Hong Kong Laboratory Accreditation Scheme

HOKLAS 016-A2

Management System Checklist

The applicant laboratory must complete the following checklist for initial application and for an application for extension of scope to a new test area/new discipline. The supplementary checklist of relevant discipline (i.e. Annex of relevant supplementary criteria) also has to be completed for initial/extension application. They will be used to assess compliance with HKAS and HOKLAS requirements.

The checklist consists of questions based on the requirements of HKAS 002, HOKLAS 015, HKAS Supplementary Criteria No. 6, and HOKLAS Supplementary Criteria No. 33. For further information, please refer to the corresponding document and clause as listed in the second column.

The laboratory should indicate in the “QM Clause” column, for every question, the clause(s) in their quality manual and operation procedures manual or other related documents which cover the requirement.

The column headed “*” is for the internal use of HKAS Executive.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
HOKLAS 015 management requirements							
Organisation and management responsibility	**4.1**						
Does the laboratory meet the relevant requirements of ISO 15189 when carrying out work in the laboratory's permanent facilities, at sites away from its permanent facilities, as well as at sites other than the permanent facilities for which it is responsible?	4.1.1.1		☐	☐	☐		
Is the laboratory or the organisation of which it is a part an entity that is legally identifiable?	4.1.1.2		☐	☐	☐		
Does laboratory management have arrangements in place to ensure the following:							
- there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity?	4.1.1.3a		☐	☐	☐		
- management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work?	4.1.1.3b		☐	☐	☐		
- where potential conflicts in competing interests may exist, they shall be openly and appropriately declared?	4.1.1.3c		☐	☐	☐		
- there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements?	4.1.1.3d		☐	☐	☐		
- confidentiality of information is maintained?	4.1.1.3e		☐	☐	☐		
Is the laboratory directed by a person or persons with the competence and delegated responsibility for the services provided?	4.1.1.4		☐	☐	☐		
Do responsibilities of the laboratory director include professional, scientific, consultative or advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory?	4.1.1.4		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory director maintain the ultimate responsibility for the overall operation and administration of the laboratory?	4.1.1.4		☐	☐	☐		
Are the duties and responsibilities of the laboratory director documented?	4.1.1.4		☐	☐	☐		
Does the laboratory director (or the designates for delegated duties) have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard?	4.1.1.4		☐	☐	☐		
Does the laboratory director (or designate/s):							
- provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities?	4.1.1.4a		☐	☐	☐		
- relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required?	4.1.1.4b		☐	☐	☐		
- ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users?	4.1.1.4c		☐	☐	☐		
- ensure the implementation of the quality policy?	4.1.1.4d		☐	☐	☐		
- implement a safe laboratory environment in compliance with good practice and applicable requirements?	4.1.1.4e		☐	☐	☐		
- serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate?	4.1.1.4f		☐	☐	☐		
- ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results?	4.1.1.4g		☐	☐	☐		
- select and monitor laboratory suppliers?	4.1.1.4h		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- select referral laboratories and monitor the quality of their service?	4.1.1.4i		☐	☐	☐		
- provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations?	4.1.1.4j		☐	☐	☐		
- define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services?	4.1.1.4k		☐	☐	☐		
- monitor all work performed in the laboratory to determine that clinically relevant information is being generated?	4.1.1.4l		☐	☐	☐		
- address any complaint, request or suggestion from staff and/or users of laboratory services?	4.1.1.4m		☐	☐	☐		
- design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable?	4.1.1.4n		☐	☐	☐		
- plan and direct research and development, where appropriate?	4.1.1.4o		☐	☐	☐		
Does laboratory management provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:							
- communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements?	4.1.2.1a		☐	☐	☐		
- establishing the quality policy?	4.1.2.1b		☐	☐	☐		
- ensuring that quality objectives and planning are established?	4.1.2.1c		☐	☐	☐		
- defining responsibilities, authorities and interrelationships of all personnel?	4.1.2.1d		☐	☐	☐		
- establishing communication processes?	4.1.2.1e		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- appointing a quality manager, however named?	4.1.2.1f		☐	☐	☐		
- conducting management reviews?	4.1.2.1g		☐	☐	☐		
- ensuring that all personnel are competent to perform their assigned activities?	4.1.2.1h		☐	☐	☐		
- ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities?	4.1.2.1i		☐	☐	☐		
Does laboratory management ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services?	4.1.2.2		☐	☐	☐		
Does laboratory management define the intent of its quality management system in a quality policy?							
- Is the quality policy appropriate to the purpose of the organisation?	4.1.2.3a		☐	☐	☐		
- Does it include a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services?	4.1.2.3b		☐	☐	☐		
- Does it provide a framework for establishing and reviewing quality objectives?	4.1.2.3c		☐	☐	☐		
- Is the quality policy communicated and understood within the organisation?	4.1.2.3d		☐	☐	☐		
- Has the quality policy been reviewed for continuing suitability?	4.1.2.3e		☐	☐	☐		
Does laboratory management establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organisation?	4.1.2.4		☐	☐	☐		
Are the quality objectives measurable and consistent with the quality policy?	4.1.2.4		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does laboratory management ensure that planning of the quality management system is carried out to meet the requirements and the quality objectives?	4.1.2.4		☐	☐	☐		
Does laboratory management ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	4.1.2.4		☐	☐	☐		
Are responsibilities, authorities and interrelationships defined, documented and communicated within the laboratory organisation, including the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel?	4.1.2.5		☐	☐	☐		
Does laboratory management have an effective means for communicating with staff?	4.1.2.6		☐	☐	☐		
Are records kept of items discussed in communications and meetings?	4.1.2.6		☐	☐	☐		
Does laboratory management ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system?	4.1.2.6		☐	☐	☐		
Does laboratory management appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:							
- ensuring that processes needed for the quality management system are established, implemented, and maintained?	4.1.2.7a		☐	☐	☐		
- reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement?	4.1.2.7b		☐	☐	☐		
- ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organisation?	4.1.2.7c		☐	☐	☐		

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Quality management system	**4.2**						
Does the laboratory establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard?	4.2.1		☐	☐	☐		
Does the quality management system provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users?	4.2.1		☐	☐	☐		
Does the laboratory:							
- determine the processes needed for the quality management system and ensure their application throughout the laboratory?	4.2.1a		☐	☐	☐		
- determine the sequence and interaction of these processes?	4.2.1b		☐	☐	☐		
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective?	4.2.1c		☐	☐	☐		
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes?	4.2.1d		☐	☐	☐		
- monitor and evaluate these processes?	4.2.1e		☐	☐	☐		
- implement actions necessary to achieve planned results and continual improvement of these processes?	4.2.1f		☐	☐	☐		
Does the quality management system documentation include:							
- statements of a quality policy and quality objectives?	4.2.2.1a		☐	☐	☐		
- a quality manual?	4.2.2.1b		☐	☐	☐		
- procedures and records required by this International Standard?	4.2.2.1c		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- documents, and records, determined by the laboratory to ensure the effective planning, operation and control of its processes?	4.2.2.1d		☐	☐	☐		
- copies of applicable regulations, standards and other normative documents.?	4.2.2.1e		☐	☐	☐		
Does the laboratory establish and maintain a quality manual that includes:							
- the quality policy or makes reference to it?	4.2.2.2a		☐	☐	☐		
- a description of the scope of the quality management system?	4.2.2.2b		☐	☐	☐		
- a presentation of the organisation and management structure of the laboratory and its place in any parent organisation?	4.2.2.2c		☐	☐	☐		
- a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard?	4.2.2.2d		☐	☐	☐		
- a description of the structure and relationships of the documentation used in the quality management system?	4.2.2.2e		☐	☐	☐		
- the documented policies established for the quality management system and reference to the managerial and technical activities that support them?	4.2.2.2f		☐	☐	☐		
Do all laboratory staff have access to and are instructed on the use and application of the quality manual and the referenced documents?	4.2.2.2		☐	☐	☐		
Document control	**4.3**						
Does the laboratory control documents required by the quality management system and ensure that unintended use of any obsolete document is prevented?	4.3		☐	☐	☐		

