



Hong Kong Laboratory Accreditation Scheme

HOKLAS 016

Assessment / Reassessment Questionnaire (Medical Laboratories)

For an initial application for accreditation and an application for extension of scope of accreditation, this questionnaire should be completed and submitted to HKAS Executive together with the application form HOKLAS 005, the application fee and all relevant documents as listed in the checklist on page 2. HKAS Executive will only process an initial application for accreditation or an application for extension of scope of accreditation when completed forms HOKLAS 005, HOKLAS 016 (with annexes) and application fee are submitted.

For a reassessment, an accredited laboratory is also required to complete and submit this questionnaire together with relevant briefing notes documents to HKAS Executive at least one month before the scheduled date of reassessment.

Fees payable for assessments are calculated in accordance with:

HOKLAS 006 (for organisations within the Hong Kong Special Administrative Region)

You should study carefully the latest version of the following documents before completing this questionnaire:

HKAS 002
HKAS SC-06
HOKLAS SC-33
HOKLAS 015 (for ISO 15189:2012)
ISO 15189:2022 and HKAS PD 002 (for ISO 15189:2022)

HONG KONG ACCREDITATION SERVICE

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Tel : 2829 4840

Fax : 2824 1302

E-mail : hkas@itc.gov.hk

Note:

1. Any personal data provided in this questionnaire or the attached documents will be retained and used by HKAS for accreditation purpose only. The personal data may be disclosed to members of the assessment team.
2. It is obligatory for you to provide all the personal data requested in this questionnaire or the attached documents. If you do not provide sufficient information, we may not be able to process the application.
3. The data subjects have the rights to obtain a printed copy of their own personal data held by HKAS and request for correction of their personal data. Please contact HKAS at the above address for access to and correction of your personal data.

List of Documents to be Submitted⁴

Before sending this completed questionnaire to HKAS Executive, please check that all required documents are attached and confirm by ticking the appropriate boxes below. Please submit electronic copies of the requested documents listed below as far as possible.

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

- ☐ Initial Assessment
 ☐ Extension of Scope
 ☐ Reassessment
- ☐ Application fee⁵ in the form of a cheque or an e-Cheque* payable to **The Government of the Hong Kong Special Administrative Region**.

*Application fee can be paid by e-Cheque through “Pay e-Cheque” portal <https://www.payechegue.gov.hk>. Please contact HKAS if special arrangement is required.

- ☐ Document(s) authenticating that the applicant laboratory is or part of an entity that can be held legally responsible (applicable for an initial application only)
- ☐ Document(s) proving that the Chief Executive has the authority to enter contractual arrangement on behalf of the applicant laboratory
- ☐ Valid business registration certificates of all sites under application and of the same legal entity as the applicant laboratory
- ☐ Management system manual or documentation
- ☐ Operation procedure manual(s)⁶
- ☐ Latest internal audit schedule and sample vertical and horizontal audit reports
- ☐ Summary of the findings of the latest management review and other technical meeting notes, if any
- ☐ Records for identifying risks to impartiality
- ☐ Examination procedure manual(s)
- ☐ CV of key personnel such as those for the Laboratory Director and consulting pathologists, if any
- ☐ CV and copies of qualification documents for each nominee for signatory approval
- ☐ Floor plan(s) of the laboratory
- ☐ Organisation chart(s) showing the laboratory’s organisation and management structure and its place in any parent organisation
- ☐ Method validation/verification report(s), if applicable
- ☐ Specimen collection instruction(s) to users
- ☐ Sample test request forms and worksheets
- ☐ Sample test reports
- ☐ One-year proficiency testing participation plan and the details of proficiency testing or interlaboratory comparisons
- ☐ Code of conduct
- ☐ Other documents; please specify

Note:

4. For a reassessment, the list of required documents will be provided to the laboratory separately by HKAS Executive.
5. An application fee will be charged for an initial application and an application for extension of scope of accreditation. No application fee is required for a reassessment. In addition to the application fee, an on-site assessment fee will be charged. An applicant will be informed of the exact amount when the on-site assessment has been arranged.
6. Operation procedure manuals refer to supporting procedures of the management system (e.g. safety manual, sample registration and reception procedures, equipment maintenance procedures, measurement uncertainty document, waste management procedures, etc).

Scope of Accreditation

For an initial application for accreditation and an application for extension of scope of accreditation, the examinations proposed for accreditation shall be detailed in HOKLAS 016-A1 – Scope of Accreditation Sought. You may wish to refer to the scopes of some accredited laboratories as examples. They are available on HKAS website.

For a reassessment, the “Scope of Accreditation to be Reassessed” should have been sent to the laboratory for confirmation by HKAS Executive together with the letter informing the laboratory of the forthcoming reassessment. The laboratory should check this scope carefully, mark only typographical errors to be corrected on the scope, sign and return the confirmed scope for reassessment to HKAS Executive.

For any voluntary suspension/termination of examinations from the scope of accreditation, a copy of HKAS 009 – Notification of Changes shall be completed and returned together with the confirmed scope of accreditation to be reassessed to HKAS Executive.

