SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

SC 1.6 - SPECIFIC CRITERIA FOR ACCREDITATION IN THE FIELD OF VETERINARY TESTING

Issue 2, 30 April 2020

(Supplementary to MS ISO/IEC 17025)

MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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Introduction

This document addresses the specific criteria that are essential for the proper conduct of test in the field of veterinary testing as stated in the scope below. It provides detail or additional information to the general stated requirements of the *Skim Akreditasi Makmal Malaysia* (SAMM) accreditation criteria.

This document shall be read in conjunction with MS ISO/IEC 17025, SAMM policies and other relevant requirements published by Department of Standards Malaysia (Standards Malaysia).

The clause numbers in this document correspond to those of MS ISO/ IEC 17025 but since not all clauses require additional requirements, the numbering may not be continuous.

1 Scope

The scope of testing shall include but is not limited to **Appendix 1.**

Specific criteria for accreditation for veterinary testing cover the following activities:

- Disease diagnosis
- Clinical examination
- Monitoring and surveillance
- Veterinary public health
- Lab testing including screening for growth promoters and drug/chemical residue
- Sampling, associated with subsequent testing

The categories of specimen include but is not limited to the following:

- Animal and aquatic animals
- Feed, feedstuffs and feeding supplements
- Products and by-product derived from animals and aquatic animals origin
- Environmental specimens
- Pharmaceutical/Pesticide
- Biologics

2 Normative references

In addition to normative references in MS ISO/IEC 17025, for veterinary testing the following OIE references should apply:

- OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- OIE Manual of Diagnostic Tests for Aquatic Animals
- OIE Terrestrial Animal Health Code
- OIE Aquatic Animal Health Code

The undated references indicate the latest edition of the referenced documents, including any amendments.

3 Terms and definitions

3.1 Animal and aquatic animals

3.1.1 Animal

All life stages of a mammal which includes horses, cattle, sheep, goats, swine, dogs, cats and any four-footed (quadrupeds) mammals, birds, reptiles, amphibians, insects, bees or any animals of any age and sex, kept in captivity or under control, domesticated or otherwise.

3.1.2 Aquatic animals

All life stages (including *eggs* and *gametes*) of fish or plant life (e.g. seaweed/algae, plankton, sea grass, sponges, corals and etc.), crustaceans, molluscs, aquatic mammals, and amphibians originating from *aquaculture establishments* or from the sea, ocean or river, wild, or for farming purposes, for release into the environment, for human consumption or for ornamental purposes according to OIE Aquatic Animal Health Code.

3.2 Feed, feedstuffs and feeding supplements

Any single or multiple material, feed additives and other ingredients whether processed, semi-processed or raw, which is intended to be fed or applied to animals and aquatic animals.

3.3 Products and By-product derived from animals and aquatic animals

3.3.1 Product

Entire body or parts of animals and/or aquatic animals intended for human consumption includes but not limited to meat, milk, egg, fat/oil including, carrageenan and gelatine.

3.3.2 By-product

Entire body or parts of animals and/or aquatic animals intended or not intended for human consumption includes but not limited to blood meal, bone meal, fish meal, feather, fur, hair/bristles, hide, pelt/fleece, wool, scales, manure and non-edible waste.

3.4 Environmental specimen

Cover various environmental parameters includes but not limited to air, water/wastewater, soil, environmental swab, solid/semi-solid hazardous waste (sediment/sludge) and animal bedding.

3.5 Pharmaceutical/Pesticide

Any substance or combination of substances having properties for treating or preventing diseases includes but not limited to veterinary medicine, antibiotic, hormones, herbs, organics and rodenticides.

3.6 Biologics

Any biological product for preventing, treatment, cure and enhancing animal health includes but not limited to vaccines, serum, hormones, enzymes, GMOs/LMOs, RNA/DNA, probiotics and prebiotics.

3.7 Specimen

The material which is exclusively of animals and/or aquatic animals' origin, and/or materials or swabs obtained from its immediate environment submitted for laboratory testing purpose. These include but not limited to blood, biological and pathological specimen, body fluids, carcass, faeces, urine, serum and scrapings. Specimen can also include biologics such as vaccines, antisera and immunoglobulin.

3.8 Sample

The material that is derived from a specimen submitted to the laboratory for testing purpose.

3.9 Veterinary laboratory

A laboratory for testing and examination of specimen derived from animal and aquatic animal origin, feed, product, by-product, environment for disease diagnosis, clinical examination, monitoring/surveillance, assessment of health or disease status and veterinary public health.