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Does the laboratory have a documented procedure to ensure that the following conditions are met:							
- all documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue?	4.3a		☐	☐	☐		
- all documents are identified to include: – a title; – a unique identifier on each page; – page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”); – authority for issue.	4.3b		☐	☐	☐		
- current authorised editions and their distribution are identified by means of a list (e.g. document register, log or master index)?	4.3c		☐	☐	☐		
- only current, authorized editions of applicable documents are available at points of use?	4.3d		☐	☐	☐		
- where a laboratory’s document control system allows for the amendment of documents by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialed and dated, and a revised document is issued within a specified time period?	4.3e		☐	☐	☐		
- changes to documents are identified?	4.3f		☐	☐	☐		
- documents remain legible?	4.3g		☐	☐	☐		
- documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose?	4.3h		☐	☐	☐		
- obsolete controlled documents are dated and marked as obsolete?	4.3i		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- at least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements?	4.3j		☐	☐	☐		
Are all controlled documents reviewed, and revised if necessary, at least annually?	4.3H		☐	☐	☐		
Service agreements	**4.4**						
Does the laboratory have documented procedures for the establishment and review of agreements for providing medical laboratory services?	4.4.1		☐	☐	☐		
Do agreements to provide medical laboratory services take into account the request, the examination and the report?	4.4.1		☐	☐	☐		
Does the agreement specify the information needed on the request to ensure appropriate examination and result interpretation?	4.4.1		☐	☐	☐		
Are the following conditions met when the laboratory enters into an agreement to provide medical laboratory services:							
- the requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, are defined, documented and understood?	4.4.1a		☐	☐	☐		
- the laboratory has the capability and resources to meet the requirements? (The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary, for the performance of the examinations in question. The review may also encompass results of earlier participation in external quality assurance schemes using samples of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.)	4.4.1b		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- laboratory personnel have the skills and expertise necessary for the performance of the intended examinations ?	4.4.1c		☐	☐	☐		
- examination procedures selected shall be appropriate and able to meet the customers' needs?	4.4.1d		☐	☐	☐		
- the customers and users are informed of deviations from the agreement that impact upon the examinations results?	4.4.1e		☐	☐	☐		
- reference are made to any work referred by the laboratory to a referral laboratory or consultant?	4.4.1f		☐	☐	☐		
Do reviews of agreements to provide medical laboratory services include all aspects of the agreement?	4.4.2		☐	☐	☐		
Are records of reviews, including any changes to the agreement and any pertinent discussions, maintained?	4.4.2		☐	☐	☐		
When an agreements needs to be amended after laboratory services have commenced, is the same agreement review process repeated and any amendment communicated to all affected parties?	4.4.2		☐	☐	☐		
Examination by referral laboratories	**4.5**						
Does the laboratory have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline?	4.5.1		☐	☐	☐		
Does the procedure ensure that the following conditions are met:			☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations?	4.5.1a		☐	☐	☐		
- Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met?	4.5.1b		☐	☐	☐		
- Records of such periodic reviews are maintained?	4.5.1c		☐	☐	☐		
- A register of all referral laboratories, and consultants from whom opinions are sought, is maintained?	4.5.1d		☐	☐	☐		
- Requests and results of all samples referred are kept for a pre-defined period?	4.5.1d		☐	☐	☐		
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?	4.5.2		☐	☐	☐		
When the referring laboratory prepares the report, does it include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation?	4.5.2		☐	☐	☐		
Does the report indicate which examinations were performed by a referral laboratory or consultant?	4.5.2		☐	☐	☐		
Is the author of any additional remarks clearly identified on the report?	4.5.2		☐	☐	☐		
Does the laboratory adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements?	4.5.2		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, is this process hindered by commercial or financial considerations?	4.5.2		☐	☐	☐		
External services and supplies	**4.6**						
Does the laboratory have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of the service?	4.6		☐	☐	☐		
Are criteria for selection of external services, equipment, reagents and consumable supplies established?	4.6		☐	☐	☐		
Is a list of selected and approved suppliers of equipment, reagents and consumables maintained?	4.6		☐	☐	☐		
Does purchasing information describe the requirements for the product or service to be purchased?	4.6		☐	☐	☐		
Is the performance of suppliers monitored to ensure that purchase services or items consistently meet the stated criteria?	4.6		☐	☐	☐		
Advisory services	**4.7**						
Does the laboratory establish arrangements for communicating with users on the following:	4.7		☐	☐	☐		
- advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination;	4.7a		☐	☐	☐		

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- advising on individual clinical cases;	4.7b		☐	☐	☐		
- professional judgments on the interpretation of the results of examinations;	4.7c		☐	☐	☐		
- promoting the effective utilisation of laboratory services;	4.7d		☐	☐	☐		
- consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.	4.7e		☐	☐	☐		
Resolution of complaints	**4.8**						
Does the laboratory have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties?	4.8		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are records of all complaints and their investigation and action taken by the laboratory maintained?	4.8 & HKAS 002 5.13		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
When an activity is involved in a complaint, are the relevant areas of the activity and responsibility promptly audited?	HKAS 002 5.14		☐	☐	☐		
Does the laboratory have arrangements to inform HKAS Executive of any complaint relating to HOKLAS Endorsed Test Reports that has not been resolved within 60 days of receipt?	HKAS 002 5.15		☐	☐	☐		

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Identification and control of nonconformities	**4.9**						
Does the laboratory have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes?	4.9		☐	☐	☐		
Does the procedure ensure that:							
- the responsibilities and authorities for handling nonconformities are designated?	4.9a		☐	☐	☐		
- the immediate actions to be taken are defined?	4.9b		☐	☐	☐		
- the extent of the nonconformity is determined?	4.9c		☐	☐	☐		
- examinations are halted and reports withheld as necessary?	4.9d		☐	☐	☐		
- the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorised individual responsible for using the results is informed?	4.9e		☐	☐	☐		
- the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary?	4.9f		☐	☐	☐		
- the responsibility for authorisation of the resumption of examinations is defined?	4.9g		☐	☐	☐		
- each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action?	4.9h		☐	☐	☐		

