the performance specifications for the same measurand can differ in different clinical settings?	7.3.7.2 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
2) Does the procedure allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method? To enable this, does the laboratory procedure avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both?	7.3.7.2 a)	☐	☐	☐		
3) Is the use of third-party IQC materials considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer?	7.3.7.2 a)	☐	☐	☐		
b) Does the laboratory select IQC materials that is fit for its intended prupose?	7.3.7.2 b)	☐	☐	☐		
When selecting IQC materials, do factors to be considered include:						
1) stability with regard to the properties of interest;	7.3.7.2 b)	☐	☐	☐		
2) the matrix is as close as possiblt ot that of patient samples;	7.3.7.2 b)	☐	☐	☐		
3) the IQC material reacts to the examination method in a manner as close as to patient samples;	7.3.7.2 b)	☐	☐	☐		
4) the IQC material provides a clinical relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the mesuremetn range of the examination method.	7.3.7.2 b)	☐	☐	☐		
c) If appropriate IQC material is not available, does the laboratory consider the use of other methods for IQC? Examples of such other methods may include:	7.3.7.2 c)	☐	☐	☐		
1) trend analysis of patient results e.g. with moving average of patient results, or percentage of sampels 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 samples.						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
d) Are IQC performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result?	7.3.7.2 d)	☐	☐	☐		
e) Are the resulting data record in such a way that trends and shifts are detectable and, where applicable, statistical techniques applied to review the results?	7.3.7.2 e)	☐	☐	☐		
f) Are IQC data reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance?	7.3.7.2 f)	☐	☐	☐		
g) Does the laboratory prevent the release of patient results in the event that IQC fails the defined acceptability criteria?	7.3.7.2 g)	☐	☐	☐		
1) When IQC defined acceptability criteria are not fulfilled and indicate result are likely to contain clinically significant errors, are the results rejected and relevant patient samples re-examined after the error has been corrected?	7.3.7.2 g)	☐	☐	☐		
2) Are the results from patient samples that were examined after the last successful IQC event evaluated?	7.3.7.2 g)	☐	☐	☐		
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.	7.3.7.3 a)	☐	☐	☐		
b) Does the laboratory establish a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available?	7.3.7.3 b)	☐	☐	☐		
c) Are EQA samples processed by personnel who routinely perform pre-examination, examination and post-examination procedures?	7.3.7.3 c)	☐	☐	☐		
d) Are the EQA programme(s) selected by the laboratory, to the extent possible,						
1) have the effect of checking pre-examination, examination, and post-examination processes;	7.3.7.3 d)	☐	☐	☐		
2) provide samples that mimic patient samples for clinically relevant challenges;	7.3.7.3 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
3) fulfill ISO/IEC 17043 requirements.	7.3.7.3 d)	☐	☐	☐		
e) When selecting EQA programme(s), does the laboratory consider the type of target value offered?	7.3.7.3 e)	☐	☐	☐		
f) When an EQA programmeis either not available, or not considered suitable, does the laboratory use alternative methodologies to monitor examination method performance? Does the laboratory justify the rationale for the chosen alternative and provide evidence of its effectiveness?	7.3.7.3 f)	☐	☐	☐		
g) Are EQA data reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance?	7.3.7.3 g)	☐	☐	☐		
h) When EQA results fall outside specified acceptability criteria, is appropriate action, including an assessment of whether the non-conformance is clinically significant as it relates to patient samples?	7.3.7.3 h)	☐	☐	☐		
i) Where it is determined that the impace is clinically significant, is a review of patient results that could have been affected and the need for amendment considered and users advised as appropriate?	7.3.7.3 i)	☐	☐	☐		
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, is a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals specified?	7.3.7.4 a)	☐	☐	☐		
b) Does the laboratory record the results of comparability performed and its acceptability?	7.3.7.4 b)	☐	☐	☐		
c) Does the laboratory periodically review the comparability of results?	7.3.7.4 c)	☐	☐	☐		
d) Where differences are identified, is the impact of those differences on biological reference intervals and clinical decision limits evaluated and acted upon?	7.3.7.4 d)	☐	☐	☐		
e) Does the laboratory inform users of any clinically significant differences in comparability of results?	7.3.7.4 e)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Post-examination processes						
Reporting of results						
General						
a) Are examination results reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure? Does the report include all available information necessary for the interpretation of the results?	7.4.1.1 a)	☐	☐	☐		
b) Does the laboratory have a proceure to notify users when examination esults are delayed, based on the impact of the delay on the patient?	7.4.1.1 b)	☐	☐	☐		
c) Is all information associated with issued reports retained in accordance with management system requirements?	7.4.1.1 c)	☐	☐	☐		
Result review and release						
Are results reviewed and authorized prior to release?	7.4.1.2	☐	☐	☐		
Does the laboratory ensure that authorized personnel review the results of examinations and evaluated them against IQC and, as appropriate, available clinical information and previous examination results?	7.4.1.2	☐	☐	☐		
Are responsibilities and procedsures for how examination results are released for reporting, including by whom and to whom, specified?	7.4.1.2	☐	☐	☐		
Critical result reports						
When examination results fall within established critical decision limits:						
a) is the user or other authorized person notified as soon as relevant, based on clinical information available?	7.4.1.3 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) are actions taken documented, including date, time, responsible person, person notified, results, conveyed, verification of accuracy of information, and any difficulties encountered in notification?	7.4.1.3 b)	☐	☐	☐		
c) is an escalation procedure available for laboratory personnel when a responsible person cannot be contacted?	7.4.1.3 c)	☐	☐	☐		
Special consideration for results						
a) When agreed with the user, are the results reported in simplified way? Is any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user readily available?	7.4.1.4 a)	☐	☐	☐		
b) When results are transmitted as a preliminary report, is the final report always be forwarded to the user?	7.4.1.4 b)	☐	☐	☐		
c) Are records of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b) kept? Are such results always followed by a report?	7.4.1.4 c)	☐	☐	☐		
d) For examination esults with serious implications for the patient (e.g. for genetic or centain infectious diseases) , does laboratory management ensure that these results are not communicated to the patient without opportunity for adequate counselling?	7.4.1.4 d)	☐	☐	☐		
e) Are risks to patient privacy and confidentiality mitigated and in accordance with any either legal or regulatory requirements, or both when results of laboratory examinations that have been anonymized are used for such purposes as epidemiology, demography, or other statistical analyses?	7.4.1.4 e)	☐	☐	☐		
Authomated selection, review, release and reporting of results						
