



Hong Kong Laboratory Accreditation Scheme

HOKLAS 016

Assessment/Reassessment Questionnaire (Medical Laboratories)

For initial applications for accreditation and applications for extension of scope of accreditation, this questionnaire should be completed and submitted to the HKAS Executive together with the application form HOKLAS 005 and all relevant documents as listed in the checklist on page 2.

For reassessments, this completed questionnaire together with any completed supplementary questionnaires must be returned to the HKAS Executive two months before the scheduled reassessment date accompanied by the relevant documents.

Fees payable for assessments are calculated in accordance with :

HOKLAS 006 Schedule of Accreditation Fees for Laboratories within the Hong Kong Special Administrative Region, or

HOKLAS 013 Schedule of Accreditation Fees for Laboratories outside of the Hong Kong Special Administrative Region.

You should study the latest versions of the following documents before completing this questionnaire.

HKAS 002 Regulations for Laboratory Accreditation

HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories)

HONG KONG ACCREDITATION SERVICE

36/F., Immigration Tower, 7 Gloucester Road, Wanchai, Hong Kong.

Tel : 2829 4840

Fax : 2824 1302

E-mail : hkas@itc.gov.hk

The personal data provided will be used for accreditation purpose only.

Attachment Checklist

Before sending this completed questionnaire to HKAS Executive, please ensure that all required documents are attached and tick the appropriate boxes below.

This Application Questionnaire is related to : (more than one box may be ticked if appropriate)

- Initial Assessment Extension of Scope Reassessment
- application fees (for initial applications and applications for extension of accreditation only, no application fees are charged for reassessments), in the form of a cheque payable to **The Government of the Hong Kong Special Administrative Region**. In addition to application fees, assessment fees will be charged. Applicants will be informed of the exact amounts when the on-site assessments have been arranged.
- documents authenticating that the applicant laboratory is or part of an entity that can be held legally responsible.
- quality manual
- operation procedure manual
- other quality documentation; please specify

- latest audit schedule
- summary of the findings of the latest quality system review
- examination procedure manual(s)
- CV's and copies of qualification documents for new nominees for signatory approval
- laboratory floor plan
- laboratory organisation charts, with key positions clearly identified
- sample examination records (see the explanation under the "Records" section in this questionnaire)
- sample examination reports (see the explanation under the section in this questionnaire)
- relevant proficiency test reports
- completed supplementary questionnaires
- documents required in any supplementary questionnaires
- other documents, please specify

- confirmed scope of accreditation

SCOPE OF ACCREDITATION

For applications for accreditation and applications for extension of Scope of Accreditation, the tests and calibrations to be included should be detailed in the “Scope of Accreditation Sought” table on pages 4 and 5.

For reassessments, the “Scope of Accreditation to be Reassessed” should have been sent to the laboratory together with this questionnaire. The laboratory should check this scope carefully and minor changes should be annotated on it. This scope should then be signed by the Authorised Representative and returned to the HKAS Executive for confirmation together with this completed questionnaire. If major additions to the Scope of Accreditation are requested, the laboratory should consult the HKAS Executive on whether an application for extension of Scope of Accreditation should be submitted.

Scope of Accreditation Sought (for application for accreditation or extension of Scope of Accreditation only)

Specify as precisely as possible below the scope of accreditation sought.

Specifications quoted in the fourth column should be national or international standards, or specifications published by reputable technical organisations or in relevant scientific texts or journals. In the absence of such standard specifications, documented and validated in-house methods may be quoted, but copies will need to be made available to the HKAS Executive prior to an assessment.

Discipline	Items, or materials examined	Specific examinations, properties measured or ranges of measurement	Standard methods, specifications, or technique used (where appropriate)
DRAFT			

Photocopy this sheet if required.

- Notes :
1. Please state the identification numbers of the laboratory internal technical procedures for the examination listed in column 3 and 4 on page 4.
 2. Please state the approximate frequency of performing the examination in number/year, number/months etc.
 3. Please state the approximate experience of the laboratory in performing the examination, in total number of examination performed or in years.
 4. Please state the identification numbers of the sample examination records provided (see the "Records" section on page 9).
 5. Please state the identification numbers of the sample examination reports provided (see the "Reporting of results" section on page 16).

Range and detection limits (where appropriate)	Examination procedure ¹	Frequency of performing ²	Experience ³	Sample examination record ⁴	Sample examination report/certificate ⁵

Photocopy this sheet if required.

General Information

Organisation name
(* See Note 1)

Laboratory name
(e.g. Anatomical Pathology Division Lab.)

General description of the organisation and
The laboratory including their history

Address
(Physical address of the laboratory)

Telephone

Fax

E-mail

Address
(for correspondence)

Hong Kong

Kowloon

N.T.

Telephone

Fax

E-mail

Questionnaire completed by

Name

Position

Telephone

Fax

E-mail

Authorised representative

Name

Position

Address
(if different from the correspondence address)

Hong Kong

Kowloon

N.T.

Telephone

Fax

E-mail

Signature

Date

* Note 1 – Organisation is the legal identity of the owners of the laboratory. It may be a Government Department, Instrumentality, Company, Person operating a laboratory or other legally identifiable organisation.

Management Requirements (HOKLAS 015, Section 4)

Organisation and management (HOKLAS 015, section 4.1)

Legal Status

Please give details of the legal status of your organisation. (The organisation under which accreditation is granted or sought) (See 4.1.1 of HOKLAS 015)

- a government department?
- a commercial operation?
- an education body?
- a subvented agency?
- a professional body?
- other?
(please specify)

Yes/No	Please give details of the relationship between the laboratory and the organisation

Activities

- an organisation with activities in addition to laboratory operation?
- are these “additional activities” the main activities?

Yes/No	If yes, please describe

Clients

The laboratory provides service to

- the parent organisation
- the public

Yes/No	Percentage of work

Size of laboratory

- number of people working for the laboratory
- floor area occupied

Management Requirements (cont'd)

Organisation and management (Cont'd)(HOKLAS 015, section 4.1)

Technical management

(please refer to 4.1.5h of HOKLAS 015 for requirements for technical management)

Please give a general description of technical management structure relevant to the Scope of Accreditation

Details of the members of the technical management team

Name	Position	Area of responsibility

Quality Manager

(please refer to 4.1.5i of HOKLAS 015 for requirements for quality manager)

Name

Position

Deputisation arrangement

(please give a general description for the deputisation arrangement for members of the technical management team, for the quality manager, the Laboratory Director, and other key functions)

Scope and function

(please describe the scope and function of the laboratory)

Management Requirements (cont'd)

Quality Management System (HOKLAS 015, Section 4.2)

Quality Manual

Please provide a copy of the quality manual and related quality documents, such as operation procedure manual. Any further comments should be stated below or on separate sheets.

Records (HOKLAS 015, Section 4.13)

Please provide copies of representative raw test data records for the examination to be assessed. These records should be obtained from real samples. For confidentiality, the identities of the clients and patients under examination should be blanked out.

For applications for accreditation and applications for extension of Scope of Accreditation, the laboratory should select which sample records to provide. It is not necessary to provide a separate sample record for every examination. Examinations which have similar record formats may be represented by a common sample record. For each examination, the identification number of the sample record selected to represent it should be entered in the "Sample examination report" column in the "Scope of Accreditation Sought" table on page 5.