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When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, does the laboratory take action to identify, document and eliminate the cause(s)? Is corrective action to be taken determined and documented?	4.9		☐	☐	☐		
Corrective action	**4.10**						
Does the laboratory take corrective action to eliminate the cause(s) of nonconformities?	4.10		☐	☐	☐		
Are corrective actions appropriate to the effects of the nonconformities encountered?	4.10		☐	☐	☐		
Does the laboratory have a documented procedure for:							
- reviewing nonconformities?	4.10a		☐	☐	☐		
- determining the root causes of nonconformities?	4.10b		☐	☐	☐		
- evaluating the need for corrective action to ensure that nonconformities do not recur?	4.10c		☐	☐	☐		
- determining and implementing corrective action needed?	4.10d		☐	☐	☐		
- recording the results of corrective action taken?	4.10e		☐	☐	☐		
- reviewing the effectiveness of the corrective action taken?	4.10f		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Preventive action	**4.11**						
Does the laboratory determine action to eliminate the cause of potential nonconformities in order to prevent their occurrence?	4.11		☐	☐	☐		
Are preventive actions appropriate to the effects of the potential problems?	4.11		☐	☐	☐		
Does the laboratory have a documented procedure for:							
- reviewing laboratory data and information to determine where potential nonconformities exist?	4.11a		☐	☐	☐		
- determining the root cause(s) of potential nonconformities?	4.11b		☐	☐	☐		
- evaluating the need for preventive action to prevent the occurrence of nonconformities?	4.11c		☐	☐	☐		
- determining and implementing preventive action needed?	4.11d		☐	☐	☐		
- recording the results of preventive action taken?	4.11e		☐	☐	☐		
- reviewing the effectiveness of the preventive action taken?	4.11f		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Continual improvement	**4.12**						
Does the laboratory continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives?	4.12		☐	☐	☐		
Are improvement activities directed at areas of highest priority based on risk assessments?	4.12		☐	☐	☐		
Are action plans for improvement developed, documented and implemented, as appropriate?	4.12		☐	☐	☐		
Is the effectiveness of the actions taken determined through a focused review or audit of the area concerned?	4.12		☐	☐	☐		
Does laboratory management ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care?	4.12		☐	☐	☐		
When the continual improvement programme identifies opportunities for improvement, does laboratory management address them regardless of where they occur?	4.12		☐	☐	☐		
Does laboratory management communicate to staff improvement plans and related goals?	4.12		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Control of records	**4.13**						
Does the laboratory have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records?	4.13		☐	☐	☐		
Are records created concurrently with performance of each activity that affects the quality of the examination?	4.13		☐	☐	☐		
Is the date and, where relevant, the time of amendments to records captured along with the identity of personnel making the amendments?	4.13		☐	☐	☐		
Does the laboratory define the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are to be retained?	4.13		☐	☐	☐		
Are reported results retrievable for as long as medically relevant or as required by regulation?	4.13		☐	☐	☐		
Is a suitable environment provided for storage of records to prevent damage, deterioration, loss or unauthorised access?	4.13		☐	☐	☐		
Do records include, at least, the following:							
- supplier selection and performance, and changes to the approved supplier list?	4.13a		☐	☐	☐		
- staff qualifications, training and competency records?	4.13b		☐	☐	☐		
- request for examination?	4.13c		☐	☐	☐		
- records of receipt of samples in the laboratory?	4.13d		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts)?	4.13e		☐	☐	☐		
- laboratory work books or work sheets?	4.13f		☐	☐	☐		
- instrument printouts and retained data and information?	4.13g		☐	☐	☐		
- examination results and reports?	4.13h		☐	☐	☐		
- instrument maintenance records, including internal and external calibration records?	4.13i		☐	☐	☐		
- calibration functions and conversion factors?	4.13j		☐	☐	☐		
- quality control records?	4.13k		☐	☐	☐		
- incident records and action taken?	4.13l		☐	☐	☐		
- accident records and action taken?	4.13m		☐	☐	☐		
- risk management records?	4.13n		☐	☐	☐		
- nonconformities identified and immediate or corrective action taken?	4.13o		☐	☐	☐		
- preventive action taken?	4.13p		☐	☐	☐		
- complaints and action taken?	4.13q		☐	☐	☐		
- records of internal and external audits?	4.13r		☐	☐	☐		
- interlaboratory comparisons of examination results?	4.13s		☐	☐	☐		
- records of quality improvement activities?	4.13t		☐	☐	☐		
- minutes of meetings that record decisions made about the laboratory's quality management activities?	4.13u		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- records of management reviews?	4.13v		☐	☐	☐		
Are all of these quality and technical records available for laboratory management review?	4.13		☐	☐	☐		
Evaluation and audits	**4.14**						
Does the laboratory plan and implement the evaluation and internal audit processes needed to:	4.14.1		☐	☐	☐		
- demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users?	4.14.1a		☐	☐	☐		
- ensure conformity to the quality management system?	4.14.1b		☐	☐	☐		
- continually improve the effectiveness of the quality management system?	4.14.1c		☐	☐	☐		
Are results of evaluation and improvement activities included in the input to the management review?	4.14.1		☐	☐	☐		
Does authorised personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received?	4.14.2		☐	☐	☐		
Does the laboratory periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand?	4.14.2		☐	☐	☐		
Does the laboratory seek information relating to user perception as to whether the service has met the needs and requirements of users?	4.14.3		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Do the methods for obtaining and using this information include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users?	4.14.3		☐	☐	☐		
Are records kept of information collected and actions taken?	4.14.3		☐	☐	☐		
Does laboratory management encourage staff to make suggestions for the improvement of any aspect of the laboratory service?	4.14.4		☐	☐	☐		
Are suggestions evaluated, implemented as appropriate and feedback provided to the staff?	4.14.4		☐	☐	☐		
Are records of suggestions and action taken by the management maintained?	4.14.4		☐	☐	☐		
Does the laboratory conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:							
- conform to the requirements of this International Standard and to requirements established by the laboratory?	4.14.5a		☐	☐	☐		
- are implemented, effective, and maintained?	4.14.5b		☐	☐	☐		
Are audits conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system?	4.14.5		☐	☐	☐		
Does the audit programme take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits?	4.14.5		☐	☐	☐		
Are the audit criteria, scope, frequency and methods defined and documented?	4.14.5		☐	☐	☐		
Does selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process?	4.14.5		☐	☐	☐		
Are auditors, wherever resources permit, independent of the activity to be audited?	4.14.5		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records?	4.14.5		☐	☐	☐		
Do personnel responsible for the area being audited ensure that appropriate action is promptly undertaken when nonconformities are identified?	4.14.5		☐	☐	☐		
Is corrective action taken without undue delay to eliminate the causes of the detected nonconformities?	4.14.5		☐	☐	☐		
Does the laboratory evaluate the impact of work processes and potential failures on examination results as they affect patient safety?	4.14.6		☐	☐	☐		
Does the laboratory modify processes to reduce or eliminate the identified risks and document decisions and actions taken?	4.14.6		☐	☐	☐		
Does the laboratory establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes?	4.14.7		☐	☐	☐		
Is the process of monitoring quality indicators planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement?	4.14.7		☐	☐	☐		
Are the indicators periodically reviewed to ensure their continued appropriateness?	4.14.7		☐	☐	☐		
Does the laboratory, in consultation with the users, establish turnaround times for each of its examinations that reflect clinical needs?	4.14.7		☐	☐	☐		
Does the laboratory periodically evaluate whether or not it is meeting the established turnaround times?	4.14.7		☐	☐	☐		
When reviews by external organisations indicate the laboratory has nonconformities or potential nonconformities, does the laboratory take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of ISO15189:2012?	4.14.8		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are records kept of the reviews and of the corrective actions and preventive actions taken?	4.14.8		☐	☐	☐		
Management review	**4.15**						
Does laboratory management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care?	4.15.1		☐	☐	☐		
Does the input to management review include information from the results of evaluations of at least the following:	4.15.1		☐	☐	☐		
- the periodic review of requests, and suitability of procedures and sample requirements?	4.15.2a		☐	☐	☐		
- assessment of user feedback?	4.15.2b		☐	☐	☐		
- staff suggestions?	4.15.2c		☐	☐	☐		
- internal audits?	4.15.2d		☐	☐	☐		
- risk management?	4.15.2e		☐	☐	☐		
- use of quality indicators?	4.15.2f		☐	☐	☐		
- reviews by external organisations?	4.15.2g		☐	☐	☐		
- results of participation in interlaboratory comparison programmes (PT/EQA)?	4.15.2h		☐	☐	☐		
- monitoring and resolution of complaints?	4.15.2i		☐	☐	☐		
- performance of suppliers?	4.15.2j		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- identification and control of nonconformities?	4.15.2k		☐	☐	☐		
- results of continual improvement including current status of corrective actions and preventive actions?	4.15.2l		☐	☐	☐		
- follow-up actions from previous management reviews?	4.15.2m		☐	☐	☐		
- changes in the volume and scope of work, personnel, and premises that could affect the quality management system?	4.15.2n		☐	☐	☐		
- recommendations for improvement, including technical requirements?	4.15.2o		☐	☐	☐		
Does the review analyse the input information for causes of nonconformities, trends and patterns that indicate process problems?	4.15.3		☐	☐	☐		
Does the review include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives?	4.15.3		☐	☐	☐		