When the laboratory implements a system for automated selection, review, release and reporting of results, does it establishe a procedure to ensure that:						
a) are the criteria for automated selection, review and release specified, approved, readily available and understood by personnel responsible for authorizing the release of results?	7.4.1.5 a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
b) are the criteria 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?	7.4.1.5 b)	☐	☐	☐		
c) are results selected by an automated reporting system for manual review identifiable; and as appropriate, date and time of selection and review, as well as identity of the reviewer are retrievable?	7.4.1.5 c)	☐	☐	☐		
d) when necessary, is rapid suspension of automated selection, review, release and reporting applied?	7.4.1.5 d)	☐	☐	☐		
Requirements for reports						
Does each report include the following information, unless the laboratory has documented reasons for omitting such 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;	7.4.1.6 a)	☐	☐	☐		
b) identification of the laboratory issuing the report;	7.4.1.6 b)	☐	☐	☐		
c) name or other unique identifier of the user;	7.4.1.6 c)	☐	☐	☐		
d) type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description);	7.4.1.6 d)	☐	☐	☐		
e) clear, umambigious identification of the examinations performed;	7.4.1.6 e)	☐	☐	☐		
f) identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principles	7.4.1.6 f)	☐	☐	☐		
g) examiantions results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units;	7.4.1.6 g)	☐	☐	☐		
h) biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary;	7.4.1.6 h)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
i) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;	7.4.1.6 i)	☐	☐	☐		
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);	7.4.1.6 j)	☐	☐	☐		
k) identification of any results that need to be considered as preliminary;	7.4.1.6 k)	☐	☐	☐		
l) indication of any critical results;	7.4.1.6 l)	☐	☐	☐		
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).	7.4.1.6 m)	☐	☐	☐		
Additional information for reports						
a) When necessary for patient care, is the time of primary sample collection included?	7.4.1.7 a)	☐	☐	☐		
b) Is time of report release, if not contained in the report, readily available when needed?	7.4.1.7 b)	☐	☐	☐		
c) Are all examiantions 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 identified?	7.4.1.7 c)	☐	☐	☐		
d) When applicable, does a report include interpretation of results and comments on:						
1) sample quality and suitability that can compromise the clinical value of examination results?	7.4.1.7 d)	☐	☐	☐		
2) descrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations?	7.4.1.7 d)	☐	☐	☐		
3) possible risk of misinterpretation when different units of measurement are in use regionally or nationally?	7.4.1.7 d)	☐	☐	☐		
4) result trends or significant changes over time?	7.4.1.7 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
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?	7.4.1.8 a)	☐	☐	☐		
b) are revised results delivered only in the form of an additional document or data transfer, and clearly identified as having been reviewed, and the date and patient's identity in the original report indicated?	7.4.1.8 b)	☐	☐	☐		
c) Is the user made aware of the revision?	7.4.1.8 c)	☐	☐	☐		
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?	7.4.1.8 d)	☐	☐	☐		
e) When the reporting system cannot capture revisions, is a record of such kept?	7.4.1.8 e)	☐	☐	☐		
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?	7.4.2	☐	☐	☐		
Does the laboratory ensure that after the examination, the						
a) patient and source identification of the sample are maintained?	7.4.2 a)	☐	☐	☐		
b) suitability of the sample for additional examination is known?	7.4.2 b)	☐	☐	☐		
c) sample is stored in a manner that optimarlly perserves suitability for additional examination?	7.4.2 c)	☐	☐	☐		
d) sample can be located and retrieved?	7.4.2 d)	☐	☐	☐		
e) samples is discarded appropriately?	7.4.2 e)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
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 condictionsl are out of specified limits, results of monitoring faile to meet specified criteria)?	7.5	☐	☐	☐		
Does the process ensure that						
a) the responsibilities and authorities for the management of nonconforming work are specified?	7.5 a)	☐	☐	☐		
b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory?	7.5 b)	☐	☐	☐		
c) examinations are halted, and reports withheld when there is a risk of harm to patients?	7.5 c)	☐	☐	☐		
d) 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?	7.5 d)	☐	☐	☐		
e) a decision that is made on the acceptability of the nonconforming work?	7.5 e)	☐	☐	☐		
f) when necessary, examination results are revised, and the user is notified?	7.5 f)	☐	☐	☐		
g) the responsibility for authorizing the resumption of work is specified?	7.5 g)	☐	☐	☐		
Does the laboratory implement corrective action commensurate with the risk of recurrence of the nonconforming work?	7.5	☐	☐	☐		
Does the laboratory retain records of nonconforming work and actions as specified in 7.5 a) to g) ?	7.5	☐	☐	☐		
Control of data and information management						
General						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory have access to the data and information needed to perform laboratory activities?	7.6.1	☐	☐	☐		
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?	7.6.2	☐	☐	☐		
Is the laboratory ultimately responsible for the laboratory information systems?	7.6.2	☐	☐	☐		
Information systems management						
Is/are the system(s) for the collection, processing, recording, reporting, storage or retrieval of examination data and information:						
a) validated by the supplier and verified for functioning by the laboratory before introduction? Are changes to the system, including laboratory software configuration or modifications to commercial off-the-shelf software, authorized, documented and validated before implementation?	7.6.3 a)	☐	☐	☐		
b) documented, and the documentation readily available to authorized users, including that for day to day functioning of the system?	7.6.3 b)	☐	☐	☐		
c) implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tempering or loss?	7.6.3 c)	☐	☐	☐		
d) operated in an environment that complies with supplier specifications or, in the case of non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription?	7.6.3 d)	☐	☐	☐		
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?	7.6.3 e)	☐	☐	☐		
Are calculations and data transfer checked in an appropriate and systematic manner?	7.6.3	☐	☐	☐		
Downtime plans						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
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?	7.6.4	☐	☐	☐		
Off site management						
When the laboratory information system(s) are managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of ISO 15189:2022?	7.6.5	☐	☐	☐		
Complaints						
Process						
Does the laboratory have a process for handling complaints that 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;	7.7.1 a)	☐	☐	☐		
b) tracking and recording the complaint, including the actions undertaken to resolve it;	7.7.1 b)	☐	☐	☐		
c) ensuring appropriate actions is taken?	7.7.1 c)	☐	☐	☐		
Is a description of the process for handling complaints publicly available?	7.7.1					
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, resolve the complaint?	7.7.2 a)	☐	☐	☐		
b) Is the laboratory receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated?	7.7.2 b)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
c) Whenever possible, does the laboratory acknowledge receipt of complaint, and provide the complainant with the outcome and, if applicable, progress reports?	7.7.2 c)	☐	☐	☐		