For reassessments, sample records are selected by the HKAS Executive. The selected examinations are marked with a tick in the "Sample examination report/certificate" column in the "Scope of Accreditation to be Reassessed" accompanying this questionnaire. For identification, the laboratory should also enter the identification numbers of the sample records provided by the side of the ticks.

Internal audits (HOKLAS 015, Section 4.14)

(please refer to HOKLAS Supplementary Criteria No.7) Please provide a copy of the latest audit schedule. Any further comments should be stated below.

Management review (HOKLAS 015, Section 4.15)

(please refer to HOKLAS Supplementary Criteria No.7 on Quality Audits and Quality System Reviews) Please provide a copy of the latest management review record. Any further comments should be stated below.

Technical Requirements (HOKLAS 003, Section 5)

Personnel (HOKLAS 015, Section 5.1)

Laboratory Director

Name

Qualifications

Experience

Date appointed as
Laboratory Director

Officer-in-charge of the division in which the work to be assessed are performed.

Name

Position

Qualifications

Experience

Date appointed
to division/unit

(Please use extra sheets if there are more than one division)

Deputy

Name

Position

Qualifications

Experience

Date appointed
to division/unit

The person to whom officer-in-charge reports

Name

Position

Technical Requirements (HOKLAS 003, Section 5)

Personnel (HOKLAS 015, Section 5.1)

Organisation chart

Please provide a copy of the organisation charts of the division in which the work to be assessed are performed. The charts should show the position of the division/unit within the organisation structure of the laboratory and any parent organisation. The key positions with respect to the work to be assessed should be clearly identified. Any further comments should be given below.



A large empty rectangular box intended for the submission of an organisation chart. A large, light grey watermark reading 'DRAFT' is oriented diagonally across the center of this box.

Other key staff (Attached extra sheets if necessary)

For staff members occupying key positions as identified in the organisation charts of the division, please provide their names, qualifications, experience, positions and dates appointed.



A large empty rectangular box intended for providing details of other key staff. A large, light grey watermark reading 'DRAFT' is oriented diagonally across the center of this box.

Technical Requirements (Cont'd) (HOKLAS 015, Section 5)

Personnel (cont'd) (HOKLAS 015, Section 5.1)

Nominated HOKLAS approved signatories

Which of the staff listed are required to be considered by the HKAS Executive for approval as signatories of HOKLAS endorsed examination reports? (See HKAS 002 and HOKLAS 015 for requirements for HOKLAS endorsed examination reports and approved signatories).

Name	Test areas	New/Existing

NOTE : please provide copies of qualification documents (degrees, diplomas, certificates, etc.) for new nominees.

Names of pathologists providing clinical interpretations of examination results

Name

Qualifications

Specialty area(s)

Position in laboratory
if full-time

Detailed arrangements
with laboratory, if not
full-time

(Please attached copies of evidence showing competence in the specialty area(s) responsible for.)

Technical Requirements (Cont'd) (HOKLAS 015, Section 5)

Personnel (cont'd) (HOKLAS 015, Section 5.1)

Personnel changes (Applicable only for reassessments)

Please give details of any changes to laboratory personnel relevant to the work to be reassessed since the last assessment/reassessment.

Accommodation and Environmental Conditions (HOKLAS 015, Section 5.2)

Please provide a floor plan of the laboratory and indicate the use of different areas. Any further comment should be given below.

Please state whether any of the tests/calibrations to be assessed require specific environmental conditions and explain how the environmental conditions in the laboratory are controlled and monitored to meet the requirements.

Please indicate how access to, and use of, areas affecting the quality of the quality of the examinations is controlled.

Technical Requirements (Cont'd) (HOKLAS 015, Section 5)

Examination procedures (HOKLAS 015, Section 5.5)

Please give a copy of the examination procedures for the examinations to be assessed. The identification numbers of the procedures should be entered into the "Examination procedure" column in the Scope of Accreditation on page 5 against the relevant examinations.

Any further comments should be given below.

Validation of method (HOKLAS 015, Section 5.5.2)

Please describe the method used to validate the tests and calibrations included in the proposed Scope of Accreditation

Estimation of uncertainty of results (HOKLAS 015, Section 5.6.2)

Please give a brief description of the methods for estimation of uncertainty for the examinations included in the proposed Scope of Accreditation.

Technical Requirements (Cont'd) (HOKLAS 015, Section 5)

Equipment, reference materials, and their calibration and verification (HOKLAS 015, Sections 5.3 and 5.6)

Please provide a list of reference equipment, reference materials and major testing equipment for the examinations to be assessed. The calibration and verification schedule should also be provided. If all of this information is already included in a separate document, please attach a copy of that document.

Description, make, model, range	Code#	Calibration/ verification interval	Last calibration/ verification date	Internal*/ External	Traceability®

* For calibrations performed internally by laboratory staff, the HKAS Executive may require the laboratory to provide a copy of their internal calibration procedures.

Code : RE = reference equipment; RM = reference materials; TE = major testing equipment

® Please name the organisation which conducts the calibration or provides the traceability link and the name of the accreditation body which accredit it, if any.

Computer and automated equipment (HOKLAS 015, 5.4.7.2)

For the examinations to be assessed, please describe below the extent to which computers and other types of automated equipment are used for the capture, processing, manipulation, recording, reporting, storage and retrieval of calibration and test data.

Technical Requirements (Cont'd) (HOKLAS 015, Section 5)

Handling of samples and specimens (HOKLAS 015, Sections 5.4 and 5.5)

For the examinations to be assessed, please briefly describe any special precautions taken in the reception, registration, transportation, storage and disposal of the samples.

Assuring the quality of examination procedures (HOKLAS 015, Section 5.6)

Please describe briefly the quality control plans and procedures for monitoring the validity of examination to be assessed.

Interlaboratory comparison and external quality assessment schemes

Please provide details of the interlaboratory comparison and external quality assessment schemes that your laboratory has participated in, for the examinations to be assessed (for reassessments, since the last assessment/reassessment). The HOKLAS requirements on proficiency testing activities are detailed in HKAS 002.

Description of the schemes	Frequency of schemes	Last date of participation

Internal Checks

Please explain any internal checks conducted to ensure the quality of results for the examinations to be assessed.

Reporting of Results (HOKLAS 015, Section 5.8)

For the examinations to be assessed, what is the approximate number of reports issued per year?

What percentage of these reports are HOKLAS endorsed?

Please provide copies of representative reports for the examinations to be assessed. These reports should be issued for real samples. For confidentiality, the identities of the patients and/or clients should be blanked out.

For applications for accreditation and applications for extension of Scope of Accreditation, the laboratory should select which sample reports to provide. It is not necessary to provide a separate sample report for every test. Tests which have similar report formats may be represented by a common sample report. For each examination, the identification number of the sample report selected to represent it should be entered in the "Sample examination report" column in the "Scope of Accreditation Sought" table on page 5.

For reassessment, sample reports are selected by the HKAS Executive. The selected examinations are marked with a tick in the "Sample test report/certificate" column in the "Scope of Accreditation to be Reassessed" accompanying this questionnaire. For identification, the laboratory should also enter the identification numbers of the sample reports provided by the side of the ticks.

Any further comments on records should be stated below.

DRAFT

Management System Checklist

The applicant laboratory or laboratory to be reassessed must complete the following checklist. It will be used to assess compliance with HOKLAS requirements.

