HOKLAS Supplementary Criteria No. 26

'Medical Testing' Test Category – Chemical Pathology

1. Introduction

1.1 This document is an application document for the requirements of HKAS 002 and HOKLAS 015 accrediting examinations in chemical pathology within the test category of 'Medical Testing'. This document only details those requirements that require further elaboration but does not include all the accreditation requirements. Therefore, it has to be read in conjunction with HKAS 002, HOKLAS 015, HOKLAS SC-33 and relevant HOKLAS supplementary criteria.

1.2 The checklist given in the Annex serves as guidance for laboratories to self-assess their management system and operation procedures against the requirements given in HOKLAS 015 and this document.

2. Scope of accreditation

HKAS provides accreditation under HOKLAS for the following areas:

2.1 Biogenic Amines

2.2 Blood Gases and Co-oximetry

2.3 Drug of Abuse Testing

2.4 General Serum Chemistry

2.5 General Urine Chemistry

2.6 Heavy Metals and Trace Elements

2.7 Hormones

2.8 Immunochemistry

2.9 Inborn Errors of Metabolism

2.10 Proteins, quantitative analysis

2.11 Proteins, qualitative and semi-quantitative analysis, including Electrophoresis and Immunofixation

2.12 Special Chemistry (other tests)

2.13 Special Lipids

2.14 Therapeutic Drug Monitoring

2.15 Toxicology

2.16 Tumour Markers

2.17 Urinalysis

Note: For molecular testing in chemical pathology, please refer to HOKLAS SC-30 for molecular genetics.

For cross-discipline tests (e.g. haemoglobin A1c and urinalysis), laboratories could seek their accreditation under the discipline of the laboratory where they are performed.

3. Personnel

3.1 Where consultations and clinical interpretations of test results are required, they shall be provided by a qualified chemical pathologist (or qualified pathologist as advised by the Hong Kong College of Pathologists (HKCPath)).

3.2 A qualified chemical pathologist shall be a pathologist who has obtained postgraduate qualification in chemical pathology, such as the Fellowship of the HKCPath, or equivalent as advised by the College.

3.3 A qualified chemical pathologist shall fulfil the 3-year cycle of CME/CPD requirement of the Hong Kong Academy of Medicine or Hong Kong Medical Council or equivalent bodies.

4. Examination processes

4.1 If a laboratory acquires new methodology for any test, verification or validation study shall be carried out before it is put into routine service.

4.1.1 Verification study shall be carried out if a laboratory acquires a new validated method without modification. Except for acquiring commercial methods or published validated methods, the laboratory shall retain a copy of the original validation data for reference.

4.1.2 For details on the performance verification of automated analysers and the preparation of verification report, please refer to HOKLAS SC-38.

4.1.3 When changes are made to a verified examination procedure (e.g. using a new generation of assay kits), the influence of such changes shall be documented and, when appropriate, a new verification shall be carried out.

4.1.4 A full scale validation study shall be carried out if the new method to be acquired has not been validated (e.g. laboratory developed method, validated method with modification, etc). The extent of such validation study should commensurate with its intended use. The laboratory shall document the justifications on determining the extent of a validation study in the study report. Source of reference shall also be listed in the study report, if applicable.

Tests to be considered include:

1. Within-batch and between-batch imprecision
2. Accuracy (which can be determined by using reference materials, EQA samples, etc)
3. Analytical specificity
4. Limits of detection or functional sensitivity, where appropriate
5. Measurement range, reportable range and extended linearity
6. Correlation with old method using patient samples
7. Clinical sensitivity and specificity
8. Determination of measurement uncertainty for all quantitative and semi-quantitative measurements
9. Interference study on the effects of lipaemia, icterus, and haemolysis

4.2 Biological reference intervals shall be verified or established as appropriate, and records shall be kept. The source of biological reference intervals to be used for all

tests shall be documented. For verification of reference intervals from other sources, please refer to HOKLAS SC-32. If the original source is not traceable, the laboratory shall evaluate the continual suitability of these reference intervals for the examinations and maintain records of these evaluations with supporting evidence.

4.3 The measurement uncertainty (MU) should be determined at the clinical decision level. The estimated MU shall be available to laboratory users upon request, but are not expected to be included routinely in test reports.

5. Ensuring quality of examination results

5.1 If a laboratory has an analyser system consisting of multiple units for an analyte, enrolment in a single external quality assessment programme for the whole system is acceptable.

5.2 For those examinations performed using more than one analyser, the laboratory shall have a defined mechanism to ensure comparability of results. For details on performing regular inter-instrument comparison, please refer to sections 3.5.5 to 3.5.6 of HOKLAS SC-38.