Resolution of complaint						
Do investigation and resolution of complaints result in any discriminatory actions?	7.7.3	☐	☐	☐		
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 any alternative approach compromise impartiality?	7.7.3	☐	☐	☐		
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?	7.8	☐	☐	☐		
Are plans periodically tested and the planned response capability exercised, where practicable?	7.8	☐	☐	☐		
Does the laboratory:						
a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel?	7.8 a)	☐	☐	☐		
b) provide information and training as appropriate to relevant laboratory personnel?	7.8 b)	☐	☐	☐		
c) repond to actual emergency situation?	7.8 c)	☐	☐	☐		
d) take action to prevent or mitigate the consquences of emergency situations, appropriate to the magnitude of the emergency and the potential impact?	7.8 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Management system requirements						
General requirements						
General						
Does the laboratory establish, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of ISO 15189:2022?	8.1.1	☐	☐	☐		
As a minimium, does the management system include the following?	8.1.1	☐	☐	☐		
- responsibilities						
- objectives and policies						
- documented information						
- actions to address risks and opportunities for improvement						
- continual improvement						
- corrective actions						
- evaluations and internal audits						
- management reviews						
Fulfilment of management system requirements						
Does the laboratory meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001)?	8.1.2	☐	☐	☐		
Does this quality management system support and demonstrate the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9 of ISO 15189:2022?	8.1.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Management system awareness						
Does the laboratory ensure persons doing work under the laboratory's control are aware of:						
a) relevant objectives and policies;	8.1.3 a)	☐	☐	☐		
b) their contribution to the effectiveness of the management system, including the benefits of improved performance;	8.1.3 b)	☐	☐	☐		
c) the consequences of not conforming with the management system requirements.	8.1.3 c)	☐	☐	☐		
Management system requirements						
General						
Does the laboratory establish, document, and maintain objectives and policies for the fulfilment of the purposes of ISO 15189:2022?	8.2.1	☐	☐	☐		
Does the laboratory ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization?	8.2.1	☐	☐	☐		
Competence and quality						
Do the objectives and policies address the competence, quality and consistent operation of the laboratory?	8.2.2	☐	☐	☐		
Evidence of commitment						
Does laboratory management provide evidence of commitment to the development and implementation of ISO 15189:2022 and to continually improving its effectiveness?	8.2.3	☐	☐	☐		
Documentation						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Are all documentation, processes, systems, and records, related to the fulfilment of the requirements of ISO 15189:2022 included in, referenced from, or linked to the management system?	8.2.4	☐	☐	☐		
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?	8.2.5	☐	☐	☐		
Control of management system documents						
General						
Does the laboratory control the documents (internal and external) that relate to the fulfilment of ISO 15189:2022?	8.3.1	☐	☐	☐		
Control of documents						
Does the laboratory ensure that:						
a) documents are uniquely identified;	8.3.2 a)	☐	☐	☐		
b) documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy;	8.3.2 b)	☐	☐	☐		
c) documents are periodically reviewed and updated as necessary;	8.3.2 c)	☐	☐	☐		
d) relevant versions of applicable documents are available at points of use and , where necessary, their distribution is controlled;	8.3.2 d)	☐	☐	☐		
e) changes and the current revision status of documents are identified;	8.3.2 e)	☐	☐	☐		
f) documents are protected from unauthorized changes and any deletion or removal;	8.3.2 f)	☐	☐	☐		
g) documents are protected from unauthorized access;	8.3.2 g)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
h) the unintended user of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;	8.3.2 h)	☐	☐	☐		
i) 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.	8.3.2 i)	☐	☐	☐		
Control of records						
Creation of records						
Does the laboratory establish and retain legible records to demonstrate fulfillment of the requirements of ISO 15189:2022?	8.4.1	☐	☐	☐		
Are records created at the time each activity that affects the quality of an examination is performed?	8.4.1	☐	☐	☐		
Amendment of records						
Does the laboratory ensure that amendments to records can be traced to previous versions or to original observations?	8.4.2	☐	☐	☐		
Are both the original and amended data and files are kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations?	8.4.2	☐	☐	☐		
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?	8.4.3 a)	☐	☐	☐		
b) Are the retention times for records specified?	8.4.3 b)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
c) Are reported examination results retrievable for as long as necessary and as required?	8.4.3 c)	☐	☐	☐		
d) Are all records accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review?	8.4.3 d)	☐	☐	☐		
Actions to address risks and opportunities for improvement						
Identification of risks and opportunities for improvement						
Does the laboratory idenfy risks and opportunities for improvement associated with the laboratory activities to:						
a) prevent or reduce undesired impacts and potential failures in the laboratory activities;	8.5.1 a)	☐	☐	☐		
b) achieve improvement, by acting on opportunities;	8.5.1 b)	☐	☐	☐		
c) assure that the management system achieves its intended results;	8.5.1 c)	☐	☐	☐		
d) mitigate risks to patient care;	8.5.1 d)	☐	☐	☐		
e) help achieve the purpose and objectives of the laboratory.	8.5.1 e)	☐	☐	☐		
Acting on risks and opporutnities for improvement						
Does the laboratory prioritize and act on identified risks?	8.5.2	☐	☐	☐		
Are actions taken to address risks proportional to the potential impact on laboratory examination results, as well as patient and personnel safety?	8.5.2	☐	☐	☐		
Does the laboratory record decisions made and actions taken on risks and opportunities?	8.5.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness?	8.5.2	☐	☐	☐		
Improvement						
Continual improvement						
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?	8.6.1 a)	☐	☐	☐		
Does the laboratory identify and select opportunities for improvement, and develop, document and implement any necessary actions?	8.6.1 b)	☐	☐	☐		
Are improvement activities directed at areas of highest priority based on risk assessments and the opportunities identified?	8.6.1 b)	☐	☐	☐		
Does the laboratory evaluate the effectiveness of the actions taken?	8.6.1 c)	☐	☐	☐		
Does laboratory management ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care?	8.6.1 d)	☐	☐	☐		
Does laboratory management communicate to personnel its improvement plans and related goals?	8.6.1 e)	☐	☐	☐		
Laboratory patients, users and personnel feedback						
Does the laboratory seek feedback from its patients, users, and personnel?	8.6.2	☐	☐	☐		
Are the feedback analysed and used to improvement the management system, laboratory activities and services to users?	8.6.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Nonconformities and corrective actions						
Actions when nonconformity occurs						
When a nonconformity occurs, does the laboratory:						
a) respond to the nonconformity, and, as applicable:	8.7.1 a)	☐	☐	☐		