Are the quality and appropriateness of the laboratory's contribution to patient care, to the extent possible, also objectively evaluated?	4.15.3		☐	☐	☐		
Is the output from the management review incorporated into a record that documents any decisions made and actions taken during management review related to:	4.15.4		☐	☐	☐		
- improvement of the effectiveness of the quality management system and its processes?	4.15.4a		☐	☐	☐		
- improvement of services to users?	4.15.4b		☐	☐	☐		
- resource needs?	4.15.4c		☐	☐	☐		
Are findings and actions arising from management reviews recorded and reported to laboratory staff?	4.15.4		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does laboratory management ensure that actions arising from management review are completed within a defined timeframe?	4.15.4		☐	☐	☐		
HOKLAS 015 technical requirements							
Personnel	**5.1**						
Does the laboratory have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements?	5.1.1		☐	☐	☐		
Does laboratory management document personnel qualifications for each position?	5.1.2		☐	☐	☐		
Do qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and are they appropriate to the tasks performed?	5.1.2		☐	☐	☐		
Do the personnel making judgments with reference to examinations have the applicable theoretical and practical background and experience?	5.1.2		☐	☐	☐		
Does the laboratory have job descriptions that describe responsibilities, authorities and tasks for all personnel?	5.1.3		☐	☐	☐		
Does the laboratory have a programme to introduce new staff to the organisation, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services?	5.1.4		☐	☐	☐		
Does the laboratory provide training for all personnel which includes the following areas:							
- the quality management system?	5.1.5a		☐	☐	☐		
- assigned work processes and procedures?	5.1.5b		☐	☐	☐		
- the applicable laboratory information system?	5.1.5c		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- health and safety, including the prevention or containment of the effects of adverse incidents?	5.1.5d		☐	☐	☐		
- ethics?	5.1.5e		☐	☐	☐		
- confidentiality of patient information?	5.1.5f		☐	☐	☐		
Are personnel undergoing training supervised at all times?	5.1.5		☐	☐	☐		
Is the effectiveness of the training programme periodically reviewed?	5.1.5		☐	☐	☐		
Following appropriate training, does the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria?	5.1.6		☐	☐	☐		
Does reassessment take place at regular intervals? Does retraining occur when necessary?	5.1.6		☐	☐	☐		
In addition to the assessment of technical competence, does the laboratory ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships?	5.1.7		☐	☐	☐		
Is a continuing education programme available to personnel who participate in managerial and technical processes?	5.1.8		☐	☐	☐		
Do personnel take part in continuing education?	5.1.8		☐	☐	☐		
Is the effectiveness of the continuing education programme periodically reviewed?	5.1.8		☐	☐	☐		
Do personnel take part in regular professional development or other professional liaison activities?	5.1.8		☐	☐	☐		
Are records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel maintained?	5.1.9		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are these records readily available to relevant personnel and include but not be limited to:							
- educational and professional qualifications?	5.1.9a		☐	☐	☐		
- copy of certification or license, when applicable?	5.1.9b		☐	☐	☐		
- previous work experience?	5.1.9c		☐	☐	☐		
- job descriptions?	5.1.9d		☐	☐	☐		
- introduction of new staff to the laboratory environment?	5.1.9e		☐	☐	☐		
- training in current job tasks?	5.1.9f		☐	☐	☐		
- competency assessments?	5.1.9g		☐	☐	☐		
- records of continuing education and achievements?	5.1.9h		☐	☐	☐		
- reviews of staff performance?	5.1.9i		☐	☐	☐		
- reports of accidents and exposure to occupational hazards?	5.1.9j		☐	☐	☐		
- immunisation status, when relevant to assigned duties?	5.1.9k		☐	☐	☐		
Accommodation and environmental conditions	**5.2**						
Does the laboratory have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors?	5.2.1	●	☐	☐	☐		
Does the laboratory evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work?	5.2.1	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Where applicable, are similar provisions made for primary sample collection and examinations at sites other than the main laboratory premises, for example point-of-care testing (POCT) under the management of the laboratory?	5.2.1	●	☐	☐	☐		
Do the laboratory and associated office facilities provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met?							
- Access to areas affecting the quality of examinations is controlled	5.2.2a		☐	☐	☐		
- Medical information, patient samples, and laboratory resources are safeguarded from unauthorised access	5.2.2b		☐	☐	☐		
- Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions	5.2.2c		☐	☐	☐		
- Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information	5.2.2d		☐	☐	☐		
- Safety facilities and devices are provided and their functioning regularly verified	5.2.2e		☐	☐	☐		
Are storage space and conditions provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results?	5.2.3	●	☐	☐	☐		
Are clinical samples and materials used in examination processes stored in a manner to prevent cross contamination?	5.2.3	●	☐	☐	☐		
Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials and as specified by applicable requirements?	5.2.3	●	☐	☐	☐		
Is there adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing?	5.2.4	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Do patient sample collection facilities have separate reception/waiting and collection areas?	5.2.5	●	☐	☐	☐		
Is consideration given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection?	5.2.5	●	☐	☐	☐		
Do facilities at which patient sample collection procedures are performed (e.g. phlebotomy) enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination?	5.2.5	●	☐	☐	☐		
Do sample collection facilities have and maintain appropriate first aid materials for both patient and staff needs?	5.2.5	●	☐	☐	☐		
Is laboratory premises maintained in a functional and reliable condition? Are work areas clean and well maintained?	5.2.6	●	☐	☐	☐		
Does the laboratory monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff?	5.2.6	●	☐	☐	☐		
Is attention paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination?	5.2.6	●	☐	☐	☐		
Is there effective separation between laboratory sections in which there are incompatible activities?	5.2.6	●	☐	☐	☐		
Are procedures in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated?	5.2.6	●	☐	☐	☐		
Does the laboratory provide a quiet and uninterrupted work environment where it is needed?	5.2.6	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Laboratory equipment	**5.3**						
Does the laboratory have a documented procedure for the selection, purchasing and management of equipment?	5.3.1.1	●	☐	☐	☐		
Is the laboratory furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage)?	5.3.1.1	●	☐	☐	☐		
In those cases where the laboratory needs to use equipment outside its permanent control, does laboratory management ensure that the requirements of this International Standard are met?	5.3.1.1	●	☐	☐	☐		
Does the laboratory replace equipment as needed to ensure the quality of examination results?	5.3.1.1	●	☐	☐	☐		
Does the laboratory verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned?	5.3.1.2	●	☐	☐	☐		
Is each item of equipment uniquely labelled, marked or otherwise identified?	5.3.1.2	●	☐	☐	☐		
Is equipment operated at all times by trained and authorised personnel?	5.3.1.3	●	☐	☐	☐		
Are current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, readily available?	5.3.1.3	●	☐	☐	☐		
Does the laboratory have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration?	5.3.1.3	●	☐	☐	☐		
Does the laboratory have a documented procedure for the calibration of equipment that directly or indirectly affects examination results?	5.3.1.4	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the procedure include:							
- taking into account conditions of use and the manufacturer's instructions?	5.3.1.4a	●	☐	☐	☐		
- recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment?	5.3.1.4b	●	☐	☐	☐		
- verifying the required measurement accuracy and the functioning of the measuring system at defined intervals?	5.3.1.4c	●	☐	☐	☐		
- recording the calibration status and date of recalibration?	5.3.1.4d	●	☐	☐	☐		
- ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated?	5.3.1.4e	●	☐	☐	☐		
- safeguards to prevent adjustments or tampering that might invalidate examination results?	5.3.1.4f	●	☐	☐	☐		
Is metrological traceability to a reference material or reference procedure of the higher metrological order available?	5.3.1.4	●	☐	☐	☐		
Where this is not possible or relevant, do other means for providing confidence in the results applied, including but not limited to the following:	5.3.1.4	●	☐	☐	☐		
- use of certified reference materials?							
- examination or calibration by another procedure?							
- mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned?							
Does the laboratory have a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions?	5.3.1.5	●	☐	☐	☐		
Is equipment maintained in a safe working condition and in working order?	5.3.1.5	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does this include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorised persons?	5.3.1.5	●	☐	☐	☐		
At a minimum, are manufacturer's schedules or instructions, or both, used?	5.3.1.5	●	☐	☐	☐		
Whenever equipment is found to be defective, is it taken out of service and clearly labelled?	5.3.1.5	●	☐	☐	☐		
Does the laboratory ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria?	5.3.1.5	●	☐	☐	☐		
Does the laboratory examine the effect of any defects on previous examinations and institute immediate action or corrective action?	5.3.1.5	●	☐	☐	☐		
Does the laboratory take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment?	5.3.1.5	●	☐	☐	☐		
When equipment is removed from the direct control of the laboratory, is performance verified before being returned to laboratory use?	5.3.1.5	●	☐	☐	☐		
Are adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to the manufacturer and appropriate authorities, as required?	5.3.1.6	●	☐	☐	☐		
Are records maintained for each item of equipment that contributes to the performance of examinations?	5.3.1.7	●	☐	☐	☐		
Do equipment records include, but not be limited to, the following:							
- identity of the equipment?	5.3.1.7a	●	☐	☐	☐		
- manufacturer's name, model and serial number or other unique identification?	5.3.1.7b	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- contact information for the supplier or the manufacturer?	5.3.1.7c	●	☐	☐	☐		