The checklist consists of questions based on the requirements of HKAS 002 and HOKLAS 015. For further information, 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 columns headed “*” and “OK” are for internal use of the HKAS Executive.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Management requirements							
Organization and management							
4.1							
Is your laboratory or the organisation of which it is part an entity that is legally identifiable?	4.1.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the laboratory services, including appropriate interpretation and advisory services, designed to meet the needs of the patients and all clinical personnel responsible for patient care?	4.1.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the same laboratory management system being used 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?	4.1.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the responsibilities of personnel in the laboratory with an involvement or influence on the examination of primary samples defined? Are potential conflicts of interest identified?	4.1.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory							
- have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests, and to initiate actions to prevent or minimise such departures?	4.1.5a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?	4.1.5b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- have policies and procedures for ensuring the protection of its clients' confidential information including procedures for protecting the electronic storage and transmission of results?	4.1.5c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- have policies and procedures for avoiding involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity?	4.1.5d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory							
- have a defined organization and management structure, including its relationship to any other associated organization?	4.1.5e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations?	4.1.5f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- provide adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent person(s) conversant with the purpose, procedures and assessment of results of the relevant examination procedures?	4.1.5g		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- have designated technical management personnel who have overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory procedures?	4.1.5h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- have a quality manager (however named) with delegated responsibility and authority to oversee compliance with requirements of the quality management system and, who reports directly to the highest level of management at which decisions are made on laboratory policy or resources?	4.1.5h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- have deputies for all key functions?	4.1.5j		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Quality management system	4.2						
Has the laboratory established, implemented and maintained a quality system appropriate to the scope of its activities?	4.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the quality system's documentation communicated to, understood by, available to, and implemented by the appropriate personnel?	4.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Has the laboratory documented its policies, processes, programmes, procedures and instructions to assure the quality of tests?	4.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the quality management system include, but is not limited to, internal quality control and participation in organised interlaboratory comparisons such as external assessment schemes?	4.2.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the policies and objectives of the quality management system defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual which is readily available to appropriate personnel and include at least the following:	4.2.3						
- the scope of service the laboratory intends to provide?	4.2.3a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the laboratory management's statement of the laboratory's standard of service?	4.2.3b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the objectives of the quality management system?	4.2.3c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- a requirement that all personnel concerned with examination activities be familiar with the quality documentation and implement the policies and procedures at all times?	4.2.3d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system?	4.2.3e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the laboratory management's commitment to compliance with ISO 15189?	4.2.3f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the quality manual include or make reference to the supporting procedures including technical procedures?	4.2.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the quality manual outline the structure of the documentation used in the quality system?	4.2.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with ISO 15189, defined in the quality manual?	4.2.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Has the laboratory management established and implemented a programme that regularly monitors and demonstrates proper calibration and functions of instruments, reagents and analytical systems?	4.2.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory management established a documented and recorded programme of preventive maintenance and calibration, which, at a minimum, follows manufacturer's recommendations?	4.2.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Document control	4.3						
<i>General</i>							
Has your laboratory established and maintained procedures to control all documents and information (from internal and external sources) that form part of its quality documentation? Is a copy of these controlled documents archived for later reference and the retention period defined by the laboratory director?	4.3.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>Document approval and issue</i>							
Are all documents issued to laboratory personnel as part of the quality management system reviewed and approved for use by authorised personnel prior to issue?	4.3.2a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is a master list or an equivalent document control procedure identifying the current revision status and distribution of documents maintained?	4.3.2b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the procedure ensure that:							
- only currently authorised versions of appropriate documents are available for active use at relevant locations?	4.3.2c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- documents are periodically reviewed, revised when necessary, and approved by authorised personnel?	4.3.2d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use?	4.3.2e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- retained or archived superseded documents are appropriately identified to prevent their inadvertent use?	4.3.2f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- if the laboratory's documentation 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, while amendments are clearly marked, initialled and dated, and a revised document is formally re-issued as soon as practicable?	4.3.2g		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- changes to documents maintained in computerised system are made and controlled as described?	4.3.2h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all documents relevant to the quality management system uniquely identified to include title; edition or current revision date, or revision number, or all these; number of pages; authority for issue; database identification?	4.3.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Review of contracts	4.4						
Has the laboratory established and maintained procedures for the review of contracts?	4.4.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the policies and procedures leading to a change in the arrangement for examinations or contracts ensure that:							
- the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5)?	4.4.1a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the laboratory has the capability and resources to meet the requirements (e.g. the laboratory's personnel have the skills and expertise necessary, for the performance of the examinations in question; and whether the laboratory has earlier participation in external quality assurance schemes)?	4.4.1b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the appropriate procedures selected are able to meet the contract requirements and the clinical needs?	4.4.1c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records of reviews, including any significant changes and pertinent discussions, maintained?	4.4.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the review also cover any work that is referred by the laboratory?	4.4.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the client (e.g. clinicians, health care bodies, health insurance companies, pharmaceutical companies) informed of any deviation from the contract?	4.4.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If a contract needs to be amended after work commences, is the same contract review process repeated and are amendments communicated to all affected parties?	4.4.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Examination by referral laboratories	4.5						
Does the laboratory have a documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology and related disciplines?	4.5.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When the laboratory refers work to referral laboratories and consultants, is there any documented procedure or policy to ensure that the requested examinations have been placed with a competent referral laboratory or consultant?	4.5.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory reviewed periodically the arrangements with referral laboratories to ensure that:							
- the requirements, including the pre-examination and post-examination procedures, are adequately defined, documented and understood?	4.5.2a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the referral laboratory is able to meet the requirements and that there is no conflict of interest?	4.5.2b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the selection of examination procedures is appropriate for the intended use?	4.5.2c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the respective responsibilities for the interpretation of results are clearly defined?	4.5.2d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory maintain records of such reviews?	4.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory maintain a register of all referral laboratories that it uses and a register of all samples that have been referred to another laboratory?	4.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Is the name and address of the laboratory responsible for the examination results provided to the user of the laboratory services?	4.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory retain a duplicate of the referral laboratory reports in both the patient record and in the permanent file of the laboratory?	4.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there documented procedure to ensure that the referral laboratory examination results and findings are provided to the person making the request?	4.5.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If the laboratory prepares the report for tests carried out by the referral laboratory, are all essential elements of the results reported by the referral laboratory included without alterations that could affect clinical interpretation?	4.5.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
External services and supplies	4.6						
Has the laboratory defined and documented policies and procedure(s) for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of the service?	4.6.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are there documented procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials?	4.6.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records kept for verification of external services and supplies?	4.6.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have a system which ensures that purchased equipment and consumable supplies that affect the quality of service are not used until they have been verified as complying with standard specifications or requirements as defined for the procedures concerned?	4.6.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there an inventory control system for supplies?	4.6.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are quality records of external services, supplies and purchased products established and maintained for a period of time, as defined in the quality management system?	4.6.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all quality records available for quality management review?	4.6.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory evaluate suppliers of critical reagents, supplies and services which affect the quality of examinations, and maintain records of these evaluations and list those approved?	4.6.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Advisory services	4.7						
Does the laboratory have appropriate laboratory professional staff to provide advice to clients on choice of examinations and use of the services?	4.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the interpretation of the results of examination, where appropriate, provided by appropriate personnel?	4.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Resolution of complaints	4.8						
Does the laboratory have a policy and procedure for the resolution of complaints or other feedback received from clinicians, patients and other parties?	4.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records of all complaints and of investigations and corrective actions taken by the laboratory maintained (see also 4.13.3)?	4.8 & HKAS 002 5.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When an activity is involved in a complaint, are the relevant areas of the activity and responsibility promptly audited?	HKAS 002 5.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have arrangements to inform the HKAS Executive of any complaint relating to HOKLAS Endorsed Test Reports not resolved within 60 days of receipt?	HKAS 002 5.15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Identification and control of nonconformities	4.9						
Does the laboratory have a policy and procedure to be implemented when it detects that any aspect of examinations does not conform to its own procedures or agreed upon requirements of its quality management system or of the requesting clinician?	4.9.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have a policy and procedure to ensure that							