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 root cause(s) of the nonconformity.	8.7.1 b)	☐	☐	☐		
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:	8.7.1 c)	☐	☐	☐		
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.	8.7.1 d)	☐	☐	☐		
e) review and evaluate the effectiveness of any correction action taken.	8.7.1 e)	☐	☐	☐		
f) update risks and opportunities for improvement, as needed.	8.7.1 f)	☐	☐	☐		
g) make changes to the management system, if necessary.	8.7.1 g)	☐	☐	☐		
Corrective action effectiveness						
Are corrective actions appropriate to the effects of the nonconformities encountered and the identified cause(s) mitigated?	8.7.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
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	8.7.3 a)	☐	☐	☐		
b) evaluation of the effectiveness of any corrective action.	8.7.3 b)	☐	☐	☐		
Evaluations						
General						
Does the laboratory conduct evaluations at planned intervals?	8.8.1	☐	☐	☐		
Quality indicator						
Does the laboratory plan the process of monitoring quality indicators which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring?	8.8.2	☐	☐	☐		
Are the indicators be reviewed periodically to ensure continued appropriateness?	8.8.2	☐	☐	☐		
Internal audits						
Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system						
a) conform to the laboratory's own requirements for its management system, including the laboratory activities;	8.8.3.1 a)	☐	☐	☐		
b) conforms to the requirements of ISO 15189:2022, and	8.8.3.1 b)	☐	☐	☐		
c) is effectively implemented and maintained.	8.8.3.1 c)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the laboratory plan, establish, implement and maintain an internal audit programme that includes:						
a) priority given to risk to patients from laboratory activities;	8.8.3.2 a)	☐	☐	☐		
b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence	8.8.3.2 b)	☐	☐	☐		
c) specified audit objectives, critiera and scope for each audit;	8.8.3.2 c)	☐	☐	☐		
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;	8.8.3.2 d)	☐	☐	☐		
e) ensuring objectivity and impartiality of the audit process;	8.8.3.2 e)	☐	☐	☐		
f) ensuring that the results of the audits are reported to relevant personnel;	8.8.3.2 f)	☐	☐	☐		
g) implementation of appropriate correction and corrective actions without undue delay;	8.8.3.2 g)	☐	☐	☐		
h) retention of records as evidence of the implementation of the audit programme and audit results.	8.8.3.2 h)	☐	☐	☐		
Management reviews						
General						
Does the laboratory review its management system at planned intervals?	8.9.1	☐	☐	☐		
Review input						
Does the laboratory record the inputs to management review and include the evaluation of at least the following:						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
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;	8.9.2 a)	☐	☐	☐		
b) fulfilment of objectives and suitability of policies and procedures;	8.9.2 b)	☐	☐	☐		
c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assesssments by external bodies;	8.9.2 c)	☐	☐	☐		
d) patient, user and personnel feedback and complaints;	8.9.2 d)	☐	☐	☐		
e) quality assurance of result validity;	8.9.2 e)	☐	☐	☐		
f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;	8.9.2 f)	☐	☐	☐		
g) performance of external providers;	8.9.2 g)	☐	☐	☐		
h) results of participation in interlaboratory comparison programmes;	8.9.2 h)	☐	☐	☐		
i) evaluation of POCT activities;	8.9.2 i)	☐	☐	☐		
j) other relevant factors, such as monitoring activities and training.	8.9.2 j)	☐	☐	☐		
Review output						
Does the laboratory record decisions and actions related to at least:						
a) the effectiveness of the management system and its processes;	8.9.3 a)	☐	☐	☐		
b) improvement of the laboratory activities related to the fulfillment of the requirements of this document;	8.9.3 b)	☐	☐	☐		
c) provision of required resources;	8.9.3 c)	☐	☐	☐		
d) improvement of services to patients and users;	8.9.3 d)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
e) any need for change.	8.9.3 e)	☐	☐	☐		
Does the laboratory ensure that actions arising from management review are completed within a specified time frame?	8.9.3	☐	☐	☐		
Does the laboratory communicate to laboratory personnel the conclusions and actions arising from the management reviews?	8.9.3	☐	☐	☐		
HKAS 002: Regulations for HKAS Accreditation						
The obligations of an accredited organisation	**5**					
After obtaining accreditation, will your laboratory at all times:-						
(a) conform with the accreditation criteria, including accreditation regulations specified in HKAS 002 and HOKLAS Supplementary Criteria No.33, technical and non-technical requirements and other conditions as specified by HKAS Executive under your terms of accreditation;	5.1 (a)	☐	☐	☐		
(b) represent honestly and truthfully to any person concerned that it is only accredited for activities stated in the scope of accreditation;	5.1 (b)	☐	☐	☐		
(c) pay such fees and charges as determined by HKAS Executive;	5.1 (c)	☐	☐	☐		
(d) endeavor to ensure the accreditation granted by HKAS is not used in a misleading manner; and	5.1 (d)	☐	☐	☐		
(e) be a legal entity; and	5.1 (e)	☐	☐	☐		
(f) conform with the Business Registration Ordinance (Cap 310)?	5.1 (f)	☐	☐	☐		
For any customers for which your laboratory performs any accredited activity, does your laboratory maintain for such activity a quality standard which is in conformity with the accreditation criteria as set by HKAS?	5.2	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Will your laboratory maintain the same quality standard at all times, no matter whether or not the HKAS accreditation symbol is used in the report or certificate covering the result of such activity?	5.2	☐	☐	☐		
When making any statement in relation to your laboratory's accreditation status in situation where non-accredited activities are mentioned, will your laboratory ensure that such a statement is accompanied by a statement indicating which activities are not accredited?	5.3	☐	☐	☐		
Is your laboratory aware of and does it comply with the following accreditation regulation: "Upon termination of accreditation for all activities of an organisation as specified in a certificate of accreditation, the organisation shall return such certificate of accreditation to HKAS Executive forthwith."?	5.4	☐	☐	☐		
Does your laboratory cooperate with HKAS Executive and its assessment teams and provide them with full support during an on-site assessment and in any other situation such as to provide all necessary information for assessment of the laboratory's competence and its conformity with the accreditation criteria?	5.5	☐	☐	☐		
Upon the request of HKAS Executive, does your laboratory provide HKAS Executive with a copy of the documentary standard for which it seeks HKAS accreditation for use during the assessment?	5.5	☐	☐	☐		
Does your laboratory ensure that it will use its accreditation status only in a manner that will not bring HKAS or any of its accreditation schemes into disputes and will not make any statement regarding its accreditation status that HKAS Executive may reasonably consider it to be misleading?	5.6	☐	☐	☐		
Does your laboratory maintain complete integrity and impartiality in all circumstances? Will the authorised representative report any impropriety or unlawful act of the laboratory or any iniquitous management and/or staff to HKAS Executive? Will the authorised representative further report immediately any corrupt practice to the ICAC (or similar authority or the police when outside the jurisdiction of the HKSAR)?	5.7	☐	☐	☐		