- date of receiving and date of entering into service?	5.3.1.7d	●	☐	☐	☐		
- location?	5.3.1.7e	●	☐	☐	☐		
- condition when received (e.g. new, used or reconditioned)?	5.3.1.7f	●	☐	☐	☐		
- manufacturer's instructions?	5.3.1.7g	●	☐	☐	☐		
- records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory?	5.3.1.7h	●	☐	☐	☐		
- maintenance carried out and the schedule for preventive maintenance?	5.3.1.7i	●	☐	☐	☐		
- equipment performance records that confirm the equipment's ongoing acceptability for use	5.3.1.7j	●	☐	☐	☐		
- damage to, or malfunction, modification, or repair of the equipment?	5.3.1.7k	●	☐	☐	☐		
Do the performance records referred to in j) include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement?	5.3.1.7	●	☐	☐	☐		
Are these records maintained and readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure?	5.3.1.7	●	☐	☐	☐		
Does the laboratory have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables?	5.3.2.1	●	☐	☐	☐		
Where the laboratory is not the receiving facility, does it verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration?	5.3.2.2	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory store received reagents and consumables according to manufacturer's specifications?	5.3.2.2	●	☐	☐	☐		
Is each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, verified for performance before use in examinations?	5.3.2.3	●	☐	☐	☐		
Are consumables that can affect the quality of examinations verified for performance before use in examinations?	5.3.2.3	●	☐	☐	☐		
Does the laboratory establish an inventory control system for reagents and consumables?	5.3.2.4	●	☐	☐	☐		
Does the system for inventory control segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use?	5.3.2.4	●	☐	☐	☐		
Are Instructions for the use of reagents and consumables, including those provided by the manufacturers, readily available?	5.3.2.5	●	☐	☐	☐		
Are adverse incidents and accidents that can be attributed directly to specific reagents or consumables investigated and reported to the manufacturer and appropriate authorities, as required?	5.3.2.6	●	☐	☐	☐		
Are records maintained for each reagent and consumable that contributes to the performance of examinations?	5.3.2.7	●	☐	☐	☐		
Do these records include but not be limited to the following:							
- identity of the reagent or consumable?	5.3.2.7a	●	☐	☐	☐		
- manufacturer's name and batch code or lot number?	5.3.2.7b	●	☐	☐	☐		
- contact information for the supplier or the manufacturer?	5.3.2.7c	●	☐	☐	☐		
- date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service?	5.3.2.7d	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- condition when received (e.g. acceptable or damaged)?	5.3.2.7e	●	☐	☐	☐		
- manufacturer's instructions?	5.3.2.7f	●	☐	☐	☐		
- records that confirmed the reagent's or consumable's initial acceptance for use?	5.3.2.7g	●	☐	☐	☐		
- performance records that confirm the reagent's or consumable's ongoing acceptance for use?	5.3.2.7h	●	☐	☐	☐		
Where the laboratory uses reagents prepared or completed in-house, do the records include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation?	5.3.2.7	●	☐	☐	☐		
Is your laboratory aware of and does it comply with the following requirements?	5.3.H (f)	●	☐	☐	☐		
"An autoanalyser or **a commercial** test kit shall be evaluated to confirm its suitability for the intended use before it is put into service. An evaluation report with details of the studies and conclusions shall be prepared. For any change of autoanalysers or commercial test kits used for any HOKLAS accredited tests, the evaluation report shall be provided to HKAS Executive for review before the analyser or test kit is put into service."							
Pre-examination processes	**5.4**						
Does the laboratory have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations?	5.4.1	●	☐	☐	☐		
Does the laboratory have information available for patients and users of the laboratory services?	5.4.2	●	☐	☐	☐		
Does the information include as appropriate:							
- the location of the laboratory?	5.4.2a	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- types of clinical services offered by the laboratory including examinations referred to other laboratories?	5.4.2b	●	☐	☐	☐		
- opening hours of the laboratory?	5.4.2c	●	☐	☐	☐		
- the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values?	5.4.2d	●	☐	☐	☐		
- instructions for completion of the request form?	5.4.2e	●	☐	☐	☐		
- instruction for preparation of the patient?	5.4.2f	●	☐	☐	☐		
- instructions for patient-collected samples?	5.4.2g	●	☐	☐	☐		
- instructions for transportation of samples, including any special handling needs?	5.4.2h	●	☐	☐	☐		
- any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed)?	5.4.2i	●	☐	☐	☐		
- the laboratory's criteria for accepting and rejecting samples?	5.4.2j	●	☐	☐	☐		
- a list of factors known to significantly affect the performance of the examination or the interpretation of the results?	5.4.2k	●	☐	☐	☐		
- availability of clinical advice on ordering of examinations and on interpretation of examination results?	5.4.2l	●	☐	☐	☐		
- the laboratory's policy on protection of personal information?	5.4.2m	●	☐	☐	☐		
- the laboratory's complaint procedure?	5.4.2n	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent?	5.4.2	●	☐	☐	☐		
Is importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), explained to the patient and user?	5.4.2	●	☐	☐	☐		
Does the request form or an electronic equivalent allow space for the inclusion of, but not be limited to, the following:							
- patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier?	5.4.3a	●	☐	☐	☐		
- name or other unique identifier of clinician, healthcare provider, or other person legally authorised to request examinations or use medical information, together with the destination for the report and contact details?	5.4.3b	●	☐	☐	☐		
- type of primary sample and, where relevant, the anatomic site of origin?	5.4.3c	●	☐	☐	☐		
- examinations requested?	5.4.3d	●	☐	☐	☐		
- clinically relevant information about the patient and the request, for examination performance and result interpretation purposes?	5.4.3e	●	☐	☐	☐		
- date and, where relevant, time of primary sample collection?	5.4.3f	●	☐	☐	☐		
- date and time of sample receipt?	5.4.3g	●	☐	☐	☐		
Does the laboratory have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time?	5.4.3	●	☐	☐	☐		
Is the laboratory willing to cooperate with users or their representatives in clarifying the user's request?	5.4.3	●	☐	☐	☐		
Does the laboratory have documented procedures for the proper collection and handling of primary samples?	5.4.4.1	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are documented procedures available to those responsible for primary sample collection whether or not the collectors are laboratory staff?	5.4.4.1	●	☐	☐	☐		
Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, are these recorded and included in all documents containing examination results and communicated to the appropriate personnel?	5.4.4.1	●	☐	☐	☐		
Is a more detailed explanation and, in some cases, written consent available for special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure?	5.4.4.1	●	☐	☐	☐		
In emergency situations, consent might not be possible; under these circumstances are necessary procedures carried out in the patient's best interest?	5.4.5	●	☐	☐	☐		
Do the laboratory's instructions for pre-collection activities include the following:							
- completion of request form or electronic request?	5.4.4.2a	●	☐	☐	☐		
- preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients)?	5.4.4.2b	●	☐	☐	☐		
- type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives?	5.4.4.2c	●	☐	☐	☐		
- special timing of collection, where needed?	5.4.4.2d	●	☐	☐	☐		
- clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs)?	5.4.4.2.e	●	☐	☐	☐		
Do the laboratory's instructions for collection activities include the following:							
- determination of the identity of the patient from whom a primary sample is collected?	5.4.4.3a	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- verification 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, etc.]?	5.4.4.3b	●	☐	☐	☐		
- instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives?	5.4.4.3c	●	☐	☐	☐		
- in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff?	5.4.4.3d	●	☐	☐	☐		
- instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected?	5.4.4.3e	●	☐	☐	☐		
- recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time?	5.4.4.3f	●	☐	☐	☐		
- instructions for proper storage conditions before collected samples are delivered to the laboratory?	5.4.4.3g	●	☐	☐	☐		
- safe disposal of materials used in the collection?	5.4.4.3h	●	☐	☐	☐		
Do the laboratory's instructions for post-collection activities include packaging of samples for transportation?	5.4.5	●	☐	☐	☐		
Does the laboratory have a documented procedure for monitoring the transportations of samples to ensure they are transported:							
- within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned?	5.4.5a	●	☐	☐	☐		
- within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples?	5.4.5b	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements?	5.4.5c	●	☐	☐	☐		
Does the laboratory's procedure for sample reception ensure that the following conditions are met:							
- Samples are unequivocally traceable, by request and labelling, to an identified patient or site?	5.4.6a	●	☐	☐	☐		
- Laboratory-developed and documented criteria for acceptance or rejection of samples are applied?	5.4.6b	●	☐	☐	☐		
- Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result?	5.4.6c	●	☐	☐	☐		
- All samples received are recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded?	5.4.6d	●	☐	☐	☐		
- Authorised personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s)?	5.4.6e	●	☐	☐	☐		
- Where relevant, there shall be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed?	5.4.6f	●	☐	☐	☐		
Are all portions of the primary sample unequivocally traceable to the original primary sample?	5.4.6	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage?	5.4.7	●	☐	☐	☐		
Do laboratory procedures include time limits for requesting additional examinations or further examinations on the same primary sample?	5.4.7	●	☐	☐	☐		
Examination processes	**5.5**						
Does the laboratory select examination procedures which have been validated for their intended use?	5.5.1.1	●	☐	☐	☐		
Is the identity of persons performing activities in examination processes recorded?	5.5.1.1	●	☐	☐	☐		
Do the specified requirements (performance specifications) for each examination procedure relate to the intended use of that examination?	5.5.1.1	●	☐	☐	☐		
