HOKLAS Supplementary Criteria No. 26

"Medical Testing" Test Category – Chemical Pathology

1. Introduction

1.1 This Supplementary Criteria is an amplification and interpretation of the requirements of HKAS 002 and HOKLAS 015 for the accreditation of examinations in chemical pathology within the Medical Testing Test Category. This document sets out only those specific requirements which require further elaboration but does not include all the accreditation requirements. This Supplementary Criteria needs to be read in conjunction with HKAS 002 and HOKLAS 015.

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

The areas for which accreditation may be offered are listed below:

2.1 General Serum Chemistry
2.2 General Urine Chemistry
2.3 Blood gases and Co-Oximetry
2.4 Therapeutic Drug Monitoring
2.5 Toxicology
2.6 Drug of Abuse Testing
2.7 Hormones
2.8 Tumour Markers
2.9 Biogenic amine
2.10 Proteins, quantitative analysis
2.11 Proteins, qualitative and semi-quantitative analysis, including Electrophoresis and Immunofixation
2.12 Heavy Metals and Trace Elements
2.13 Inborn Error of Metabolism Testing
2.14 Special Lipids
2.15 Molecular Pathology
2.16 Special Chemistry (other tests)

3. Personnel

3.1 Medical personnel

3.1.1 Where consultations and clinical interpretations of test results are required, they shall be provided by a chemical pathologist.

3.1.2 A chemical pathologist shall be a pathologist who has obtained postgraduate qualification in chemical pathology such as Fellowship of Hong Kong College of Pathologists or equivalent as advised by the College.

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

4. Post-examination procedures

The minimum requirements for the retention of laboratory documents and specimens are listed as follow.

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

HKAS Executive
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