Does your laboratory notify HKAS Executive within one calendar month if a new authorised representative has been appointed?	5.8	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does the authorised representative or in his absence, other responsible person of the laboratory inform HKAS Executive in writing immediately of any changes or intended changes in the laboratory's circumstances which may affect its conformity with relevant accreditation criteria?	5.9	☐	☐	☐		
Does your laboratory implement the following HKAS regulation on confidentiality: "An accredited organisation shall pay due regard to the confidentially of its customer's information and shall make internal rules and guidelines in order to ensure protection of its customer's information. Confidential information about a particular customer shall not be disclosed to a third party without the consent of the customer, except where the law requires such information to be so disclosed. However, an applicant organisation or an accredited organisation shall allow HKAS Executive to examine all its records which are relevant to the scope of accreditation in order to assess its competence and compliance with the relevant accreditation criteria. An applicant organisation and an accredited organisation shall obtain consent from their customers for the disclosure of any relevant information to HKAS."?	5.10	☐	☐	☐		
Does your laboratory ensure that no unofficial contact with assessors, technical experts and/or AAB members will be made on any matter relating to or in connection with the assessment of any activity for the purpose of granting or maintaining accreditation?	5.11	☐	☐	☐		
Are all communications concerning the laboratory's assessment make between the authorised representative or his/her representative or its chief executive or his/her representative and HKAS Executive?	5.11	☐	☐	☐		
Does your laboratory have a clear policy in writing concerning the offering, solicitation and acceptance of advantages by its personnel? Does the policy document contain a statement notifying its personnel the law under Section 9 of the Prevention of Bribery Ordinance (Cap. 201)? Does your laboratory further ensure that the policy is made known to all its personnel?	5.12	☐	☐	☐		
Does your laboratory have a policy and procedure in writing for handling and resolving complaints, disputes and appeals made to it by its customers or other parties?	5.13	☐	☐	☐		
Does your laboratory keep records of all complaints, disputes and appeals and actions taken for a minimum of 3 years and make available to HKAS Executive for inspection upon request?	5.13	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Where a complaint, dispute or appeal received from your customers or other parties raise any doubt on your compliance with your policies or procedures, does your laboratory ensure that the relevant areas of its accredited activities are promptly audited?	5.14	☐	☐	☐		
If a complaint, dispute or appeal received from your customers or other parties relating to any of your accredited activities is not satisfactorily resolved within 60 days from the date of receipt, does your laboratory notify HKAS Executive in writing of the matter?	5.15	☐	☐	☐		
Is your laboratory aware that any concerned party may lodge complaints with HKAS on any of your accredited activities?	5.16	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation?						
Upon the request of HKAS Executive, an accredited organisation shall confirm the authenticity or otherwise of a report, certificate or other document purporting to have been issued by it for an accredited activity. Where such a report, certificate or document is found to be a forged document, the organisation shall cooperate with HKAS Executive in the investigation of its cause and taking mutually agreeable steps to prevent recurrence.	5.17	☐	☐	☐		
An accredited organisation shall not provide certification service to any other party for any standard used by HKAS as accreditation criteria. HKAS Executive will take immediate action to suspend the accreditation of an accredited organisation in violation of this requirement.	5.18	☐	☐	☐		
Use of HKAS accreditation symbols and claims of accreditation status						
Does your laboratory conform with the following HKAS regulation:-						
"An accredited organisation may use the relevant HKAS accreditation symbol of its accreditation as described in HKAS Supplementary Criteria No. 1 and claim its accreditation status as described in HKAS Supplementary Criteria No. 1 provided that the following conditions are complied with:-						
(a) all advertising and promotional materials (including letterheads) shall not, in the opinion of HKAS Executive, give a false or misleading impression regarding the accreditation status of the organisation;	8.1 (a)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
(b) HKAS Supplementary Criteria No. 1 and requirements relevant to the accreditation scheme concerned as described in the relevant specific regulations, are conformed with at all times; and	8.1 (b)	☐	☐	☐		
(c) any statement made by the organisation in connection with its accreditation status shall not, in the opinion of HKAS Executive, give a false or misleading impression to any third party of its accreditation status."?	8.1 (c)	☐	☐	☐		
Is your laboratory aware that an accredited organisation shall not allow its accreditation be used to imply that any subject of its accredited activities, for example, a product, process, system or person is approved by HKAS or HKAS Executive and does it take suitable actions to stop any incorrect reference to accreditation.	8.2	☐	☐	☐		
Does your laboratory ensure that its customers, on receiving any report or certificate which bears a HOKLAS accreditation symbol are aware that the subject of the activity (e.g. the sample, instrument, product, design or system tested, calibrated) as referred to in such report or certificate is in no way approved nor disapproved by HKAS or HKAS Executive?	8.2	☐	☐	☐		
Upon suspension or termination of the accreditation of any activities carried out by your laboratory, whether or not voluntarily made, does your laboratory discontinue to make reference to the accreditation in any report, certificate, letterhead, brochure, advertising material, stationery, and Internet websites, etc., immediately?	8.2	☐	☐	☐		
HKAS SC-06: Code of conduct						
Has your laboratory documented the code of conduct within its management system for stating its policies on impartiality, confidentiality, professionalism, integrity, conflict of interest, and the organisation's commitment to complying with the Prevention of Bribery Ordinance (Cap 201) of Hong Kong or applicable laws and regulations of the country where your laboratory is located?	2.1	☐	☐	☐		
Does the code of conduct cover at least the following aspects:						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
(a) solicitation and acceptance of advantage; (b) offer of advantage; (c) entertainment; (d) compliance with laws of Hong Kong or of relevant jurisdictions; (e) compliance with relevant requirements of applicable professional standards; (f) conflict of interest; (g) use of company assets; (h) confidentiality of company information; (i) outside employment; (j) relationship with customers, suppliers and contractors; (k) procedures for reporting suspected violation and established mechanism for the prompt and fair adjudication of alleged violations; and (l) disciplinary actions to be taken against violations.	2.2	☐	☐	☐		
Does your laboratory determine the contents of the code of conduct in accordance with its circumstances to ensure that all persons working for it act lawfully, ethically, professionally, and honestly and protect the impartiality, independence and integrity of the laboratory?	2.3	☐	☐	☐		