Are validated examination procedures used without modification subject to independent verification by the laboratory before being introduced into routine use?	5.5.1.2	●	☐	☐	☐		
Does the laboratory obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure?	5.5.1.2	●	☐	☐	☐		
Does the independent verification by the laboratory confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met.?	5.5.1.2	●	☐	☐	☐		
Are the performance claims for the examination procedure confirmed during the verification process relevant to the intended use of the examination results?	5.5.1.2	●	☐	☐	☐		
Does the laboratory document the procedure used for the verification and record the results obtained?	5.5.1.2	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Do staff with the appropriate authority review the verification results and record the review?	5.5.1.2	●	☐	☐	☐		
Does the laboratory validate examination procedures derived from the following sources:							
- non-standard methods?	5.5.1.3a	●	☐	☐	☐		
- laboratory designed or developed methods?	5.5.1.3b	●	☐	☐	☐		
- standard methods used outside their intended scope?	5.5.1.3c	●	☐	☐	☐		
- validated methods subsequently modified?	5.5.1.3d	●	☐	☐	☐		
Is the validation as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled?	5.5.1.3	●	☐	☐	☐		
Does the laboratory document the procedure used for the validation and record the results obtained?	5.5.1.3	●	☐	☐	☐		
Do staff with the authority review the validation results and record the review?	5.5.1.3	●	☐	☐	☐		
When changes are made to a validated examination procedure, is the influence of such changes documented and, when appropriate, a new validation carried out?	5.5.1.3	●	☐	☐	☐		
Does the laboratory determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples?	5.5.1.4	●	☐	☐	☐		
Does the laboratory define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty?	5.5.1.4	●	☐	☐	☐		
Does the laboratory consider measurement uncertainty when interpreting measured quantity values?	5.5.1.4	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Upon request, does the laboratory make its estimates of measurement uncertainty available to laboratory users?	5.5.1.4	●	☐	☐	☐		
Where examinations include a measurement step but do not report a measured quantity value, does the laboratory calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result?	5.5.1.4	●	☐	☐	☐		
Does the laboratory define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users?	5.5.2	●	☐	☐	☐		
When a particular biological reference interval or decision value is no longer relevant for the population served, are appropriate changes made and communicated to the users?	5.5.2	●	☐	☐	☐		
When the laboratory changes an examination procedure or pre-examination procedure, does the laboratory review associated reference intervals and clinical decision values, as applicable?	5.5.2	●	☐	☐	☐		
Are examination procedures documented?	5.5.3	●	☐	☐	☐		
Are they written in a language commonly understood by the staff in the laboratory and be available in appropriate locations?	5.5.3	●	☐	☐	☐		
Does any condensed document format (e.g. card files or similarly used systems) correspond to the documented procedure?	5.5.3	●	☐	☐	☐		
Are all documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, subject to document control?	5.5.3	●	☐	☐	☐		
In addition to document control identifiers, does documentation include, when applicable to the examination procedure, the following:							
- purpose of the examination?	5.5.3a	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- principle and method of the procedure used for examinations?	5.5.3b	●	☐	☐	☐		
- performance characteristics?	5.5.3c	●	☐	☐	☐		
- type of sample (e.g. plasma, serum, urine)?	5.5.3d	●	☐	☐	☐		
- patient preparation?	5.5.3e	●	☐	☐	☐		
- type of container and additives s?	5.5.3f	●	☐	☐	☐		
- required equipment and reagents?	5.5.3g	●	☐	☐	☐		
- environmental and safety controls?	5.5.3h	●	☐	☐	☐		
- calibration procedures (metrological traceability)?	5.5.3i	●	☐	☐	☐		
- procedural steps?	5.5.3j	●	☐	☐	☐		
- quality control procedures?	5.5.3k	●	☐	☐	☐		
- interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions?	5.5.3l	●	☐	☐	☐		
- principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values?	5.5.3m	●	☐	☐	☐		
- biological reference intervals or clinical decision values?	5.5.3n	●	☐	☐	☐		
- reportable interval of examination results?	5.5.3o	●	☐	☐	☐		
- instructions for determining quantitative results when a result is not within the measurement interval?	5.5.3p	●	☐	☐	☐		
- alert/critical values, where appropriate?	5.5.3q	●	☐	☐	☐		
- laboratory clinical interpretation?	5.5.3r	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- potential sources of variation?	5.5.3s	●	☐	☐	☐		
- references?	5.5.3t	●	☐	☐	☐		
If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, are the implications explained to users of the laboratory services after validating the procedure?	5.5.3	●	☐	☐	☐		
Ensuring quality of examination results	**5.6**						
Does the laboratory ensure the quality of examinations by performing them under defined conditions?	5.6.1	●	☐	☐	☐		
Are appropriate pre and post-examination processes implemented?	5.6.1	●	☐	☐	☐		
Does the laboratory fabricate any results?	5.6.1	●	☐	☐	☐		
Does the laboratory design quality control procedures that verify the attainment of the intended quality of results?	5.6.2.1	●	☐	☐	☐		
Does the laboratory use quality control materials that react to the examining system in a manner as close as possible to patient samples?	5.6.2.2	●	☐	☐	☐		
Are quality control materials periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result?	5.6.2.2	●	☐	☐	☐		
Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure?	5.6.2.3	●	☐	☐	☐		
When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, are the results rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified?	5.6.2.3	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory also evaluate the results from patient samples that were examined after the last successful quality control event?	5.6.2.3	●	☐	☐	☐		
Are quality control data reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system?	5.6.2.3	●	☐	☐	☐		
When such trends are noted, are preventive actions taken and recorded?	5.6.2.3	●	☐	☐	☐		
Does the laboratory participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results?	5.6.3.1	●	☐	☐	☐		
Does the laboratory monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled?	5.6.3.1	●	☐	☐	☐		
Does the laboratory establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme?	5.6.3.1	●	☐	☐	☐		
Are interlaboratory comparison programme(s) chosen by the laboratory, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible?	5.6.3.1	●	☐	☐	☐		
Whenever an interlaboratory comparison is not available, does the laboratory develop other approaches and provide objective evidence for determining the acceptability of examination results?	5.6.3.2	●	☐	☐	☐		
Whenever possible, does this mechanism utilise appropriate materials such as certified reference materials, sample previously examined, material from cell or tissue repositories; exchange of samples with other laboratories; control materials that are tested daily in interlaboratory comparison programmes?	5.6.3.2	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples?	5.6.3.3	●	☐	☐	☐		
Are interlaboratory comparison samples examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples?	5.6.3.3	●	☐	☐	☐		
Does the laboratory communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data?	5.6.3.3	●	☐	☐	☐		
Does the laboratory refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples?	5.6.3.3	●	☐	☐	☐		
Is the performance in interlaboratory comparisons reviewed and discussed with relevant staff?	5.6.3.4	●	☐	☐	☐		
When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), do staff participate in the implementation and recording of corrective action?	5.6.3.4	●	☐	☐	☐		
Is the effectiveness of corrective action monitored?	5.6.3.4	●	☐	☐	☐		
Are the returned results evaluated for trends that indicate potential nonconformities and preventive action shall be taken?	5.6.3.4	●	☐	☐	☐		
Is there a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals? (This is applicable to the same or different procedures, equipment, different sites, or all of these.)	5.6.4	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed?	5.6.4	●	☐	☐	☐		
Does the laboratory document, record and, as appropriate, expeditiously act upon results from the comparisons performed?	5.6.4	●	☐	☐	☐		
Are problems or deficiencies identified acted upon and records of actions retained?	5.6.4	●	☐	☐	☐		
Post-examination processes	**5.7**						
Does the laboratory have procedures to ensure that authorised personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results?	5.7.1	●	☐	☐	☐		
When the procedure for reviewing results involves automatic selection and reporting, are review criteria established, approved and documented?	5.7.1	●	☐	☐	☐		
Does the laboratory have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples?	5.7.2	●	☐	☐	☐		
Does the laboratory define the length of time clinical samples are to be retained?	5.7.2	●	☐	☐	☐		
Is retention time defined by the nature of the sample, the examination and any applicable requirements?	5.7.2	●	☐	☐	☐		
Is safe disposal of samples carried out in accordance with local regulations or recommendations for waste management?	5.7.2	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Reporting of results	**5.8**						
Are the results of each examination reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures?	5.8.1	●	☐	☐	☐		
Does the laboratory define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory?	5.8.1	●	☐	☐	☐		
Does the laboratory have a procedure to ensure the correctness of transcription of laboratory results?	5.8.1	●	☐	☐	☐		
Do reports include the information necessary for the interpretation of the examination results?	5.8.1	●	☐	☐	☐		
Does the laboratory have a process for notifying the requester when an examination is delayed that could compromise patient care?	5.8.1	●	☐	☐	☐		
Does the laboratory ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:							
- comments on sample quality that might compromise examination results?	5.8.2a	●	☐	☐	☐		
- comments regarding sample suitability with respect to acceptance/rejection criteria?	5.8.2b	●	☐	☐	☐		
- critical results, where applicable?	5.8.2c	●	☐	☐	☐		
- interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.1) in the final report?	5.8.2d	●	☐	☐	☐		
Does the report include, but not be limited to, the following							

