

**AF01
HOKLAS OBSERVATION AND ACTION RECORD FORM**

Name or Registration Number of Laboratory/
Proficiency Testing Provider/Reference Material Producer : _____ Visit date (DD/MM/YY) : _____ Case ID : _____

Team Leader : _____ Reporting assessor(s) : _____

Signature of Team Leader : _____ Signature of Reporting Assessor(s) : _____
(Name of Team Leader) (Name of Reporting Assessor(s))

<i>To be completed by the assessment team</i>					<i>To be completed by the laboratory</i>		<i>To be completed by HKAS</i>
Obs. No.	Test / Area / Document number where observation was made	Description of observation	Grading ^a	Clause No. ^b	Action Plan / Action Taken ¹ (Target date of completion)	Document evidence of actions taken ²	Comments
<p>a. i. R = Recommendation; M = Minor nonconformity; S = Significant nonconformity; C = Critical nonconformity ii. Rectification of nonconformity identified is a MANDATORY REQUIREMENT. iii. If the observation is a critical nonconformity, please give the rationale and the specified timeframe for rectification.</p> <p>b. Please specify the nonconformity observed against Clause number of HOKLAS 003 (for non-medical laboratory); HOKLAS 015 (for medical laboratory); HOKLAS 017 (for proficiency testing provider); HOKLAS 022 (for reference material producers); HKAS 002 or HKAS/HOKLAS Supplementary Criteria.</p> <p>c. If the observation is related to a test seeking Extension of Accreditation, please put (E) after the observation number.</p>							
Area where observations are made :							
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							

Note: 1. Please include description of investigation taken and the root cause identified if CAR is not provided as document evidence. Enter date (DD/MM/YY) that action plans and document evidence are submitted and describe your action plans. Please do not overwrite previous communications.
 2. If the investigation and root cause are not described in the Action Plan/Action Taken column, please attach also the CAR form with supporting documents. Please either embed the document file or enter the document name/identification number and submit the document(s) separately.

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Obs. No.	Test / Area / Document number where observation was made	Description of observation	Grading ^a	Clause No. ^b	Action Plan / Action Taken¹ (Target date of completion)	Document evidence of actions taken²	Comments
9.							
Area where observations are made :							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							

- Note: 1. Please include description of investigation taken and the root cause identified if CAR is not provided as document evidence. Enter date (DD/MM/YY) that action plans and document evidence are submitted and describe your action plans. Please do not overwrite previous communications.
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