Does your laboratory ensure that all its directors, staff and other personnel working for it understand and practice the code of conduct?	3.1	☐	☐	☐		
Has your laboratory provided training to all personnel as part of the orientation training when they join the laboratory and refresher training to all members periodically thereafter?	3.2	☐	☐	☐		
Does your laboratory periodically remind all personnel working for it the code of conduct?	3.3	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is the code of conduct accessible to all personnel working for the laboratory?	3.4	☐	☐	☐		
Is the authorised representative aware that he/she shall report any impropriety or unlawful act of the laboratory or any iniquitous management and/or personnel to HKAS Executive in accordance with clause 5.7 of HKAS 002?	3.5	☐	☐	☐		
Does your laboratory periodically review the code's suitability and adequacy; and implement improvement as appropriate?	3.6	☐	☐	☐		
HOKLAS SC-33: Accreditation Regulations Specific for HOKLAS - Laboratory						
Is your laboratory aware of and does it comply with the following accreditation regulation on accreditation procedure: "An assessment team may require a laboratory to demonstrate a test, a calibration or other laboratory activities as part of an assessment. It may also require the laboratory to participate in proficiency testing in order to evaluate its standard and competence. The specific laboratory activities to be demonstrated will be selected from those covered in the proposed scope of accreditation at the discretion of the assessment team. With effect from 30 November 2020, the laboratory shall have, where applicable, legally enforceable arrangements with their customers that commit the customers to provide, on request, access to HKAS assessment teams to assess the laboratory's performance when carrying out laboratory activities at their customers' site."?	2.1	☐	☐	☐		
Is your laboratory aware of and does it comply with the following accreditation regulation on accreditation procedure: "HKAS Executive shall conduct a reassessment on the accredited activities of a laboratory:-						

	Clause	Y	N	NA	Management system	Remarks (for internal use)
(a) twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the laboratory;	2.2 (a)	☐	☐	☐		
(b) every two years after the due date of the first reassessment or at such time intervals as specified for the Monitoring Plan adopted by the laboratory (refer to HKAS Supplementary Criteria No. 4 for details);	2.2 (b)	☐	☐	☐		
(c) at such other times as may be specified in the terms of accreditation;	2.2 (c)	☐	☐	☐		
(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited laboratory, of any change in the structure and circumstances of the laboratory since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the laboratory's competence or conformity with the accreditation criteria; and	2.2 (d)	☐	☐	☐		
(e) HKAS Executive may, at its discretion, vary the reassessment schedule.	2.2 (e)	☐	☐	☐		
Is your laboratory aware of and does it comply with the following accreditation regulation on accreditation procedure: (cont'd) "HKAS Executive shall conduct a surveillance visit to an accredited laboratory if no reassessment nor assessment for extension of accreditation nor surveillance visit to it has been conducted within the past twelve months' period or at such time intervals as specified for the Monitoring Plan adopted by the laboratory. HKAS Executive may, at its discretion, vary the surveillance visit schedule."?	2.3	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "Upon granting of accreditation for a test category to a laboratory, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for such test category."?	2.4	☐	☐	☐		
Does your laboratory at all times comply with the following HOKLAS accreditation criteria? HKAS 002, ISO 15189:2022, HKAS Policy Document No. 2, relevant HOKLAS Supplementary Criteria and relevant HKAS Supplementary Criteria.	3.1	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does your laboratory ensure that its accreditation status will not be used in a way that may be interpreted by any person that any product, material or any other subject of an activity for which HOKLAS accreditation has been granted has been approved or disapproved by HKAS or HKAS Executive? Does your laboratory further endeavor to ensure that no person use any certificate or report issued by it for such activity in a misleading manner?	3.2	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation on cooperation: "A laboratory accredited under HOKLAS shall afford its customers or their representative reasonable cooperation to monitor the laboratory's performance (in so far as to their respective contracts are concerned). This cooperation shall include: (a) performing any reasonable check tests or calibrations or checks for other laboratory activities, including to prepare, pack and dispatch the test pieces, samples and other items for such check activities, which serve to verify its capability or standard of service as requested by the customer; and	3.3 (a)	☐	☐	☐		
(b) allowing each of its customers or their representatives reasonable access to the laboratory in order to observe any test, calibration or other activity performed by it for the customer. However, the laboratory shall ensure that the confidentiality of its other customers will be protected and their information will not be divulged to any third party (subject to clause 5.10 of HKAS 002)."? For avoidance of doubt, the laboratory may also take reasonable steps to protect its proprietary information and agree with its customers the cost the customers have to pay to the laboratory for performing or taking part in such monitoring activities.	3.3 (b)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is your laboratory aware of and does it comply with the following HKAS regulation on subcontracting: "If an accredited laboratory intends to subcontract any part of its activities to which HOKLAS accreditation has been granted, it shall ensure that the activities of the laboratory to which the activities will be subcontracted have been accredited by HKAS or an accreditation body recognised by HKAS under a mutual recognition arrangement. A list of such accreditation bodies is available at the HKAS website. The accredited laboratory shall notify its customer concerned in writing of its intention to subcontract the activities and the extent of such subcontract. It shall obtain agreement from the customer regarding such arrangement and shall further keep records of such agreement. In the report or certificate, the accredited laboratory shall identify the activities performed and the results obtained by such subcontractor."?	3.4	☐	☐	☐		
Does your laboratory take part in proficiency testing (PT) programmes which are relevant to its scope of accreditation organised or specified by HKAS Executive unless it can demonstrate to HKAS Executive that it has already participated in alternative programmes which are acceptable to HKAS Executive?	3.5	☐	☐	☐		
Is the performance of your laboratory in any proficiency testing activity relevant to its scope of accreditation acceptable to HKAS Executive?	3.5	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation on proficiency testing: "An applicant laboratory shall have taken part in appropriate proficiency testing activity(ies), representative of each test area of the laboratory's scope of accreditation to demonstrate its competence in each test area, and obtain satisfactory result before initial accreditation or accreditation extended to a new test area will be granted."?	3.6	☐	☐	☐		