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- a clear, unambiguous identification of the examination including, where appropriate, the examination procedure?	5.8.3a	●	☐	☐	☐		
- the identification of the laboratory that issued the report?	5.8.3b	●	☐	☐	☐		
- identification of all examinations that have been performed by a referral laboratory?	5.8.3c	●	☐	☐	☐		
- patient identification and patient location on each page?	5.8.3d	●	☐	☐	☐		
- name or other unique identifier of the requester and the requester's contact details?	5.8.3e	●	☐	☐	☐		
- date of primary sample collection (and time, when available and relevant to patient care)?	5.8.3f	●	☐	☐	☐		
- type of primary sample?	5.8.3g	●	☐	☐	☐		
- measurement procedure, where appropriate?	5.8.3h	●	☐	☐	☐		
- examination results reported in SI units, units traceable to SI units, or other applicable units?	5.8.3i	●	☐	☐	☐		
- biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable?	5.8.3j	●	☐	☐	☐		
- interpretation of results, where appropriate?	5.8.3k	●	☐	☐	☐		
- other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure)?	5.8.3l	●	☐	☐	☐		
- identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available?	5.8.3m	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available when needed)?	5.8.3n	●	☐	☐	☐		
- date of the report, and time of release (if not contained in the report, readily available when needed)?	5.8.3o	●	☐	☐	☐		
- page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.)?	5.8.3p	●	☐	☐	☐		
Release of results	**5.9**						
Does the laboratory establish documented procedures for the release of examination results, including details of who may release results and to whom?	5.9.1	●	☐	☐	☐		
Do the procedures ensure that the following conditions are met?							
- When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report?	5.9.1a	●	☐	☐	☐		
- When examination results fall within established “alert” or “critical” intervals? ● a physician (or other authorised health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination] ● records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications	5.9.1b	●	☐	☐	☐		
- Results are legible, without mistakes in transcription, and reported to persons authorised to receive and use the information?	5.9.1c	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- When results are transmitted as an interim report, the final report is always forwarded to the requester?	5.9.1d	●	☐	☐	☐		
- There are processes for ensuring that results distributed by telephone or electronic means reach only authorised recipients? Results provided orally shall be followed by a written report. There shall be a record of all oral results provided?	5.9.1e	●	☐	☐	☐		
If the laboratory implements a system for automated selection and reporting of results, does it establish a documented procedure to ensure that:							
- the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff?	5.9.2a	●	☐	☐	☐		
- the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning?	5.9.2b	●	☐	☐	☐		
- there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination?	5.9.2c	●	☐	☐	☐		
- there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate?	5.9.2d	●	☐	☐	☐		
- results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection?	5.9.2e	●	☐	☐	☐		
- there is a process for rapid suspension of automated selection and reporting?	5.9.2f	●	☐	☐	☐		
When an original report is revised, are there written instructions regarding the revision so that:							
- the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report?	5.9.3a	●	☐	☐	☐		
- the user is made aware of the revision?	5.9.3b	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- the revised record shows the time and date of the change and the name of the person responsible for the change?	5.9.3c	●	☐	☐	☐		
- the original report entries remain in the record when revisions are made?	5.9.3d	●	☐	☐	☐		
Are results that have been made available for clinical decision making and revised retained in subsequent cumulative reports and clearly identified as having been revised?	5.9.3	●	☐	☐	☐		
When the reporting system cannot capture amendments, changes or alterations, is a record of such kept?	5.9.3	●	☐	☐	☐		
Laboratory information management	**5.10**						
Does the laboratory have access to the data and information needed to provide a service which meets the needs and requirements of the user?	5.10.1	●	☐	☐	☐		
Does the laboratory have a documented procedure to ensure that the confidentiality of patient information is maintained at all times?	5.10.1	●	☐	☐	☐		
Does the laboratory ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care?	5.10.2	●	☐	☐	☐		
Does the laboratory define the authorities and responsibilities of all personnel who use the system, in particular those who:							
- access patient data and information?	5.10.2a	●	☐	☐	☐		
- enter patient data and examination results?	5.10.2b	●	☐	☐	☐		
- change patient data or examination results?	5.10.2c	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- authorise the release of examination results and reports?	5.10.2d	●	☐	☐	☐		
Is/are the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information:							
- validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorised, documented and verified before implementation?	5.10.3a	●	☐	☐	☐		
- documented, and the documentation, including that for day to day functioning of the system, readily available to authorised users?	5.10.3b	●	☐	☐	☐		
- protected from unauthorised access?	5.10.3c	●	☐	☐	☐		
- safeguarded against tampering or loss?	5.10.3d	●	☐	☐	☐		
- operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription?	5.10.3e	●	☐	☐	☐		
- 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?	5.10.3f	●	☐	☐	☐		
- in compliance with national or international requirements regarding data protection?	5.10.3g	●	☐	☐	☐		
Does the laboratory verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices).?	5.10.3	●	☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
When a new examination or automated comments are implemented, does the laboratory verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory?	5.10.3	●	☐	☐	☐		
Does the laboratory have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service?	5.10.3	●	☐	☐	☐		
When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, is laboratory management responsible for ensuring that the provider or operator of the system complies with all applicable requirements of ISO15189:2012?	5.10.3	●	☐	☐	☐		