3.10 National authority

The competent government authority performing official control for all matters related to animal, aquatic animal and wildlife health.

3.11 OIE

Office International des Epizooties or World Organisation for Animal Health.

4 General requirements

Same as in MS ISO/IEC 17025.

5 Structural requirements

5.1 Organisation

The laboratory shall have a clearly defined organisational structure appropriate to the Scopes of Veterinary Testing, which may include, but not limited to **Appendix 1**.

The head of laboratory shall be a practicing veterinary surgeon/veterinarian or veterinary officer, registered by the national authority or a person appointed by National Authority or qualified person with a related Science degree in a related field as in **Appendix 1** and at least 2 years of working experience in a veterinary/medical or other related laboratory.

The laboratory shall comply with all relevant legal and other requirements which include but not limited to National Acts, Rules and Regulations such as Animals Act [Act 647], Feed Act [Act 698], Fisheries Act [Act 317], Wildlife Conservation Act [Act 716] and Veterinary Surgeons Act [Act 147].

6 Resource requirements

6.1 General

Same as in MS ISO/IEC 17025.

6.2 Personnel

6.2.1 Signatory

Test reports shall be signed by approved signatories as follows:

a) Veterinary surgeon/veterinarian or veterinary officer, registered and practicing by the national authority; and/or

b) Chemist registered in their own country as defined in SC 1.2: *Specific Criteria for Accreditation in the Field of Chemical Testing;* or

c) Microbiologist as defined in SC 1.3: *Specific Criteria for Accreditation in the Field of Microbiological Testing*; or

d) Fisheries officer, research officer, pharmacist or gazetted officer authorised/appointed under relevant Acts, Rules and/ or Regulations by National Authority.

6.2.2 Technical and operational requirements for signatory.

Laboratory signatory shall have the knowledge and understanding of the technical and laboratory operational requirements as follows:

i) Requirements of MS ISO/IEC 17025 and related SAMM requirements and relevant regulatory requirements;

ii) The principles of testing;
iii) The standards, methods and specifications for accreditation sought or held;
iv) The estimation of measurement uncertainties for the accreditation sought or held.

6.3 Accommodation and environmental conditions

6.3.1 The laboratory shall have separation of activities to avoid cross contamination ("clean" and "dirty" areas, polymerase chain reaction assay, virology, bacteriology) that may affect or influence the test results. The laboratory shall also take measures to manage hazards in the laboratory (tests involving pathogens, toxins, radioisotopes or chemicals) and to provide a quiet and uninterrupted work environment as required (e.g. microscopy).

6.3.2 A safety manual detailing the laboratory's policies and procedures in relation to safety and health shall be readily available to all staff. Safe laboratory practice should be emphasized for tests which include but not limited to infectious, zoonotic pathogens, radioisotopes and chemicals hazardous to health but the review of safety during an assessment should not constitute to a formal safety audit. It is the responsibility of the laboratory to meet the requirement of the Biosafety Act [Act 678], Occupational Safety and Health Act [Act 514], or any other relevant laws and regulations currently enforced in the country.

6.3.3 The laboratory should have biosecurity measures in place for various risk group of pathogens and classes of hazardous materials.

Note: The laboratory should follow Chapter 1.1.4 Biosafety and Biosecurity: Standard for managing biological risk in the Veterinary Laboratory and Animal Facilities, of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals).

6.4 Equipment

6.4.1 The equipment calibration shall comply with SAMM Policy 2 (SP2): *Policy on the Traceability of Measurement Results* and equipment manual and planned preventive maintenance (PPM) schedule.

6.4.2 The laboratory shall ensure that the equipment used has been verified, as appropriate, for the range of species being tested example in Clinical Pathology subfield Haematology & Biochemistry.

6.5 Metrological traceability

Same as in MS ISO/IEC 17025 and SAMM Policy 2 (SP2): *Policy on the Traceability of Measurement Results.*

6.5.3 Reference standards and reference materials

The reference standards or materials should be traceable to OIE reference laboratory, international standard, culture collection centres, locally recognised depository or locally verified materials.

6.6 Externally provided products and services

Same as in MS ISO/IEC 17025.