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- personnel responsible for problem resolution are designated?	4.9.1a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the action to be taken is defined?	4.9.1b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the medical significance of the nonconforming examinations is considered and where appropriate, the requesting clinician is informed?	4.9.1c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- examinations are halted and reports withheld as necessary?	4.9.1d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- corrective action is taken immediately?	4.9.1e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the results of nonconforming examinations already released are recalled or appropriately identified, if necessary?	4.9.1f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the responsibility for authorisation of the resumption of examinations is defined?	4.9.1g		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- each episode of nonconformity is documented and recorded?	4.9.1h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- each episode of nonconformity is reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action?	4.9.1h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where the evaluation indicates that the nonconforming examinations could recur or that there is doubt about the laboratory's compliance with its own policies or procedures as given in the quality manual, are procedures to identify, document and eliminate the root cause(s) promptly implemented?	4.9.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory define and implement procedures for the release of results in the case of nonconformities, including the review of such results?	4.9.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are these events recorded?	4.9.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Corrective action	4.10						
Does the procedure for corrective action include an investigative process to determine the underlying cause(s) of the problem?	4.10.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Do these procedures, where appropriate, lead to preventive action?	4.10.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the corrective actions of a degree appropriate to the magnitude and the risk of the problem?	4.10.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory document and implement any required changes to its operational procedures resulting from corrective action investigations?	4.10.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory management monitor the results to ensure that the corrective actions taken have been effective in overcoming the identified problems?	4.10.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where the identification of non-conformities or the corrective action investigation casts doubts on compliance with the policies and procedures or quality management system, are the appropriate areas of activity audited in accordance with clause 4.14 of ISO 15189?	4.10.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are results of corrective action submitted for laboratory management review?	4.10.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Preventive action	4.11						
Are needed improvement and potential sources of non-conformities, either technical or concerning the quality system, identified?	4.11.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where preventive action is required, are action plans developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities?	4.11.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do procedures for preventive actions include the initiation of actions for further improvement and application of controls to ensure that they are effective?	4.11.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Continual improvement	4.12						
Are all operational procedures systematically reviewed by laboratory management at regular intervals, as defined in the quality management system, in order to identify any potential sources of non-conformities or other opportunities for improvement in the quality management system or technical practices?	4.12.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are action plans for improvement developed, documented and implemented, as appropriate?	4.12.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
After action has been taken resulting from the review, does laboratory management evaluate the effectiveness of the action through a focused review or audit of the area concerned?	4.12.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the results of action following the review submitted to laboratory management for review and implementation of any needed changes to the quality management system?	4.12.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory management implemented quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care?	4.12.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When this programme identifies opportunities for improvement, does the laboratory management address them regardless of where they occur?	4.12.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory participate in quality improvement activities that deal with relevant areas and outcomes of patient care?	4.12.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory management provide access to suitable educational and training opportunity for all laboratory personnel and relevant users of laboratory services?	4.12.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Quality and technical records	4.13						
Has the laboratory established and implemented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records?	4.13.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all records legible and stored such that they are readily retrievable?	4.13.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is a suitable environment provided to prevent damage, deterioration, loss or access to the records?	4.13.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have a policy that defines the length of time various records pertaining to the quality management system and examination results are to be retained?	4.13.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Is the retention time of each type of records specifically defined?	4.13.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Internal audits	4.14						
Does the laboratory conduct internal audits of all elements of the system, both managerial and technical, to verify that the operations continue to comply with the requirements of the quality management system?	4.14.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are internal audits conducted at intervals as defined by the system itself?	4.14.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the internal audit programme address all elements of the quality management system and emphasize areas critically important to patient care?	4.14.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is it the responsibility of the quality manager or designated qualified personnel to plan, organise and carried out audits as required by the schedule and requested by management?	4.14.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are procedures in place to ensure personnel do not audit their own activities?	4.14.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the procedures for internal audits defined and documented including to the type of audit, frequencies, methodologies and required documentation?	4.14.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When deficiencies or opportunities for improvement are noted in the audit, does the laboratory take appropriate corrective or preventive action, documented and carried out within an agreeable time?	4.12.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the results of internal audits submitted to the laboratory management for review?	4.14.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Management review	4.15						
Does the laboratory management review the laboratory's quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes for improvements?	4.15.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are the results of the review incorporated into a plan that includes goals, objectives and action plans?	4.15.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are management reviews carried out according to its documented frequency?	4.15.1						
Does the management review take account of:							
- follow-up of previous management reviews?	4.15.2a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- status of corrective actions taken and required preventive action?	4.15.2b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- report from managerial and supervisory personnel?	4.15.2c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the outcome of recent internal audits?	4.15.2d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- assessment by external bodies?	4.15.2e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the outcome of external quality assessment and other forms of interlaboratory comparison?	4.15.2f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- any changes in the volume and type of work undertaken?	4.15.2g		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- feedback, including complaints and other relevant factors, from clinicians, patients and other parties?	4.15.2h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- quality indicators for monitoring the laboratory's contribution to patient care?	4.15.2i		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- non-conformities?	4.15.2j		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- monitoring of turnaround time?	4.15.2k		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- results of continuous improvement processes?	4.15.2l		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- evaluation of suppliers?	4.15.2m		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the quality and appropriateness of the laboratory's contribution to patient care monitored and evaluated objectively?	4.15.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are findings and actions that arise from management reviews recorded?	4.15.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the laboratory staff informed of the findings of management review and the decisions made as a result of the review?	4.15.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory management ensure that these actions are discharged within an appropriate and agreed-upon time?	4.15.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Technical requirements							
Personnel							
5.1							
Does the laboratory management have an organization plan, personnel policies and job descriptions that define qualifications and duties of all personnel?	5.1.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records of the relevant educational and professional qualifications, training and experience, and competence of all personnel maintained?	5.1.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the personal records readily available to relevant personnel?	5.1.2						
Is the laboratory directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided?	5.1.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the responsibilities of the laboratory director or designees include professional, scientific, consultative or advisory, organizational, administrative and educational matters?	5.1.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are these relevant to the services provided by the laboratory?	5.1.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system?	5.1.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the personnel have training specific to quality assurance and quality management for the services offered?	5.1.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Has the laboratory management authorised personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment, including use of computers in the laboratory information system?	5.1.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Have policies which define who may use the computer system, who may access patient data and who is authorised to enter and change patient results, correct billing or modify computer programmes, been established?	5.1.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are there continuing education programmes available to staff at all levels?	5.1.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Have the employees been trained to prevent or contain the effects of adverse incidents?	5.1.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the competency of each person to perform assigned tasks been assessed following training and periodically thereafter?	5.1.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is retraining and reassessment provided, when necessary?	5.1.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the personnel making professional judgments with reference to examinations have the applicable theoretical and technical background as well as recent experience?	5.1.12		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the personnel take part in regular professional development or other professional liaison?	5.1.12		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the confidentiality of information regarding patients maintained by all personnel?	5.1.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Accommodation and environmental conditions	5.2						
