HOKLAS Supplementary Criteria No. 52

'Veterinary Testing' Test Category

0 Introduction

(a) This document serves to clarify and supplement the requirements of ISO/IEC 17025:2017 and HKAS PD001 for the accreditation of laboratories performing tests under the test category of 'Veterinary Testing'. This document shall be read in conjunction with ISO/IEC 17025:2017, HKAS PD001 and the relevant HKAS and HOKLAS supplementary criteria documents.

(b) Laboratories should note that fulfilling the requirements in this document might not necessarily meet all the requirements of test standards. Individual test standards may have specific requirements which shall be met when conducting the concerned tests.

1 Scope

(a) HKAS offers accreditation under HOKLAS in the following areas:

(i) Anatomical Pathology
(ii) Clinical Pathology
(iii) Microbiology
(iv) Immunology
(v) Molecular Diagnosis

2 Normative reference

(No additional explanation)

3 Terms and definition

(No additional explanation)

4 General requirements

(No additional explanation)

5 Structural requirements

(a) The technical management of the laboratory shall include at least one member with relevant knowledge and experience in veterinary testing. The level of qualification and experience shall be equivalent to and preferably higher than an approved signatory as stated in Clause 6.2(a).

6 Resource requirements

6.1. General

(No additional explanation)

6.2. Personnel

(a) An approved signatory shall be

(i) a veterinary surgeon registered under the Veterinary Surgeons Registration Ordinance (Cap. 529) or equivalent with postgraduate qualifications in veterinary pathology; or

(ii) a medical laboratory technologist who is Part I registered under the Supplementary Medical Professions Ordinance (Cap. 359), or a person who is exempt from the ordinance, with at least three years of relevant working experience, one year of which shall be related to veterinary testing.

Only approved signatories with qualifications stated in (i) shall sign reports containing opinions and interpretations, including diagnoses. Candidates will be asked to demonstrate to the assessment team his/her competence in assuming the duties of approved signatories before such approval is granted.

(b) Continuing education shall be provided to all technical staff, preferably

following the requirements of professional bodies. Records of participation shall be maintained.

6.3. Facilities and environmental conditions

(a) The laboratory shall have appropriate facilities and environmental conditions to ensure the quality of the service provided and the safety of personnel.

(b) Suitable storage space and conditions shall be provided to ensure the integrity of samples, documents, records, reagents, equipment and any items that may affect the quality of test results.

(c) For a laboratory that provides molecular diagnosis, the laboratory shall provide separate rooms or clearly designated areas for the preparation of reagents and master mix, sample preparation and nucleic acid extraction, amplification, and manipulation of amplified nucleic acids in order to reduce the risk of contamination. This is not applicable when the whole process is performed in the same instrument system.

(d) The movement of specimens and equipment used for molecular testing should be unidirectional as far as practicable.

6.4. Equipment

(a) Records shall be maintained for reagents and consumables that contribute to the performance of the tests. The records shall include the date of receipt, the date of entering into service and the expiry date. For reagents that are prepared in-house, their records shall include, but not limited to, ingredients and quantities used, date of preparation, person who prepared the reagents and the expiry date. Containers of all reagents shall be labelled appropriately.

6.5. Externally provided products and services

(a) The laboratory may advise customers of the referral arrangement in collection instructions, price lists, catalogues, etc.

(b) Requests and results of all samples referred shall be kept for a defined period of not less than four years.

7 Process requirements

7.1. Review of requests, tenders and contracts

(No additional explanation)

7.2. Selection, verification and validation of methods

(a) The laboratory shall define and document the basis for the reference intervals. Reference intervals from published references can be adopted provided that they are verified using the laboratory's species population and methods. The source of reference interval shall be documented.

(b) When the laboratory changes test method, the laboratory shall review suitability of the reference intervals.

7.3. Sampling

(a) The laboratory shall document information for specimen collection, which include but not limited to the following:

(i) containers required;
(ii) type and amount of specimen required;
(iii) specimen collection, storage and transportation requirements;
(iv) instructions for filling request forms and labelling specimen containers;
(v) relevant clinical information.

(b) When specimen collection is outside the control of the laboratory, the laboratory shall provide the above information (clause 7.3(a)), where relevant, to the person responsible for collection.

7.4. Handling of test or calibration items

(a) The laboratory shall document instructions for specimen reception. The instructions shall include the criteria for acceptance or rejection of specimens.

(b) Each test request form and specimen container (including glass slides) shall be labelled with unique identification. For inadequately labelled request form or specimens, the laboratory shall take appropriate actions to verify the

identity before testing.

7.5. Technical records

(a) Specimen shall be retained for a pre-defined period before disposal. The minimum retention times for specimens are defined in Table 1. The laboratory may retain specimen for a longer period when such is appropriate for education, quality improvement etc.

Table 1: Retention times for specimens

General	
Blood, serum and plasma, other body fluids	3 days after reporting
Swabs, specimen or other materials	
Anatomical Pathology	
Histology slides	3 years
Blocks	10 years
Fixed or fresh tissue	30 days after reporting
Containers with no residual tissue	14 days after reporting
Haematology	
Blood film	60 days
Molecular	
Extracted nucleic acid	3 days after reporting

7.6. Evaluation of measurement uncertainty

(a) Evaluation of measurement uncertainty (MU) applies to quantitative tests. This includes those tests where a numerical value is reported as a qualitative

result, such as serological assays with a ‘cut off’ value where the numerical result is reported as detected or not detected.

7.7. Ensuring the validity of results

(a) The laboratory shall document, in its quality control plan, the types of QC materials, the levels of QC materials, frequency of performing quality control, the acceptance criteria and actions to be taken when QC results fall outside of acceptance criteria.

(b) The laboratory shall choose concentration of QC materials appropriate for the test and species.

(c) The laboratory shall routinely participate in veterinary specific proficiency testing (PT) programmes when such programmes are available and applicable to the tests conducted. When no veterinary specific PT programmes is available, the laboratory shall adopt alternative means and provide evidence for determining the acceptability of test results.

7.8. Reporting of results

(a) In addition to the requirements for reports as stipulated in ISO/IEC 17025, each test report shall include the following:

(i) Date of specimen collection and, when available and relevant for the interpretation of test results, the time of collection;

(ii) Type of specimen and animal;

(iii) Unique identification of the animal, owner and submitter, where applicable;

(iv) Reference intervals, where appropriate;

(v) Other comments, such as explanatory notes (e.g. quality of adequacy of the primary specimen).

(b) If test results are provided to customers orally, a record of the date and time of the results reported, the reporting staff member, person notified and results conveyed shall be kept. Results provided orally shall be followed by a written

report.

(c) The person giving opinions and interpretations, including diagnoses, shall be a veterinary surgeon registered under the Veterinary Surgeons Registration Ordinance (Cap. 529) or equivalent with postgraduate qualifications in veterinary pathology.

7.9. Complaints

(No additional explanation)

7.10. Nonconforming work

(No additional explanation)

7.11. Control of data and information management

(No additional explanation)

8 Management system requirements

(No additional explanation)