7 Process requirements

7.1 Review of requests, tenders and contracts

Same as in MS ISO/IEC 17025.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate test methods and related procedures for testing. For infectious animal/aquatic animal disease, diagnostic testing, the laboratory should follow OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and OIE Manual of Diagnostic Tests for Aquatic Animal and/or other international, regional or national methods where possible.

7.2.1.2 The laboratory shall select appropriate methods that have been published either at international, regional or national level. The laboratory shall verify that it can achieve the performance characteristics before introducing the methods. Each of this verified method to be conducted in the laboratory shall be authorised and dated.

7.2.2 Validation of methods

The extent to which validation/verification is to be performed by the laboratory depends on the type of test method.

An in-house test method shall be validated in which they will be used. Validation includes the estimation of the analytical and diagnostic performance characteristics of a test guided by appropriate international recognised procedure.

The user is not required to validate international, regional or national standards, but shall conduct verification to show evidence of ability to conform to the performance of the test characteristics.

For commercial test kits, full validation is not required if it has been recognised by national/international authorities/organisations or if a validation report is available from the manufacturer, the laboratory shall

conduct verification to show evidence of ability to conform to the performance of the test characteristics.

Note: The laboratory should follow the OIE Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases in Chapter 1.1.6 and Section 2.2 on Validation of Diagnostic Test, of OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals or equivalent.

7.3 Sampling

The laboratory investigation of an animal disease is critically dependent on the quality and appropriateness of the specimens collected for analysis.

If the laboratory conducts sampling, the laboratory shall have procedures for the collection of specimens to ensure that it is appropriate for the test and the intended purpose of testing such as diagnostic, surveillance, disease eradication, certified freedom, monitoring for vaccination and treatment. Reference may be made to sampling guides such as “Field Guide to Submission of Veterinary Specimens” from relevant authority.

If the laboratory does not conduct sampling, guidelines for specimen submission should be made available to the customer.

For monitoring and surveillance, an epidemiological approach should be applied to provide scientifically and statistically valid results. Reference may be made to *Protokol Veterinar Malaysia* (PVM).

Note: The laboratory should follow chapter 1.1.2 Collection, submission and storage of diagnostic specimens, of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals or equivalent.

7.4 Handling of test items

7.4.1 Specimen reception

The laboratory shall have documented reception procedures which may include but not limited to the following:

a) The date and the time of receipt of specimens at the laboratory;

b) Criteria for acceptance/rejection of unsuitable specimens (e.g. leaking or broken containers, specimens collected in wrong containers, specimens unsuitable for the examination requested, inadequately labelled specimen containers);

c) Action to be taken in the event that an unsuitable specimen is received;

d) Handling of urgent specimens;

e) The integrity of specimens, which include transportation, receipt, handling and protection;

7.4.2 Specimen Storage

Specimen should be processed as soon as possible upon receipt.

7.4.3 Specimen retention

Specimen retention means the holding period of the specimen after completion of test and prior to disposal.

The laboratory should follow the following retention times, unless specified by the regulatory authority: -

<u>Haematology</u>	
Samples of blood, serum, plasma	7 days
Blood film	14 days
<u>Biochemistry</u>	
Samples of serum, plasma and other body fluids	7 days
<u>Immunology</u>	
Samples of material examined	7 days
<u>Serology</u>	
Samples of material examined	7 days
For samples where retesting and/or referral is likely	30 days
<u>Microbiology</u>	
Cultures and stained slides	7 days
Swabs, specimens or other material examined	7 days
<u>Parasitology</u>	
Samples of material examined	3 days
<u>Histopathology</u>	
Slides	1 years
Blocks	3 years
Unblocked, fixed tissue	30 days
<u>Necropsy</u>	
Necropsy tissue after sample collection	14 days (≤ -20^{o}C)
<u>Virology/Molecular Biology</u>	
Specimens for tissue culture	7 days (≤ -20^{o}C)
Virus Isolation	1 month (≤ -80^{o}C)
<u>Feed Samples</u>	1 month

7.4.4 Disposal of test items

The lab should have appropriate procedures for disposal of hazardous/non-hazardous chemical, infectious/non-infectious waste after testing following legal or national requirement of waste disposal to environment.

7.5 Technical records

Same as in MS ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

The laboratory shall be required to show the estimate of uncertainty of measurement wherever possible according to SAMM Policy 5 (SP5): *Policy on Measurement Uncertainty Requirements for SAMM Testing Laboratories.*

Tests involved in enumeration shall generally be required to demonstrate measurement uncertainty/intermediate precision.