Does the laboratory have adequate space allocated so that the workload can be performed without compromising the quality of work, quality control procedures, safety of personnel or patient care services?	5.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the laboratory's resources maintained in a functional and reliable condition?	5.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the resources of a degree necessary to support the activities of the laboratory?	5.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Is the laboratory designed for the efficiency of the operation, to optimise the comfort of its occupants and to minimise the risk of injury and occupational illness?	5.2.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are patients, employees and visitors protected from recognised hazards?	5.2.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where primary sample collection facilities are provided, has consideration been given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimisation of collection conditions?	5.2.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory design and environment suitable for the tasks carried out such that the quality of the primary samples collected or examinations results are not adversely affected?	5.2.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory monitor, control and record environmental conditions as required by relevant specifications or where they may influence the quality of the results?	5.2.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there effective separation between adjacent laboratory sections in which there are incompatible activities?	5.2.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are measures taken to prevent cross-contamination?	5.2.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is access to and use of areas affecting the quality of the examinations controlled?	5.2.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are appropriate measures taken to safeguard samples and resources from unauthorised access?	5.2.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the communication system within the laboratory appropriate to the size and complexity of the facility and the efficient transfer of messages?	5.2.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are relevant storage space and conditions provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results?	5.2.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are work areas clean and well maintained?	5.2.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the storage and disposal of dangerous materials comply with relevant regulations?	5.2.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are there any measures taken to ensure good house keeping in the laboratory?	5.2.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Laboratory equipment	5.3						
Is the laboratory furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and processing, examination and storage)?	5.3.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where the laboratory needs to use equipment outside its permanent control, has the laboratory management ensured that the requirements of ISO 15189 are met?	5.3.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the equipment shown, upon installation and during routine use, to be capable of achieving the performance required and complying with specifications relevant to the examinations concerned?	5.3.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has laboratory management established a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems?	5.3.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a documented and recorded programme of preventive maintenance, which, at a minimum, follows the manufacturer's recommendations?	5.3.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is each item of equipment uniquely labelled, marked or otherwise identified?	5.3.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records maintained for each item of equipment contributing to the performance of examinations?	5.3.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records maintained for							
- identity of the equipment?	5.3.4a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- manufacturer's name, type identification and serial number or other unique identification?	5.3.4b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- manufacturer's contact person and telephone number, as appropriate?	5.3.4c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- date of receiving and date of putting into service?	5.3.4d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- current location, where appropriate?	5.3.4e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- condition when received (e.g. new, used or reconditioned)?	5.3.4f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- manufacturer's instructions, if available, or a reference to their retention?	5.3.4g		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- equipment performance records that confirms the equipment's suitability for use?	5.3.4h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- maintenance carried out and that planned for the future?	5.3.4i		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- damage to, or malfunction, modification or repair, of the equipment?	5.3.4j		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- predicted replacement date, if possible?	5.3.4k		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the maintained records readily available for the life span of the equipment, or for any period required by law or regulation?	5.3.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is equipment operated by authorised personnel only?	5.3.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) readily available to laboratory personnel?	5.3.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is equipment maintained in a safe working condition?	5.3.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does this include examination of electrical safety, emergency stop devices and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons?	5.3.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are manufacturer's specifications or instructions, or both, used, as appropriate?	5.3.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the defective equipment, when taken out of service, clearly labelled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specific acceptance criteria?	5.3.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory examine the effect of this defect on previous examinations and institute the procedure given in clause 4.9?	5.3.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory take reasonable measures to decontaminate equipment prior to service, repair or decommissioning?	5.3.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is a list of measures taken to reduce contamination provided to the person working on the equipment?	5.3.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are suitable space for repairs and appropriate personal protective equipment provided?	5.3.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all equipment under the control of the laboratory labelled or otherwise coded to indicate the status of calibration or verification and the date when re-calibration or re-verification is due?	5.3.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory check and show that the equipment is functioning satisfactorily before returning it to laboratory use after the equipment has been removed from the direct control of the laboratory, or is repaired or serviced?	5.3.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data,							
- is computer software, including that built into equipment, documented and suitably validated as adequate for use in the facility?	5.3.11a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- are procedures established and implemented for protecting the integrity of data at all times?	5.3.11b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- are computers and automated equipment maintained to ensure proper functioning?	5.3.11c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- are computers and automated equipment provided with environmental and operating conditions necessary for maintaining the integrity of data?	5.3.11c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- are computer programmes and routines adequately protected to prevent access, alteration or destruction by casual or unauthorised persons?	5.3.11d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory have procedures for safe handling, transport, storage and use of equipment, to prevent its contamination or deterioration?	5.3.12		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where calibrations give rise to a set of correction factors, does the laboratory have procedures for ensuring that copies of prior correction factors are correctly updated?	5.3.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all equipment, including hardware, software, reference materials, consumables, reagents and analytical systems, safeguarded against adjustments or tampering that might invalidate examination results?	5.3.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Pre-examination procedures	5.4						
Does the request form contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data? National, regional or local requirements shall apply?	5.4.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are specific instructions for the proper collection and handling of primary samples documented and implemented by laboratory management and made available to others responsible for primary sample collection?	5.4.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are these instructions contained in a primary sample collection manual?	5.4.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the primary sample collection manual include the following:							
copies of or references to							
- lists of available laboratory examinations offered?	5.4.3a 1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- consent forms, when applicable?	5.4.3a 2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- information and instructions provided to patients in relation to their own preparation before primary sample collection?	5.4.3a 3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- information for users of laboratory services on medical indications and appropriate selections of available procedures?	5.4.3a 4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
procedures for							
- preparation of the patient (e.g. instructions to caregivers and phlebotomists)?	5.4.3b 1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- identification of primary sample?	5.4.3b 2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives?	5.4.3b 3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
instructions for							
- completion of request form or electronic requests?	5.4.3c 1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- type and amount of the primary sample to be collected?	5.4.3c 2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- special timing of collection, if required?	5.4.3c 3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery, etc.)?	5.4.3c 4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- labelling of primary samples?	5.4.3c 5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- clinical information (e.g. history of administration of drugs)?	5.4.3c 6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
positive identification, in detail, of the patient from whom a primary sample is collected?	5.4.3c 7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- recording the identity of the person collecting the primary sample?	5.4.3c 8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- safe disposal of materials used in the collection?	5.4.3c 9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
instructions for							
- storage of examined samples?	5.4.3d 1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- time limits for requesting additional examinations?	5.4.3d 2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- additional examinations?	5.4.3d 3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- repeat examination due to analytical failure or further examinations of same primary sample?	5.4.3d 4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the primary sample collection manual a part of the document control system?	5.4.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the primary samples traceable, normally by request form, to an identified individual?	5.4.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the primary samples lacking proper identification accepted or processed by the laboratory?	5.4.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory monitor the transportation of samples to the laboratory such that they are transported							
