

**AF 06**  
**HOKLAS ASSESSMENT REPORT (MEDICAL LABORATORIES)**

**This report is prepared by the assessment team and is addressed to the authorised representative of the laboratory**

*A declaration has been signed by individual members of the assessment team that they shall comply with HKAS regulations stipulated in HKAS 002, including those relating to confidentiality and independence from commercial or other interests, and shall not disclose to a third party any information provided by the laboratory in relation to its accreditation or obtained during or in connection with this assessment.*

*Assessment is a sampling exercise and findings given in this report relate only to those areas examined during the assessment.*

This assessment report is subject to review by HKAS Executive and

any amendment will be issued within 10 working days following the assessment.

an outcome letter to supersede *this assessment report/ the part of this report in relation to the extension of scope of accreditation to a new test category<sup>#</sup>* will be issued.

Name of Laboratory : \_\_\_\_\_

Site Address : \_\_\_\_\_

This assessment was conducted on \_\_\_\_\_ for the

initial assessment /  reassessment /  extension of accreditation /  surveillance visit

of the laboratory for examinations under the test category of Medical Testing.

and  assessment for adopting / maintaining<sup>#</sup> monitoring Plan B / C<sup>#</sup>.

The laboratory is a sub-licensee for using the Accredited CAB Combined ILAC MRA Mark  Yes  No

Assessment case ID(s) : \_\_\_\_\_

<sup>#</sup> *please delete where appropriate*

**CONTENTS**

- A. AF06 – HOKLAS Assessment Report
- B. Appendix I – Scope of Activities Covered
- C. Appendix II – List of Personnel Recommended for Approval
- D. Appendix III – List of Proficiency Testing Activities (Page 15 of HOKLAS 016 updated)
- E. \_\_\_\_\_ pages of AF01 – HOKLAS Observation and Action Record Form
- F. \_\_\_\_\_ pages of AF05 – HOKLAS Signatory Assessment Form (Medical Laboratories)
- G. \_\_\_\_\_ pages of AF17 – HOKLAS Monitoring Plan B/C Assessment Form

**NAMES AND SIGNATURES OF ASSESSMENT TEAM MEMBERS**

Team Leader :	_____	Date(s) of Assessment:	_____
Member :	_____	Date(s) of Assessment:	_____
Member :	_____	Date(s) of Assessment:	_____
Member :	_____	Date(s) of Assessment:	_____
Member :	_____	Date(s) of Assessment:	_____
Member :	_____	Date(s) of Assessment:	_____
Member :	_____	Date(s) of Assessment:	_____

## 1. ASSESSMENT RESULTS

### 1.1 Overall findings

The documented management system is in general  appropriate /  inappropriate in assuring the quality of activities covered in this assessment. Implementation of the system is in general  effective /  ineffective.

*Summary of assessment findings on Management Requirements:*

*Summary of assessment findings on Technical Requirements:*

Supervision is in general  adequate /  inadequate in the aspects detailed in AF01.

Corrective actions are in general  effective in addressing root causes of nonconformities /  ineffective in the aspects detailed in AF01.

Measures to uphold the impartiality and integrity of the organisation are in general  effective /  ineffective in the aspects detailed in AF01.

A summary of findings against the accreditation requirements is given in Section 1.2.

The activities witnessed during the assessment are indicated by ticks in Appendix I.

Other comments :

*The assessment team is grateful to the management and staff for their cooperation and hospitality during the assessment.*

**1. ASSESSMENT RESULTS (Continued)**

**1.2 Areas where critical /significant nonconformities with HOKLAS criteria were identified (as marked with “X”)**

***Management Requirements (HOKLAS 015 - 5<sup>th</sup> edition)***

- Organisation and management responsibility (Section 4.1)
- Quality management system (Section 4.2)
- Document control (Section 4.3)
- Service agreements (Section 4.4)
- Examination by referral laboratories (Section 4.5)
- External services and supplies (Section 4.6)
- Advisory services (Section 4.7)
- Resolution of complaints (Section 4.8)
- Identification and control of nonconformities (Section 4.9)
- Corrective action (Section 4.10)
- Preventive action (Section 4.11)
- Continual improvement (Section 4.12)
- Control of records (Section 4.13)
- Evaluation and audits (Section 4.14)
- Management review (Section 4.15)

***Technical Requirements (HOKLAS 015 - 5<sup>th</sup> edition)***

- Personnel (Section 5.1)
- Accommodation and environmental conditions (Section 5.2)
- Laboratory equipment, reagents, and consumables (Section 5.3)
- Pre-examination processes (Section 5.4)
- Examination processes (Section 5.5)
- Ensuring quality of examination results (Section 5.6)
- Post-examination processes (Section 5.7)
- Reporting of results (Section 5.8)
- Release of results (Section 5.9)
- Laboratory information management (Section 5.10)

***Other HOKLAS Requirements***

- HKAS 002
- Use of accreditation symbols and claim of accreditation status
- Proficiency testing (PT) activities
- Mandatory requirements arising from previous assessment report / outcome letter
- Relevant HOKLAS/HKAS Supplementary Criteria

*Comments:*

**2. PERFORMANCE OF THE LABORATORY FOR THE ACTIVITIES COVERED IN THIS ASSESSMENT\***

1.	No. of system critical/significant nonconformities (NC)		
2.	No. of activities having critical/significant NC [a]		% of activities having no critical/significant NC
	No. of accredited activities [b]		[1 - (a / b)] x 100%
3.	No. of satisfactory PT activity results since last reassessment [c]		% of satisfactory PT activity results since last reassessment
	No. of PT activity results since last reassessment [d]		(c / d) x 100%

\* Applicable to reassessments and surveillance visits only

Remarks:

**3. ASSESSMENT OUTCOMES**

**a. Recommendation on accreditation:**

- Accreditation will be  granted for the activities listed in Appendix I (assessment) /  
 continued for the activities listed in Appendix I (reassessment) /  
 maintained (surveillance visit)

on condition that the laboratory has

notified HKAS Executive in writing of the actions taken or planned against all the identified nonconformities within **one month** of the assessment / reassessment /surveillance visit.

rectified to the satisfaction of HKAS Executive:

- (i) all *significant* nonconformities within  
 **six months** of the assessment for new activities proposed for accreditation.  
 **three months** of the reassessment for activities already accredited.

- (ii) all *critical* nonconformities  
 **on or before** \_\_\_\_\_ or as specified in 3.b.

and has informed HKAS Executive of the same in writing, within the specified period with supporting evidence and information necessary for evaluation of the remedial actions.

agreed to rectify all minor nonconformities prior to the next reassessment for the relevant activities.

Another full assessment is required to review the granting of accreditation after HKAS Executive is satisfied that appropriate remedial actions have been taken against all critical and significant nonconformities.

The laboratory is encouraged to consider and respond to the additional recommendations, if any, given in AF01 forms.

**b.  Other recommendation / remark:**

**c. Evaluation of remedial actions:**

HKAS will evaluate the remedial actions through:

- reviewing the documents, evidence and other information provided by the laboratory.  
 a follow-up visit in \_\_\_\_\_

**d. Recommendation on personnel approval:**

- Recommendations for approval for new nominee(s) are detailed in the attached AF 05 form(s).  
 Approval for existing personnel is to be  maintained /  modified as specified in Appendix II.

**- End of Report -**