General Information

Organisation name
(See Note 7)

English

Chinese

Laboratory name (See Note 8)
(e.g. Histopathology Laboratory, Microbiology Laboratory, Pathology Laboratory, etc.)

General description of the parent organisation and the laboratory including their history and relationship

Address
(Physical address of the laboratory)

English

Chinese

Telephone

Fax

E-mail

Website (if any)

Address (for correspondence)

Hong Kong ☐

Kowloon ☐

N.T. ☐

Telephone

Fax

E-mail

Questionnaire completed by

Name and Position

Telephone

Fax

E-mail

Authorised representative

Name and Position

Address
(if different from the correspondence address)

Hong Kong ☐

Kowloon ☐

N.T. ☐

Telephone

Fax

E-mail

Note 7 – The organisation name should be the name of the legal identity that owns the laboratory. It may be a government department, instrumentality, company, sole proprietor or other types of legal entity.

Note 8 – The name used by the organisation to identify the laboratory.

Regulations for HKAS Accreditation (HKAS 002)

The Obligations of an Applicant or Accredited Organisation (HKAS 002, Section 5)

Was there any convicted case of unlawful act related to integrity and impartiality of your organisation, management and/or staff in the past 24 months?

- ☐ No.
- ☐ Yes. Details are provided below. (Please use additional sheet if necessary)

Declaration of the Authorised Representative

I, undersigned, declare that the information given in this questionnaire is correct to the best of my knowledge and belief.

Signature of the Authorised Representative

Date

Structure and Governance

Legal status

Please give details of the legal status of the organisation under which accreditation is granted or sought.

Yes/No	Please give details of the relationship between the laboratory and the organisation
- a government department? - a commercial operation? - an education body? - a subvented agency? - other? (please specify)	

Sites to be accredited under the same legal entity

Yes/No	Please list the business name used for each site, its address and the distribution of work/relationship with the main laboratory (Please use a separate sheet if necessary)
Branch laboratory	
Specimen collection centre	
Others	

Structure and Governance

Activities

- does the organisation conduct activities other than laboratory operation?
- are these “other activities” the main activities of the organisation?

Yes/No	If <input type="checkbox"/> yes, please describe

Clients

The laboratory provides service to

- public hospitals
- private hospitals
- clinics
- medical centres
- other? (please specify)

Yes/No	Percentage of work

Size of laboratory

- number of people working for the laboratory (please specify the respective number of technical personnel registered with the MLT board and not registered with the MLT board, supporting staff, and administrative staff)
- floor area occupied (in m²)

Pathologist	
Scientific officer	
Medical laboratory technologist	
Supporting staff	
Administrative staff	
Others	

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Laboratory management

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

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HOKLAS 016: Assessment / Reassessment Questionnaire (Medical Laboratories)

Please list any changes to laboratory management/technical personnel relevant to the examinations to be reassessed since the last assessment/reassessment. For requesting removal of names of approved signatories from the list of approved personnel, please also complete and submit a copy of HKAS 009 – Notification of Changes to HKAS Executive.

Resources

Quality Management

Please list the personnel responsible for the implementation, maintenance and improvement of the management system.

Name	Position	Area of responsibility

Nominees for signatory approval

Please list the staff to be considered by HKAS Executive for approval as signatories of HOKLAS endorsed examination reports.

(Please use extra sheets if necessary)

Name (as shown on HKID card)	Test area(s)	Giving clinical interpretations of examination results (please enter NA if not applicable)		Approved signatories New/Existing ¹
		Specialty area(s)	Full time/ Consulting ²	

1. Please provide copies of CV and qualification documents (degrees, diplomas, certificates of professional qualifications, practising certificates, etc.) for new nominees. For an initial assessment, all are 'new' nominees. For those who wish to extend their signatory status to cover other new test areas, they are 'existing' signatories.
2. Please provide evidence of written agreement for consulting pathologists.

External Quality Assessment (EQA)

Please provide details of the EQA programmes or interlaboratory comparisons that the laboratory has participated in, for the examinations to be assessed. For a reassessment, please provide details of such participation since last the assessment/reassessment visit. If there are new examinations under application for extension of scope, please list the results in a separate row.

Name of Laboratory / Division / Discipline:						
Name of External Proficiency Testing Programme or Interlaboratory Comparison	Test area	Target analyte / measurand / microorganism / property	No. of samples per distribution and Frequency per year	Performance in the last 12 months (no. of satisfactory result as defined by the PT provider among total no. of PT results in a stated period of 12 months) e.g. 11 / 12 total from Feb 2019 to Jan 2020		Brief description of any actions taken if some results are unsatisfactory (Please put down relevant CAR no. where actions are recorded)
				Period that the provided results covered: MM/YY to MM/YY		
				No. of satisfactory results	No. of PT results	
			Total:	[a]	[b]	
			% of satisfactory PT results: (a / b) x 100%	%		

HOKLAS 016-A1 – Scope of Accreditation Sought

(For an initial application or an application for extension of scope of accreditation)

HOKLAS 016-A2 – Management System Checklist

(For an initial application or when there has been a significant change to the management system)

End