- within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned?	5.4.6a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- within a temperature range specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples?	5.4.6b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with national, regional or local regulatory requirements?	5.4.6c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all primary samples received recorded in an accession book, worksheet, computer or other comparable system?	5.4.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the date and time of receipt of samples, as well as the identity of the receiving officer recorded?	5.4.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are criteria developed and documented for acceptance or rejection of primary samples?	5.4.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Where compromised primary samples are accepted, does the final report indicate the nature of the problem and, if applicable, that caution is required when interpreting the result?	5.4.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected?	5.4.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are requests and samples systematically reviewed by authorised personnel to decide which examinations are to be performed and the methods to be used in performing them?	5.4.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory, if relevant, have a documented procedure for the receipt, labelling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent?	5.4.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the procedure include details of any special labelling of the request form and primary sample for urgent examination, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed?	5.4.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are sample portions traceable to the original primary sample?	5.4.12		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have a written policy concerning verbal requests for patient examinations?	5.4.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are samples stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations?	5.4.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Examination procedures	5.5						
Do examination procedures used, including those for selecting/taking sample portions, meet the needs of the users of laboratory services and are they appropriate for the examinations?	5.5.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Where in-house procedures are used, are they appropriately validated for their intended use and fully documented?	5.5.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory use only validated procedures for confirming that the examination procedures are suitable for the intended use?	5.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the validations as extensive as are necessary to meet the needs in the given application or field of application?	5.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the results obtained and the procedure used for the validation recorded?	5.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the methods and procedures selected for use evaluated and found to give satisfactory results before being used for medical examinations?	5.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are procedures undertaken reviewed initially, and at defined intervals, by the laboratory director or designated person?	5.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are these reviews documented?	5.5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all procedures and necessary instructions documented in a language commonly understood by the staff in the laboratory and available at the workstation for relevant staff?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where card files or similar systems that summarize key information are used as a quick reference at the work bench, do the card files or similar systems correspond to the complete manual?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is any such abridged procedures part of the document control system?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the procedure described as it is performed in the laboratory and according to the instructions for use (e.g. package inserts) as provided by manufacturers?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is deviation from the described procedure or from manufacturer's instructions reviewed and documented?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is additional information required to perform the examination documented?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Is each new version of examination kit with major changes in reagents or procedure checked for performance and suitability for intended use?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are procedural changes dated and authorized?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the same requirements for document control applied to electronic manuals?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the contents of examination procedures complete, current and have been thoroughly reviewed?	5.5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do performance specifications for each procedure used in an examination relate to the intended use of that procedure?	5.5.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are biological reference intervals periodically reviewed?	5.5.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, is investigation undertaken followed by necessary corrective action?	5.5.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are biological reference intervals reviewed when the laboratory changes an examination procedure or pre-examination procedure?	5.5.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, available to users of laboratory services?	5.5.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where the laboratory intends to change an examination procedure such that results of their interpretations could be significantly different, are the implications explained to users of the laboratory services in writing, prior to the introduction of the change?	5.5.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Assuring quality of examination procedures	5.6						
Are internal quality control systems designed to verify the attainment of the intended quality of results?	5.6.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the uncertainty of results determined taking into account uncertainty components that are of importance?	5.6.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Is there a programme for calibration of measuring systems and verification of trueness designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference?	5.6.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where none of these are possible or relevant, are other means for providing confidence in the results applied, including but not limited to the following:							
- participation in a suitable programme of interlaboratory comparisons?	5.6.3a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- use of suitable reference materials, certified to indicate the characterisation of the material?	5.6.3b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- examination or calibration by another procedure?	5.6.3c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- ratio or reciprocity-type measurements?	5.6.3d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned?	5.6.3e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer?	5.6.3f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory participate in interlaboratory comparisons such as those organized by external quality assessment schemes?	5.6.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does laboratory management monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled.?	5.6.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are interlaboratory comparison programmes in substantial agreement with ISO/IEC Guide 43-1?	5.6.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Whenever a formal interlaboratory comparison programme is not available, does the laboratory develop a mechanism for determining the acceptability of procedures not otherwise evaluated?	5.6.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does this mechanism utilize externally derived challenge materials such as exchange of samples with other laboratories, whenever possible?	5.6.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does laboratory management monitor the results of this mechanism of interlaboratory comparison and participate in the implementation and recording of corrective actions?	5.6.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is comparability of results throughout the clinically appropriate intervals verified for those examinations performed using different procedures or equipment or at different sites or all theses?	5.6.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is such verification performed at defined periods of time appropriate to the characteristics of the procedure or instrument?	5.6.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory document, record and, as appropriate, expeditiously act upon results from these comparisons?	5.6.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are problems or deficiencies identified acted upon and records of actions retained?	5.6.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Post-examination procedures	5.7						
Are the results of examinations systematically reviewed, evaluated in conformity with the clinical information available regarding the patient, and released by authorized personnel?	5.7.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is storage of the primary sample and other laboratory samples in accordance with approved policy?	5.7.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the safe disposal of samples no longer required for examination carried out in accordance with local regulations or recommendations for waste management?	5.7.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Reporting of results	5.8						
Is the laboratory management responsible for formatting reports?	5.8.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does laboratory management share responsibility with the requester for ensuring that the appropriate individuals receive reports within an agreed-upon time interval?	5.8.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are results legible, without mistakes in transcription and reported to persons authorized to receive and use medical information?	5.8.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the report include, but is not limited to, the following:							
- clear, unambiguous identification of the examination including, where appropriate, the measurement method?	5.8.3a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- the identification of the laboratory that issued the report?	5.8.3b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- unique identification and location of the patient and destination of the report?	5.8.3c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- name or other unique identifier of the requester and the requester's address?	5.8.3d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory?	5.8.3e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- date and time of release of report, which, if not on the report, shall be readily accessible when needed?	5.8.3f		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- source and system (or primary sample type)?	5.8.3g		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- results of the examination reported in SI units or units traceable to SI units (see ISO Guide 31), where applicable?	5.8.3h		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- biological reference intervals, where applicable?	5.8.3i		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- interpretation of results, where appropriate?	5.8.3j		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- other comments (e.g. quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure)? The report should identify examinations undertaken as part of a development programme and for which no specific claims on measurement performance are made, and, where applicable, information on detection limit and uncertainty of measurement should be proved upon request?	5.8.3k		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- identification of the person authorizing the release of the report?	5.8.3l		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
- if relevant, original and corrected results?	5.8.3m		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
- signature or authorization of the person checking or releasing the report, where possible?	5.8.3n		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the report indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the result?	5.8.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are copies or files of reported results retained by the laboratory such that prompt retrieval of the information is possible?	5.8.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the reported results retrievable for as long as medically relevant or as required by national, regional or local requirements?	5.8.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established "alert" or "critical" intervals?	5.8.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does this include results received on samples sent to referral laboratories for examination?	5.8.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
In order that local clinical needs can be served, does the laboratory determine the critical properties and their "alert/critical" intervals, in agreement with the clinicians using the laboratory?	5.8.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does this apply to all examinations, including nominal and ordinal properties?	5.8.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
