

## HOKLAS AP009

### HKAS Application Package - Accreditation of Medical Laboratories

(申請指南中文版本見第 4 頁)

This document provides information relating to the processing of an application for accreditation of a laboratory which provides medical testing services. Laboratories interested in seeking HKAS accreditation for their medical testing services are reminded to study related accreditation requirements carefully before submitting an application.

#### **1. Accreditation Standard**

The applicant medical laboratory shall comply with the accreditation requirements given in the following documents:

- 1a. ISO 15189: 2022  
Medical laboratories – Requirements for quality and competence

Note: The applicant laboratory may purchase this standard through the Quality Services Division of the Innovation and Technology Commission (ITC).

- 1b. [HKAS Policy Document No. 2](#)  
HKAS Policy for Accreditation of Medical Laboratories according to ISO 15189: 2022 under HOKLAS (ISO 15189: 2022 HOKLAS Policy)

#### **2. Regulations for HKAS Accreditation and HKAS/HOKLAS Supplementary Criteria**

The applicant medical laboratory shall comply with the requirements of the following documents, where relevant:

- 2a. [HKAS 002](#)  
Regulations for HKAS Accreditation
- 2b. [HKAS Supplementary Criteria No. 1](#)  
Use of HKAS Accreditation Symbols and Claims of Accreditation Status
- 2c. [HKAS Supplementary Criteria No. 2](#)  
Nonconformities and Their Grading
- 2d. [HKAS Supplementary Criteria No. 4](#)  
Interval between On-site Reassessment and Surveillance Visits of an Accreditation Cycle
- 2e. [HKAS Supplementary Criteria No. 6](#)  
Code of Conduct
- 2f. [HOKLAS Supplementary Criteria No. 1](#)  
Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment
- 2g. [HOKLAS Supplementary Criteria No. 2](#)  
All Test Categories - Equipment Calibration and Verification
- 2h. [HOKLAS Supplementary Criteria No. 23](#)  
'Medical Testing' Test Category – Hospital Autopsy

- 2i. [HOKLAS Supplementary Criteria No. 24](#)  
'Medical Testing' Test Category – Cytopathology
- 2j. [HOKLAS Supplementary Criteria No. 25](#)  
'Medical Testing' Test Category – Histopathology
- 2k. [HOKLAS Supplementary Criteria No. 26](#)  
'Medical Testing' Test Category – Chemical Pathology
- 2l. [HOKLAS Supplementary Criteria No. 27](#)  
'Medical Testing' Test Category – Clinical Microbiology and Infection
- 2m. [HOKLAS Supplementary Criteria No. 28](#)  
'Medical Testing' Test Category – Haematology
- 2n. [HOKLAS Supplementary Criteria No. 29](#)  
'Medical Testing' Test Category – Immunology
- 2o. [HOKLAS Supplementary Criteria No. 30](#)  
'Medical Testing' Test Category – Molecular Genetics
- 2p. [HOKLAS Supplementary Criteria No. 32](#)  
'Medical Testing' Test Category – Verification of Biological Reference Intervals from Other Sources
- 2q. [HOKLAS Supplementary Criteria No. 33](#)  
Accreditation Regulations Specific for HOKLAS - Laboratory
- 2r. [HOKLAS Supplementary Criteria No. 35](#)  
'Medical Testing' Test Category – Cytogenomics
- 2s. [HOKLAS Supplementary Criteria No. 38](#)  
'Medical Testing' Test Category – Performance Verification of Automated Analysers

The above documents are available at the website of HKAS (<https://www.itc.gov.hk/en/quality/hkas/publications/index.html>).

### **3. Application Process**

The applicant laboratory is required to complete the following forms, submit them together with the required documents and pay an application fee (as detailed in [HOKLAS 006](#) - Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region) to HKAS Executive for processing:

- 3a. [HOKLAS 005](#)  
Application for Laboratory Accreditation (including Proficiency Testing Providers and Reference Material Producers) / Extension of Scope of Accreditation
- 3b. [HOKLAS 016](#)  
Assessment / Reassessment Questionnaire (Medical Laboratories)
  - [A1](#)– Scope of Accreditation Sought (for new application for accreditation or extension of scope of accreditation only)
  - [A2](#) – Management System Checklist

Detailed procedures for HKAS accreditation are given in [HOKLAS IN003](#) [Application Procedures for HOKLAS Accreditation (Informative)].

Please contact Dr Daria WONG Ching-hang at 2829 4801 if you have any further queries.