5.3 The laboratory shall document its quality control plan in detail, including the levels of quality control materials run each day, frequency of performing QC, types of QC materials and the QC acceptance criteria to be observed by the laboratory staff. The selection of QC levels should be optimised for clinical decision and patient management. The laboratory shall provide clear and easily understood information on actions to be taken in case the QC result falls out of the acceptance limit. All actions taken shall be recorded.

5.4 The key goal of a laboratory's QC plan is to reduce the risk of harm to a patient due to an erroneous result. The laboratory shall identify and, where necessary, correct erroneous patient results when an out-of-control condition in a measurement procedure has been detected.

6. Post-examination processes

The minimum requirements for the retention of laboratory documents and specimens are listed as follows:

1. Personnel records : employment + 3 years
2. QC & QA records : 3 years
3. Equipment maintenance : life of machine + 3 years
4. Evaluation study raw data and report of new analyser/method : life of machine/while method current + 3 years
5. Lab methods/procedure manuals : while methods current + 3 years
6. Request forms, worksheets, copies of reports & other lab records and documentation including calculations, observations, diagrams & charts etc : 3 years
7. Specimens : under appropriate storage conditions for 7 days from the date of receipt or 2 days after date of issued report (whichever is later)

7. Reporting of results

7.1 The report of the following tests shall have direct input from a qualified chemical pathologist (or qualified pathologist as advised by the HKCPath):

- Blood for antibiotic assay for patients susceptible to drug toxicity
- Urine organic acids
- Urine and plasma amino acids
- Acyl carnitine pattern
- Toxicology confirmatory tests
- Challenge tests for metals, e.g. penicillamine challenge test
- Dynamic function tests (excluding oral glucose tolerance test)
- Renin activity and aldosterone
- 17-hydroxyprogesterone
- Immunosuppressants
- Urine steroid profile
- Urine and plasma catecholamine profile
- Mutational analysis for diagnosis of genetic diseases

7.2 For any test results of significant clinical implication, input from a qualified chemical pathologist (or qualified pathologist as advised by the HKCPath) is recommended.

8. Release of results

8.1 For computer auto-validated reports, the laboratory shall define and document the person(s) authorising the use of a particular algorithm for automatic release of results. The reports shall be traceable to the person(s) who authorise and release the results; and the requesters shall be informed on such reports that the results are auto-validated by computer system.

9. Laboratory information management

9.1 There shall be a procedure established to periodically verify if results from calculated formulae are accurately reported.

- End -

HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Discipline Specific Technical Requirements							
Pre-examination processes	**5.4**						
Is there a list of procedures broadly categorised, for example, by methodology?	5.4.2	•	☐	☐	☐		
Examination processes	**5.5**						
Are new autoanalysers or methods evaluated before putting into routine use?	5.5.1.2 5.5.1.3	•	☐	☐	☐		
Is the evaluation report of the new autoanalyser/method well documented with details of the dates of the studies, the study group, evaluation tests conducted, raw data, results, statistical analysis, where applicable, and conclusions?	5.5.1.2 5.5.1.3	•	☐	☐	☐		
Have the reference intervals in use been verified before use and reviewed when there are changes in an examination procedure or pre-examination procedure?	5.5.2	•	☐	☐	☐		
Are records of reviewing the reference intervals kept?	SC-26 4.2	•	☐	☐	☐		
Has the measurement uncertainty been determined at the clinical decision level?	5.5.1.4	•	☐	☐	☐		

Note: 1. The assessor should concentrate on items marked with a ●; other items will be checked by the team leader.
2. Please put down the laboratory's document reference(s) where there are descriptions or procedures related to the requirement.

HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Does the procedure manual							
- include performance specifications such as the linearity of method and instructions for appropriate dilution protocols?	5.5.3	•	☐	☐	☐		
- document source of the reference intervals and their verification?	5.5.3	•	☐	☐	☐		
Ensuring quality of examination results	**5.6**						
Is there a defined mechanism to ensure that results obtained in the laboratory from different analysers for the same test are comparable?	5.6.4	•	☐	☐	☐		
Are there written guidelines or instructions for staff on how to deal with QC failures?	5.6.2.3	•	☐	☐	☐		
Are actions taken to address QC failures well recorded?	SC-26 6.2	•	☐	☐	☐		
Are erroneous patient results identified and, where necessary, corrected when an out-of-control condition in a measurement procedure has been detected?	SC-26 5.4	•	☐	☐	☐		
Post-examination processes	**5.7**						
Are specimens stored under appropriate conditions for 7 days from the date of receipt or 2 days after the report issued (whichever is later)?	SC-26 6.7	•	☐	☐	☐		

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Laboratory information management	**5.10**						
Is there any procedure established to periodically verify if results from calculated formulae are accurately reported?	5.10.3	•	☐	☐	☐		

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