For results transmitted as an interim report, is the final report always forwarded to the requester?	5.8.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are records maintained of actions taken in response to "alert/critical" results?	5.8.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the date, time, responsible laboratory staff member, person notified and examination results included in these records?	5.8.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are difficulties encountered in meeting this requirement recorded and reviewed during audits?	5.8.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does laboratory management, in consultation with the requesters, establish turnaround times for each of its examinations?	5.8.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the turnaround time reflect clinical needs?	5.8.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a policy for notifying the requester when an examination is delayed?	5.8.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are turnaround times as well as any related feedback from clinicians monitored, recorded and reviewed by laboratory management?	5.8.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where necessary, is corrective action taken to address any problems so identified?	5.8.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When examination results from a referral laboratory need to be transcribed by the referring laboratory, are procedures for verifying the correctness of all transcriptions in place?	5.8.12		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are procedures for the release of examination results, including details of who may release results and to whom, clearly documented?	5.8.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are guidelines for the release of results directly to patients also included?	5.8.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory established policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorized receivers?	5.8.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the results provided verbally followed by properly recorded reports?	5.8.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have written policies and procedures regarding the alteration of reports?	5.8.15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When altered, does the record show the time, date and name of the person responsible for the change?	5.8.15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the original entries remain legible when alterations are made?	5.8.15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are original electronic records retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration?	5.8.15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Are original and revised results that have been available for clinical decision-making retained in subsequent cumulative reports and clearly identified as having been revised?	5.8.16		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is an audit log used if the reporting system cannot capture amendments, changes or alterations?	5.8.16		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
HKAS Regulations (as required under HKAS 002)							
The obligations of an accredited organisation							
After obtaining accreditation, will your laboratory at all times:-							
◆ comply with the accreditation criteria, including accreditation regulations specified in HKAS 002, technical and non-technical requirements and other conditions as specified by HKAS Executive under its terms of accreditation;	5.1a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ represent honestly and truthfully to any person concerned that it is only accredited for activities stated in the scope of accreditation;	5.1b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ pay such fees and charges as determined by HKAS Executive;	5.1c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ endeavor to ensure the accreditation granted by HKAS is not used in a misleading manner; and	5.1d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ be a legal entity?	5.1e		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory maintain a quality standard in compliance with the accreditation criteria as set by HKAS for any clients for which your laboratory performs any accredited activity?	5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory maintain the same quality standard at all times, no matter whether or not the HKAS accreditation mark is used in the report or certificate covering the result of such activity?	5.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
When making any statement in relation to your laboratory's accreditation status in situation where non-accredited activities are mentioned, does the laboratory ensure that a statement indicating which activities are not accredited is included?	5.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory aware of the following accreditation regulation? ◆ "Upon termination of accreditation for all activities of an organisation as specified in a certificate of accreditation, the organisation shall return such certificate of accreditation to HKAS Executive forthwith."	5.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Will the 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 compliance with the accreditation criteria?	5.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Upon the request of HKAS Executive, will the laboratory be able to provide HKAS Executive with a copy of the documentary standard for which it seeks HKAS accreditation for use during the assessment?	5.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory ensure that it will use its accreditation status only in a manner that will not bring HKAS or any of its accreditation schemes into disputes and will not make any statement regarding its accreditation status that HKAS Executive may reasonably consider it to be misleading?	5.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory maintain complete integrity and impartiality in all circumstances? Will the authorized representative report impropriety or unlawful act of the laboratory or iniquitous management and/or staff, if any, to HKAS Executive? In case of any corrupt practice, will the authorised representative report immediately to the ICAC (or similar authority or the police when outside the jurisdiction of the HKSAR)?	5.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory notified HKAS Executive within one calendar month if a new authorised representative has been appointed?	5.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the HKAS Executive been informed by the authorised representative or in his absence, other responsible person of the laboratory in writing immediately of any changes or intended changes in the laboratory's circumstances that may affect its compliance with relevant accreditation criteria?	5.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Is your laboratory aware of the following HKAS regulation on confidentiality?							
◆ “An accredited organisation shall pay due regard to the confidentiality of its client’s information and shall make internal rules and guidelines in order to ensure protection of its client’s information. Confidential information about a particular client shall not be disclosed to a third party without the consent of the client, 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 clients for the disclosure of any relevant information to HKAS.”	5.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory ensure that no unofficial contact with assessors, technical experts and/or AAB members is made on any matter relating to or in connection with the assessment of any activity for the purpose of granting or maintaining accreditation?	5.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all communications concerning the laboratory’s assessment only made between the authorised representative or his/her representative and HKAS Executive?	5.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have a clear policy in writing concerning the provision or receipt of commissions by its staff? Does the policy document contain a statement notifying its staff the law under Section 9 of the Prevention of Bribery Ordinance (Cap. 201)? Does the laboratory further ensure that the policy is made known to all its staff members?	5.12		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory have a policy and procedure in writing for handling and resolving complaints, disputes and appeals made to it by its clients or other parties?	5.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory keep records of all complaints, disputes and appeals and actions taken for a minimum of 3 years and make available to HKAS Executive for inspection upon request?	5.13		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Where a complaint, dispute or appeal made to the laboratory by its clients or other parties raise any doubt on its compliance with its policies or procedures, will the laboratory ensure that the relevant areas of its accredited activities are promptly audited?	5.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If a complaint, dispute or appeal made to the laboratory by its clients or other parties relating to any of its accredited activities is not satisfactorily resolved within 60 days from the date of receipt, does the laboratory notify HKAS Executive in writing of this matter?	5.15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is your laboratory aware of the following HKAS regulation?							
◆ “Any concerned party may lodge complaints with HKAS on any accredited activities carried out by an accredited organisation.”	5.16		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Use of HKAS accreditation marks and claims of accreditation status							
Is the laboratory aware of the following HKAS regulation?							
◆ “An accredited organisation may use the relevant HKAS accreditation mark as described in HKAS Supplementary Criteria No. 1 and claim its accreditation status provided that the following conditions are complied with:-							
(a) all advertising and promotional materials (including letterheads) in which the accreditation status of an organisation is referred to shall be submitted to HKAS Executive for approval before use;	8.1a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(b) HKAS Supplementary Criteria No. 1 and requirements relevant to the accreditation scheme concerned as described in the relevant specific regulations, are complied with at all times; and	8.1b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(c) any statement made by the organisation in connection with its accreditation status shall not, in the opinion of HKAS Executive, give a false or misleading impression to any third party of its accreditation status.”	8.1c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the laboratory ensure that its clients, on receiving any report or certificate which bears a HOKLAS accreditation mark are aware that the subject of the activity (e.g. the sample, instrument, product, design or system tested, calibrated, certified or inspected) as referred to in such report or certificate is in no way approved nor disapproved by HKAS or HKAS Executive?	8.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Upon termination of the accreditation of any activities carried out by an accredited laboratory, whether or not voluntarily made, is the laboratory aware that all references to the accreditation status of the laboratory in any report, certificate, letterhead, brochure and advertising material have to be removed immediately?	8.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Specific regulations for HOKLAS							
Is the laboratory aware of 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, or to participate in proficiency testing in order to evaluate the laboratory’s 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.”	9.1.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ “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;	9.1.2a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(b) every two years after the due dates of the first reassessment;	9.1.2b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(c) at such other times as may be specified in the terms of accreditation; and	9.1.2c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(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 compliance with the accreditation criteria. HKAS Executive, may at its discretion, vary the reassessment schedule.”	9.1.2d		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ “HKAS Executive shall conduct a surveillance visit to an accredited laboratory if no reassessment nor surveillance visit to the laboratory has been conducted for the past twelve months. HKAS Executive may, at its discretion, vary the surveillance visit schedule.”	9.1.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ “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.”	9.1.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory at all times comply with the following HOKLAS accreditation criteria as documented in HKAS002, HOKLAS003, relevant HOKLAS Supplementary Criteria and relevant HKAS Supplementary Criteria?	9.2.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the 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?	9.2.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory ensure that no person used any certificate or report issued by it for such activity in a misleading manner?	9.2.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory aware of the following HKAS regulation on cooperation? ◆ “A laboratory accredited under HOKLAS shall afford its clients 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:							