Please complete the following checklist on HKAS Regulations for reassessment

HKAS Regulations (as required under HKAS 002)							
The obligations of an accredited organisation							
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;	002 5.1a		☐	☐	☐		
(b) represent honestly and truthfully to any person concerned that it is only accredited for activities stated in the scope of accreditation;	002 5.1b		☐	☐	☐		
(c) pay such fees and charges as determined by HKAS Executive;	002 5.1c		☐	☐	☐		
(d) endeavor to ensure the accreditation granted by HKAS is not used in a misleading manner; and	002 5.1d		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(e) be a legal entity; and	002 5.1e		☐	☐	☐		
(f) conform with the Business Registration Ordinance (Cap 310)?	002 5.1f		☐	☐	☐		
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?	002 5.2		☐	☐	☐		
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?	002 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?	002 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."?	002 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?	002 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?	002 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?	002 5.6		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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)?	002 5.7		☐	☐	☐		
Does your laboratory notify HKAS Executive within one calendar month if a new authorised representative has been appointed?	002 5.8		☐	☐	☐		
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?	002 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."?	002 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?	002 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?	002 5.11		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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?	002 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?	002 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?	002 5.13		☐	☐	☐		
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?	002 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?	002 5.15		☐	☐	☐		
Is your laboratory aware that any concerned party may lodge complaints with HKAS on any of your accredited activities?	002 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.	002 5.17		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
● 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.	002 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 symbolsymbols 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;	002 8.1a		☐	☐	☐		
(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	002 8.1b		☐	☐	☐		
(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."?	002 8.1c		☐	☐	☐		
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.	002 8.2		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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?	002 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?	002 8.3		☐	☐	☐		
Specific regulations for HKAS							
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?	HKAS SC-06 2.1		☐	☐	☐		
Does the code of conduct cover at least the following aspects:			☐	☐	☐		
(a) solicitation and acceptance of advantage;	HKAS SC-06 2.2a		☐	☐	☐		
(b) offer of advantage;	HKAS SC-06 2.2b		☐	☐	☐		
(c) entertainment;	HKAS SC-06 2.2c		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(d) compliance with laws of Hong Kong or of relevant jurisdictions;	HKAS SC-06 2.2d		☐	☐	☐		
(e) compliance with relevant requirements of applicable professional standards;	HKAS SC-06 2.2e		☐	☐	☐		
(f) conflict of interest;	HKAS SC-06 2.2f		☐	☐	☐		
(g) use of company assets;	HKAS SC-06 2.2g		☐	☐	☐		
(h) confidentiality of company information;	HKAS SC-06 2.2h		☐	☐	☐		
(i) outside employment;	HKAS SC-06 2.2i		☐	☐	☐		
(j) relationship with customers, suppliers and contractors;	HKAS SC-06 2.2j		☐	☐	☐		
(k) procedures for reporting suspected violation and established mechanism for the prompt and fair adjudication of alleged violations; and	HKAS SC-06 2.2k		☐	☐	☐		
(l) disciplinary actions to be taken against violations.	HKAS SC-06 2.2l		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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?	HKAS SC-06 2.3		☐	☐	☐		
Does your laboratory ensure that all its directors, staff and other personnel working for it understand and practice the code of conduct?	HKAS SC-06 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?	HKAS SC-06 3.2		☐	☐	☐		
Does your laboratory periodically remind all personnel working for it the code of conduct?	HKAS SC-06 3.3		☐	☐	☐		
Is the code of conduct accessible to all personnel working for the laboratory?	HKAS SC-06 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?	HKAS SC-06 3.5		☐	☐	☐		
Does your laboratory periodically review the code's suitability and adequacy; and implement improvement as appropriate?	HKAS SC-06 3.6		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at 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."?	HOKLAS SC-33 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:- (a) twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the laboratory;	HOKLAS SC-33 2.2a		☐	☐	☐		
(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);	HOKLAS SC-33 2.2b		☐	☐	☐		
(c) at such other times as may be specified in the terms of accreditation;	HOKLAS SC-33 2.2c		☐	☐	☐		
(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	HOKLAS SC-33 2.2d		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
HKAS Executive may, at its discretion, vary the reassessment schedule.	HOKLAS SC-33 2.2		☐	☐	☐		
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."?	HOKLAS SC-33 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."?	HOKLAS SC-33 2.4		☐	☐	☐		
Does your laboratory at all times comply with the following HOKLAS accreditation criteria? HKAS002, HOKLAS015, relevant HOKLAS Supplementary Criteria and relevant HKAS Supplementary Criteria.	HOKLAS SC-33 3.1		☐	☐	☐		
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?	HOKLAS SC-33 3.2		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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	HOKLAS SC-33 3.3a		☐	☐	☐		
(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.	HOKLAS SC-33 3.3b		☐	☐	☐		
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."?	HOKLAS SC-33 3.4		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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?	HOKLAS SC-33 3.5		☐	☐	☐		
Is the performance of your laboratory in any proficiency testing activity relevant to its scope of accreditation acceptable to HKAS Executive?	HOKLAS SC-33 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."?	HOKLAS SC-33 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?	HOKLAS SC-33 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?	HOKLAS SC-33 3.7		☐	☐	☐		
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)?	HOKLAS SC-33 3.7		☐	☐	☐		
Has any change to the plan been documented and justified?	HOKLAS SC-33 3.7		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
When the laboratory updates its PT plan, does your laboratory ensure its continual suitability in relation to its scope of accreditation?	HOKLAS SC-33 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."?	HOKLAS SC-33 3.8		☐	☐	☐		
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."?	HOKLAS SC-33 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?	HOKLAS SC-33 3.10		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are relevant records of corrective actions kept?	HOKLAS SC-33 3.10		☐	☐	☐		
Are the actions taken effective to achieve satisfactory performance in PT activity for the test in question?	HOKLAS SC-33 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?	HOKLAS SC-33 3.10		☐	☐	☐		
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."?	HOKLAS SC-33 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."?	HOKLAS SC-33 3.12		☐	☐	☐		

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HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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?	HOKLAS SC-33 4.1		☐	☐	☐		
Is your laboratory aware of and does it comply with the following HKAS regulation on suspension and termination: "HKAS Executive may publish information relating to any suspension and termination of accreditation granted by HKAS in any HKAS publications and in the website of HKAS."?	002 2.10		☐	☐	☐		
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."?	HOKLAS SC-33 5.1		☐	☐	☐		
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;	HOKLAS SC-33 5.2a		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(b) 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”.).	HOKLAS SC-33 5.2.b(iii)		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory’s quality documentation that describes the laboratory’s procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(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.	HOKLAS SC-33 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."	HOKLAS SC-33 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?	HOKLAS SC-33 5.4		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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?	HOKLAS SC-33 5.5		☐	☐	☐		
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."	HOKLAS SC-33 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."?	HOKLAS SC-33 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?	HOKLAS SC-33 5.8		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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."?	HOKLAS SC-33 5.9		☐	☐	☐		
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?	HOKLAS SC-33 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?	HOKLAS SC-33 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	HOKLAS SC-33 5.12a		☐	☐	☐		
(b) the sample or samples concerned were taken by staff of the accredited laboratory using the accredited sampling procedure."?	HOKLAS SC-33 5.12b		☐	☐	☐		

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2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.

HOKLAS Requirements and HKAS Regulations	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
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;	HOKLAS SC-33 5.13a		☐	☐	☐		
(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	HOKLAS SC-33 5.13b		☐	☐	☐		
(c) where an instrument or measuring device is calibrated such statements shall be limited to:-	HOKLAS SC-33 5.13c						
(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."?	HOKLAS SC-33 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."?	HOKLAS SC-33 6.1		☐	☐	☐		

End

Note: 1. * The assessor should concentrate on items marked with a ●; other items will be checked by the team leader.
2. QM Clause stands for the clause number of the laboratory's quality documentation that describes the laboratory's procedures for the areas concerned.