Does your laboratory establish a 1-year PT participation plan with the coverage being representative and adequate to demonstrate your laboratory's competence in performing tests under its scope of accreditation?	3.7	☐	☐	☐		
Where suitable PT programme does not exist or is not practical, has your laboratory included suitable alternative means aiming to demonstrate the laboratory's competence in the plan?	3.7	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Has the plan been regularly reviewed and updated where necessary (for example, in response to changes of the scope of accreditation, staffing, methodology, instrumentation, and other factors that may affect the quality of the laboratory's test or calibration results)?	3.7	☐	☐	☐		
Has any change to the plan been documented and justified?	3.7	☐	☐	☐		
When the laboratory updates its PT plan, does your laboratory ensure its continual suitability in relation to its scope of accreditation?	3.7	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation on proficiency testing: "Records of PT participation for the past four years shall be available to show that the laboratory participated in PT activities representative of the accredited tests/calibration activities under each test area of its scope of accreditation. PT activities participated to represent a group of tests in a test area are expected to vary in subsequent cycles. It should be noted that the necessary level of participation in PT for certain technical disciplines may be specifically defined in the relevant HOKLAS Supplementary Criteria. Where defined, the laboratory shall ensure that the planned participation fulfils the respective PT requirements as stated in the relevant supplementary criteria. Where more stringent PT requirements are stipulated in the relevant supplementary criteria, the more stringent requirements shall be followed."?	3.8	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is your laboratory aware of and does it comply with the following HKAS regulation on proficiency testing: "An assessment team shall determine the adequacy of the PT participation plan and the appropriateness of any PT activities and may, at its discretion, require the laboratory to participate in other forms of PT activity so as to evaluate its competence in performing specific tests, calibrations or other laboratory activities. Where an applicant or an accredited laboratory is unable to participate in any appropriate PT activity because it fails to identify a suitable PT programme, it shall demonstrate to the satisfaction of the assessment team that it has taken all reasonable steps to identify such PT programme and any justification to use alternative suitable means shall be documented. In this clause, PT activity includes any international, regional and national interlaboratory comparisons as well as measurement audits and check samples acceptable to HKAS."?	3.9	☐	☐	☐		
Where the performance of an accredited laboratory in a PT activity is unsatisfactory, has your laboratory investigated the cause and take effective corrective actions where necessary?	3.10	☐	☐	☐		
Are relevant records of corrective actions kept?	3.10	☐	☐	☐		
Are the actions taken effective to achieve satisfactory performance in PT activity for the test in question?	3.10	☐	☐	☐		
If the laboratory cannot rectify the unsatisfactory PT performance for an accredited activity within a reasonable timeframe (e.g. 3 months), has your laboratory notified HKAS Executive in writing of the actions taken to address the problem and the measures taken to deal with request for the problematic test?	3.10	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is your laboratory aware of and does it comply with the following HKAS regulation on approved signatory: "An applicant laboratory shall nominate persons to HKAS Executive for approval as approved signatories for signing HOKLAS endorsed reports and certificates for every test, calibration or other laboratory activity for which it seeks accreditation. Accreditation for such activity will not be granted unless HKAS Executive is satisfied that at least one nominee meets the requirements for approved signatories as laid down in the accreditation criteria. An accredited laboratory shall maintain at least one approved signatory for each accredited activity. Additional persons may be nominated by an accredited laboratory to HKAS Executive for approval as approved signatories at any time."?	3.11	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation on approved signatory: "An accredited laboratory shall inform HKAS Executive of any change in the availability and duties of any of its HOKLAS approved signatories. HKAS shall withdraw the approval concerning such approved signatory who no longer meets the requirements for approved signatories as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation of a laboratory for a test, calibration or other laboratory activity if it does not have any approved signatory for such activity and has failed to obtain approval from HKAS Executive for a new signatory within three months from the date when it ceased to have any approved signatory for such activity."?	3.12	☐	☐	☐		
Does the authorised representative of your laboratory, which has its accreditation suspended or terminated (voluntarily or by HKAS Executive) within 14 days from the effective date of such suspension or termination, identify the customers to whom the laboratory has issued results for tests, calibrations or other activities, which are found to be unreliable because of the deficiencies discovered during the investigation of the suspension and termination, and inform them that the results are unreliable?	4.1	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "An accredited laboratory may display the appropriate HOKLAS accreditation symbol in a report or certificate issued by it for reporting the result(s) of an activity accredited under HOKLAS. Such a document is referred to hereafter as a HOKLAS endorsed report or certificate."?	5.1	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is your laboratory aware of and does it comply with the following HKAS regulation on the use of HKAS accreditation symbol and claims of accreditation status: "An accredited laboratory shall include in a HOKLAS endorsed report or certificate the following:- (a) the HOKLAS accreditation symbol (which includes the laboratory's registration number and identification code of the accreditation programme) at the top right hand corner of the front page;	5.2 (a)	☐	☐	☐		
on the same page one of the following statements (except as specified in (d) below):- (iii) for medical laboratories accredited for performing examinations and, in some cases, giving clinical interpretations of examination results: "HKAS has accredited this laboratory (Reg. No. – MED) under HOKLAS for performing specific examinations and, in some cases, for providing clinical interpretation as listed in its scope of accreditation. " accredited for performing examinations only: "HKAS has accredited this laboratory (Reg. No. – MED) under HOKLAS for performing specific examinations as listed in its scope of accreditation." The word "this laboratory" in the first sentence of the above statement may be replaced by the full organisation name of the laboratory as listed in the scope of accreditation. When the statement is used alone to claim a laboratory's accreditation status without displaying the accreditation symbol (See clause 5.3), the same words shall be replaced by the full organisation name, registration number and identification code of the accreditation programme (in form of e.g., ABC Testing Limited, Registration Number HOKLAS 999 and the appropriate identification code such as "TEST", "CAL" or "MED".).	5.2.b (iii)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