* The assessor should concentrate on items marked with a ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(a) to perform 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 client; and	9.2.3a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(b) to allow each of its clients or their representatives reasonable access to the laboratory in order to observe any test, calibration or other laboratory activity performed by it for the client. However, the laboratory shall ensure the confidentiality of its other clients will be protected and their information will not be divulged to any third party (subject to clause 5.10)."	9.2.3b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory aware of 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/agreement. A list of such accreditation bodies is obtainable from HKAS Executive. The accredited laboratory shall notify its client concerned in writing of its intention to subcontract the activities and the extent of such subcontract. It shall obtain agreement from the client regarding such arrangement and shall further keep records of such agreement. In the report or certificate, the accredited laboratory shall specify the name of such contractor and identify the activities performed and the results obtained by such contractor."?	9.2.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory take part in proficiency testing programmes relevant to its scope of accreditation organised or specified by HKAS Executive or in alternative programmes acceptable to HKAS Executive?	9.2.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the performance of the laboratory in any proficiency testing activity relevant to its scope of accreditation acceptable to HKAS Executive?	9.2.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory aware of the following HKAS regulation on proficiency testing?							

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
<p>◆ “An applicant laboratory shall take part in at least one appropriate proficiency testing activity, where available, before accreditation will be granted. After accreditation has been granted, the laboratory shall take part in at least one appropriate proficiency testing activity, when available, which is related to each major sub-area of major disciplines of the accredited activities as specified in its scope of accreditation, every four years. The assessment team shall determine the appropriateness of any proficiency testing activities and may, at its discretion, require the laboratory to participate in other forms of proficiency testing 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 proficiency testing activity because such activity is not available, it shall demonstrate to the satisfaction of the assessment team that it has taken all reasonable steps to identify such activity. In this clause, proficiency testing activity includes any international, regional and national interlaboratory comparisons as well as measurement audits and check samples acceptable to HKAS.”</p>	9.2.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Where the performance of the laboratory in a proficiency testing activity is unsatisfactory, does the laboratory investigate the cause and take effective remedial actions?</p>	9.2.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Is the laboratory aware of the following HKAS regulation on approved signatory?</p> <p>◆ “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.”</p>	9.2.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
<p>◆ “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.”</p>	9.2.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Does the authorised representative of the laboratory, within 14 days from the effective date of any suspension or termination (voluntarily or by HKAS Executive), identify the clients to whom the laboratory has issued results for tests, calibrations or other laboratory activities which are found to be unreliable because of the deficiencies which have been brought to light and inform them that the results are unreliable?</p>	9.3.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Is the laboratory aware of the following HKAS regulation on suspension and termination?</p>							
<p>◆ “HKAS Executive may report a suspension or termination for a major part of the activities as specified in the scope of accreditation of an accredited laboratory in the next issue of the HOKLAS Directory and the website of HKAS.”</p>	9.3.2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Is the laboratory aware of the following HKAS regulation on the use of HKAS accreditation marks and claims of accreditation status?</p>							
<p>◆ “An accredited laboratory may display the HOKLAS accreditation mark in a report or certificate issued by it for reporting the result of an activity accredited under HOKLAS. Such a document is referred to hereafter as a HOKLAS endorsed report or certificate.”</p>	9.4.1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>◆ “An accredited laboratory shall include in a HOKLAS endorsed report or certificate the following:-</p>							
<p>(a) the HOKLAS accreditation mark (which includes the laboratory’s registration number) at the top right hand corner of the front page;</p>	9.4.2 (a)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
<p>(b) on the same page the following statement for reports and certificates showing the results of examinations and their clinical interpretations which have been accredited under the “medical testing” test category:</p> <p>“Hong Kong Accreditation Service (HKAS) has accredited this laboratory under the Hong Kong Laboratory Accreditation Scheme (HOKLAS) for specific examinations and clinical interpretations of examination results as listed in the HOKLAS directory of accredited laboratories. The results and their clinical interpretation shown in this report (or certificate, where appropriate) were determined by this laboratory in accordance with its terms of accreditation”</p>	9.4.2 (d)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the term “HOKLAS” and the HOKLAS accreditation mark only used in a HOKLAS endorsed report or certificate?	9.4.3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the form, size, colour and usage of the HOKLAS accreditation mark are in accordance with HKAS Supplementary Criteria No. 1?	9.4.4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is your laboratory aware of the following HKAS regulation?							
<p>◆ “A HOKLAS endorsed report or certificate shall be signed by a HOKLAS approved signatory of the issuing laboratory. Such signature can be made in hand-written form or in the form of an electronic signature acceptable under the Electronic Transactions Ordinance (Cap. 533). The full name of the approved signatory shall be typed on the endorsed report or the certificate.”</p>	9.4.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>◆ “A HOKLAS endorsed report or certificate may contain signatures of others provided that the laboratory’s HOKLAS approved signatory has signed the report or certificate.”</p>	9.4.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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?	9.4.7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the results of any activity, which has not been accredited (whether obtained by the laboratory or its subcontractor) included in a HOKLAS endorsed report or certificate only when HKAS Executive has explicitly approved such inclusion in writing?	9.4.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
Does the HOKLAS endorsed report or certificate which contains the said results clearly state therein that the activities are not covered by the laboratory's HOKLAS accreditation?	9.4.8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory keep at least one copy of each HOKLAS endorsed report or certificate for record? Does the laboratory also keep such copies, 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?	9.4.9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is every HOKLAS endorsed report or certificate complied with all relevant accreditation criteria as specified by HKAS Executive from time to time?	9.4.10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does a HOKLAS endorsed report or certificate issued by the laboratory bear either:-							
(a) a statement indicating that such report or certificate shall not be reproduced except in full, or	9.4.11a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(b) a statement indicating the conditions under which such report or certificate may be reproduced either in full or in part.	9.4.11b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory aware that an extract or abstract of a HOKLAS endorsed report or certificate shall not contain the HOKLAS accreditation mark nor other details as specified in clause 9.4.2 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; and that 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?	9.4.11		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory aware of 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 qualities 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	9.4.12a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.

HOKLAS Requirement	Clause	*	Y	N	NA	QM Clause	Remarks / Questions to be asked at laboratory
(b) the sample or samples concerned were taken by staff of the accredited laboratory using the accredited sampling procedure.”	9.4.12b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
◆ “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;	9.4.13a		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(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	9.4.13b		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(c) where an instrument or measuring device is calibrated such statements shall be limited to:-	9.4.13c		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
(i) the uncertainty to be associated with its use, or							
(ii) the information referred to in (a) or (b) above as appropriate.”?							
Has the laboratory obtained approval in writing from HKAS Executive for including opinions or interpretation for which the laboratory is not accredited for providing in a HOKLAS endorsed report or certificate?	9.4.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does a HOKLAS endorsed report or certificate containing such opinions or interpretations in all cases clearly state that the laboratory is not accredited for providing such opinions or interpretation?	9.4.14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory made its application for HOKLAS service from HKAS in appropriate forms which are obtainable from the office of HKAS Executive or from the HKAS website?	9.5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory submitted its letterhead and formats for HOKLAS endorsed report and certificates to HKAS Executive for approval before use?	9.6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* The assessor should concentrate on items marked with a * ; other items will be checked by the team leader.