HKAS Executive  
April 2024

# HOKLAS AP009

## 香港認可處申請指南 - 醫務化驗所的認可

本指南乃為有意申請認可處認可資格的醫務化驗所而設，內容包括有關申請認可資格的資訊。有興趣申請認可資格的醫務化驗所在提交申請前應先細心閱讀相關的認可要求。

### 1. 認可標準

申請認可資格的醫務化驗所須符合載於以下文件的認可要求：

- 1a. [ISO 15189: 2022](#) (只有英文版本)  
Medical laboratories – Requirements for quality and competence

備註： 申請認可資格的實驗所可聯絡創新科技署轄下品質事務部，購買此標準。

- 1b. [HKAS Policy Document No. 2](#) (只有英文版本)  
香港認可處在香港實驗所認可計劃下根據 [ISO 15189: 2022](#) 向醫務化驗所提供認可服務的政策（香港實驗所認可計劃有關 [ISO 15189: 2022](#) 的政策）

### 2. 認可規例及香港認可處/香港實驗所認可計劃補充準則

申請認可資格的醫務化驗所亦符合載於以下文件的認可要求（如適用）：

- 2a. [HKAS 002C](#)  
認可處認可規例
- 2b. [認可處補充準則第 1 號](#)  
使用認可處認可標誌及聲稱具備認可處認可資格
- 2c. [認可處補充準則第 2 號](#)  
不符合項及其評級
- 2d. [認可處補充準則第 4 號](#)  
認可周期內進行實地覆審與監察訪問之間相隔的時間
- 2e. [認可處補充準則第 6 號](#)  
紀律守則
- 2f. [HOKLAS Supplementary Criteria No. 1](#) (只有英文版本)  
Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment
- 2g. [HOKLAS Supplementary Criteria No. 2](#) (只有英文版本)  
All Test Categories - Equipment Calibration and Verification
- 2h. [HOKLAS Supplementary Criteria No. 23](#) (只有英文版本)  
'Medical Testing' Test Category – Hospital Autopsy
- 2i. [HOKLAS Supplementary Criteria No. 24](#) (只有英文版本)  
'Medical Testing' Test Category – Cytopathology
- 2j. [HOKLAS Supplementary Criteria No. 25](#) (只有英文版本)  
'Medical Testing' Test Category – Histopathology

- 2k. [HOKLAS Supplementary Criteria No. 26](#) (只有英文版本)  
'Medical Testing' Test Category – Chemical Pathology
- 2l. [HOKLAS Supplementary Criteria No. 27](#) (只有英文版本)  
'Medical Testing' Test Category – Clinical Microbiology and Infection
- 2m. [HOKLAS Supplementary Criteria No. 28](#) (只有英文版本)  
'Medical Testing' Test Category – Haematology
- 2n. [HOKLAS Supplementary Criteria No. 29](#) (只有英文版本)  
'Medical Testing' Test Category – Immunology
- 2o. [HOKLAS Supplementary Criteria No. 30](#) (只有英文版本)  
'Medical Testing' Test Category – Molecular Genetics
- 2p. [HOKLAS Supplementary Criteria No. 32](#) (只有英文版本)  
'Medical Testing' Test Category – Verification of Biological Reference Intervals from Other Sources
- 2q. [實驗所認可計劃補充準則第 33 號](#)  
實驗所認可計劃的認可規例 - 實驗所
- 2r. [HOKLAS Supplementary Criteria No. 35](#) (只有英文版本)  
'Medical Testing' Test Category – Cytogenomics
- 2s. [HOKLAS Supplementary Criteria No. 38](#) (只有英文版本)  
'Medical Testing' Test Category – Performance Verification of Automated Analysers

上述文件可於本處網頁下載

(<https://www.itc.gov.hk/ch/quality/hkas/publications/index.html>).

### **3. 申請程序**

申請認可資格的實驗所須填妥以下表格(只有英文版本)並提交有關文件和按照[HOKLAS 006](#) (只有英文版本) (Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region) 繳付申請費用。

- 3a. [HOKLAS 005](#)  
Application for Laboratory Accreditation (including Proficiency Testing Providers and Reference Material Producers) / Extension of Scope of Accreditation
- 3b. [HOKLAS 016](#)  
Assessment / Reassessment Questionnaire (Medical Laboratories)
  - [A1](#) – Scope of Accreditation Sought (for new application for accreditation or extension of scope of accreditation only)
  - [A2](#) – Management System Checklist

如需了解詳細的申請程序，請參閱 [HOKLAS IN003](#) [Application Procedures for HOKLAS Accreditation (Informative)](只有英文版本)。

如有任何疑問，歡迎聯絡本處黃政珩博士(電話: 2829 4801)查詢。

認可處執行機關  
2024 年 4 月