(c) A HOKLAS endorsed report or certificate shall also bear either:- (i) a statement indicating that such report or certificate shall not be reproduced except in full, or (ii) a statement indicating the conditions under which such report or certificate may be reproduced either in full or in part. Any extract or abstract of a HOKLAS endorsed report or certificate shall not contain the HOKLAS accreditation symbol nor other details as specified in clause 5.2 (b) above unless the authorised representative of the accredited laboratory which issues the report or certificate has approved in writing of such inclusion in the extract or abstract. The Authorised Representative, if granting approval under this clause, shall ensure that such extract or abstract will not be used for any purpose which HKAS Executive may consider it as having misleading effect.	5.2.c	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "For reports and certificates issued for internal use and where it is technically not possible or very difficult to display the accreditation symbol on a report or certificate, claiming of accreditation status may be made with the statements in 5.2 (b) without displaying the accreditation symbol. Such claim without displaying the accreditation symbol is subject to prior written agreement by the HKAS Executive. The laboratory should note that an endorsed report or certificate shall bear the accreditation symbol. It should also note that if it selects to claim the accreditation status with one of the statements in 5.2(b) without displaying the accreditation symbol, requirements that govern the issue of HOKLAS endorsed report as detailed in this document and HKAS 002 shall also apply to such reports or certificates."	5.3	☐	☐	☐		
Does your laboratory ensure that the term "HOKLAS", the HOKLAS accreditation symbol and/or a statement claiming accreditation status under HOKLAS will not be used in any report or certificate of laboratory activities except as described above in clause 5.2 and 5.3?	5.4	☐	☐	☐		
Does your laboratory ensure that the form, size, colour and usage of the HOKLAS accreditation symbol are in accordance with HKAS Supplementary Criteria No. 1?	5.5	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Is your laboratory aware of and does it comply with the following HKAS regulation: "A HOKLAS endorsed report or certificate shall be signed by a HOKLAS approved signatory of the issuing laboratory. For printed reports or certificates, such signature shall be made in hand-written form. For reports or certificates in an electronic form, the signature shall be in the form of an electronic signature acceptable under the Electronic Transactions Ordinance (Cap. 553). The full name of the approved signatory (as in his/her identify document such as identity card or passport) shall be clearly shown alongside the signature. Other arrangements of signing HOKLAS endorsed reports or certificates may be acceptable subject to agreement from HKAS Executive. When determining the acceptability of such an arrangement, HKAS Executive will consider all pertinent factors such as the reliability of the arrangement in ensuring proper and traceable authorisation by approved signatories and the demand of users of the accredited service."	5.6	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "A HOKLAS endorsed report or certificate may contain signatures of others provided that one of the laboratory's HOKLAS approved signatory has signed the report or certificate. Where signatures other than the approved signatory also appear on the report or certificate, the capacity of the one who signed (such as his capacity as the quality manager) shall appear on the report or certificate."?	5.7	☐	☐	☐		
Does HOKLAS endorsed report or certificate issued by your laboratory contain only the results of the tests, calibrations or other laboratory activities for which your laboratory is holding valid HOKLAS accreditation?	5.8	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "The results of any activity which has not been accredited (whether obtained by the laboratory or its subcontractor) can only be included in a HOKLAS endorsed report or certificate if HKAS Executive has explicitly approved such inclusion in writing. The HOKLAS endorsed report or certificate which contains the said results shall clearly state therein that the activities are not covered by the laboratory's HOKLAS accreditation."?	5.9	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
Does your laboratory keep at least one exact copy of the HOKLAS endorsed report or certificate issued by it for record? Does your laboratory also keep such copies of report or certificate, all original observations and records in relation to any accredited activity performed by it for a period of not less than three years or for a period specified by the HKAS Executive?	5.10	☐	☐	☐		
Does your laboratory ensure that every HOKLAS endorsed report or certificate comply with all relevant accreditation criteria as specified by HKAS Executive from time to time?	5.11	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "An accredited laboratory may issue a HOKLAS endorsed report or certificate which extends the results of a test, a calibration or another laboratory activity on a sample or samples to the properties or quantities of the inspected lot, batch or consignment from which the sample(s) was drawn provided that:						
(a) the accredited laboratory's scope of accreditation covers the sampling involved; and	5.12 (a)	☐	☐	☐		
(b) the sample or samples concerned were taken by staff of the accredited laboratory using the accredited sampling procedure."?	5.12 (b)	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "A HOKLAS endorsed report or certificate may include statements in amplification of results reported therein provided that:-						
(a) where a sample, batch or consignment is tested, calibrated or examined to specification requirements such statements shall be limited to information as to whether or not the sample, batch or consignment conforms with the specification requirements and the manner or degree in which it departs from such specification requirements;	5.13 (a)	☐	☐	☐		
(b) where a sample is not tested, calibrated or examined to specification requirements such statements shall be limited to explanation of the results as is necessary for interpretation of their meaning; and	5.13 (b)	☐	☐	☐		
(c) where an instrument or measuring device is calibrated such statements shall be limited to:-	5.13 (c)	☐	☐	☐		

	Clause	Y	N	NA	Management system	Remarks (for internal use)
(i) the uncertainty to be associated with its use, or (ii) the information referred to in (a) or (b) above as appropriate."?						
Is your laboratory aware of and does it comply with the following HKAS regulation: "Opinions or interpretation for which a laboratory is not accredited for providing can only be included in a HOKLAS endorsed report or certificate if HKAS Executive has given its approval for such inclusion in writing. An endorsed report or certificate containing such opinions or interpretations shall in all cases clearly state that the laboratory is not accredited for providing such opinions or interpretation."?	5.14	☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation: "Application for any HOKLAS service from HKAS shall be made in appropriate forms. These forms are obtainable from the office of HKAS Executive or downloadable at the HKAS website."?	6.1	☐	☐	☐		

End