

**AF 11**  
**HOKLAS ASSESSMENT REPORT (PROFICIENCY TESTING PROVIDER)**

**This report is prepared by the assessment team and is addressed to the authorised representative of the proficiency testing provider** \_\_\_\_\_

*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 proficiency testing provider 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 PT provider : \_\_\_\_\_

Office Address : \_\_\_\_\_

PT Provider's Laboratory: *(Name and Address, if different from above)* \_\_\_\_\_

Accreditation status of the laboratory:     Accredited     Not accredited

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

initial assessment /  reassessment /  extension of accreditation /  surveillance visit

of the PT provider for the following PT scheme: \_\_\_\_\_

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

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

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

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- B. Appendix I – Scope of Activities Covered
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- F. \_\_\_\_\_ pages of AF01 – HOKLAS Observation and Action Record Form
- G. \_\_\_\_\_ pages of AF10 – HOKLAS Signatory Assessment Form (Proficiency Testing Providers)
- H. \_\_\_\_\_ 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: \_\_\_\_\_

## 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.

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")**

**Technical Requirements (HOKLAS 017)**

- General (Sec 4.1)
- Personnel (Sec 4.2)
- Equipment, accommodation and environment (Sec 4.3)
- Design of proficiency testing schemes (Sec 4.4)
  - Planning
  - Preparation of proficiency test items
  - Homogeneity and stability
  - Statistical design
  - Assigned values
- Choice of method or procedure (Sec 4.5)
- Operation of proficiency testing schemes (Sec 4.6)
  - Instructions for participants
  - PT items handling and storage
  - Packaging, labeling and distribution of PT items
- Data analysis and evaluation of PT scheme results (Sec 4.7)
  - Data analysis and records
  - Evaluation of performance
- Reports (Sec 4.8)
- Communication with participants (Sec 4.9)
- Confidentiality (Sec 4.10)

**Management Requirements (HOKLAS 017)**

- |  |  |
|--|--|
| <input type="checkbox"/> Organisation (Sec 5.1)                              | <input type="checkbox"/> Control of nonconforming work (Sec 5.9) |
| <input type="checkbox"/> Management system (Sec 5.2)                         | <input type="checkbox"/> Improvement (Sec 5.10)                  |
| <input type="checkbox"/> Document control (Sec 5.3)                          | <input type="checkbox"/> Corrective actions (Sec 5.11)           |
| <input type="checkbox"/> Review of requests, tenders and contracts (Sec 5.4) | <input type="checkbox"/> Preventive actions (Sec 5.12)           |
| <input type="checkbox"/> Subcontracting services (Sec 5.5)                   | <input type="checkbox"/> Control of records (Sec 5.13)           |
| <input type="checkbox"/> Purchasing services and supplies (Sec 5.6)          | <input type="checkbox"/> Internal audits (Sec 5.14)              |
| <input type="checkbox"/> Service to the customer (Sec 5.7)                   | <input type="checkbox"/> Management review (Sec 5.15)            |
| <input type="checkbox"/> Complaints and appeals (Sec 5.8)                    |  |

**Other HOKLAS Requirements**

- |  |   |
|--|---|
| <input type="checkbox"/> HKAS 002  | <input type="checkbox"/> Relevant HOKLAS/HKAS Supplementary Criteria    |
| <input type="checkbox"/> Proficiency testing (PT) activities   | <input type="checkbox"/> Check samples or audit devices (if applicable) |
| <input type="checkbox"/> Mandatory requirements arising from previous assessment report / outcome letter |   |

## 2 PERFORMANCE OF THE PT PROVIDER 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]		$[1 - (a / b)] \times 100\%$
3.	No. of satisfactory PT activity results since last reassessment [c] <sup>@</sup>		% of satisfactory PT activity results since last reassessment
	No. of PT activity results since last reassessment [d] <sup>@</sup>		$(c / d) \times 100\%$

\* Applicable to reassessments and surveillance visits only

<sup>@</sup> PT results of the provider's laboratory related to activities of the PT scheme (own laboratory or subcontracted laboratory)

## 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 PT provider 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.
- obtained acceptable results for the check sample(s)/audit device provided.

- 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 PT provider 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 PT provider.
- a follow-up visit in \_\_\_\_\_

### d. Recommendation on personnel approval:

- Recommendations for approval for new nominee(s) are detailed in the attached AF 10 form(s).
- Approval for existing personnel is to be  maintained /  modified as specified in Appendix II.

- End of Report -