7.7 Ensuring the validity of results

7.7.1 Specific quality control guidelines for various scopes of testing

7.7.1.1 Bacteriology

7.7.1.1.1 An appropriate range of reference culture with a full history of its properties shall be maintained for quality control and shall be stored under appropriate conditions. A quality control programme shall be established for the verification of the reference culture.

7.7.1.1.2 Quality control shall be performed on each batch of kits with a new production lot number using at least one of the strains of organisms recommended by the manufacturers.

7.7.1.1.3 Quality control on antimicrobial susceptibility testing must be performed in accordance with the recognised standard methods. Departures from recognised standard methods must be validated.

7.7.1.1.4 The laboratory is responsible to ensure that an appropriate level of quality control is performed on the media it uses:

i) In-house media preparation and quality control

The laboratory shall maintain an effective media preparation and quality control programme designed to suit the scope of testing. The preparation details for all media used shall be recorded.

ii) Media purchased from manufacturers

The laboratory shall initially assess the suitability of the manufacturer's media for its intended use. Manufacturers may provide a quality control report on each batch of media. Media shall be stored and used in

accordance with the manufacturer's instructions. The laboratory shall keep a log on the type of media, batch number and date received.

7.7.1.2 Mycology

Preliminary screening, use of selective media, inclusion of antibiotics or growth suppression, incubation conditions and differential tests shall be documented.

7.7.1.3 Haematology

A multi-level control shall be run at least once on each day of testing on automated cell counters. There shall also be a means of monitoring drift.

7.7.1.4 Serology

Positive and negative controls shall be used for each run of tests. Haemagglutination test: back titration of antigen shall be used where appropriate.

7.7.1.5 Histopathology

7.7.1.5.1 When using special stains, positive and negative control slides shall be available for reference.

7.7.1.5.2 To avoid mix-up during preparation of slides, the following precautions may be taken, but not limited to:

- checking of stained sections against the corresponding block prior to reporting;
- checking slides and blocks against the details on the request form prior to reporting;
- handling one case at a time during sectioning;
- labelling cassettes and slides for one case at a time.

7.7.1.6 Parasitology

References on endoparasites and ectoparasites, such as mounts, preserved specimen, atlases or illustrations and descriptions relating to the identification shall be available. Phenotypic or structural descriptions in the examination of parasites shall be recorded.

7.7.1.7 Immunology

7.7.1.7.1 A positive and negative reaction shall be demonstrated as a minimum on every immunofluorescence run and as an optimum on every immunofluorescence slide.

7.7.1.7.2 Reactive controls (known positives) with defined immunofluorescence patterns for the antibodies under investigation shall be tested as a minimum on every new batch of slides.

7.7.1.7.3 The appropriate working concentration of every new batch of fluorescein labelled Immunoglobulin conjugate shall be determined before use. This shall be performed for every new batch of individual substrate.

Note: If commercial kits are used, this should have already been done by the manufacturer. If conjugates and slides are purchased separately from the same manufacturer, the assay would still need to be validated.

7.7.1.8 Virology

7.7.1.8.1 An appropriate range of reference culture with a full history of its properties shall be maintained for quality control and shall be stored under appropriate conditions. A quality control programme shall be established for the verification of the reference culture.

7.7.1.8.2 Continuous cell lines and other biological systems shall be tested free of selected mycoplasma and extraneous viruses. Continuous cell lines shall be regularly monitored for contamination.

7.7.1.8.3 Each batch of purchased or prepared growth media or animal sera used for cell propagation shall be checked for absence of toxicity and contamination.

7.7.1.8.4 Records for the above shall indicate cell types, passage number, source and media used for their growth and maintenance.

7.7.1.9 Molecular biology

7.7.1.9.1 The laboratory shall document quality control procedures to prevent cross contamination that may arise from personnel, poor handling techniques, consumables, equipment, clean-up and maintenance.

7.7.1.9.2 Reagent blank (water/buffer instead of the template), negative and positive controls shall be used with each batch of tests. Controls shall be set up last and the blank control shall always be set up at the very last. If necessary, an internal amplification control shall be used in every sample.

7.8 Reporting of results

Same as in MS ISO/IEC 17025.

7.8.7 Reporting opinions and interpretations

When the results of a battery/series of tests are considered in formulating an opinion or making a diagnosis, it is necessary to describe to the customer, the rationale behind the sequence of testing and the decision making process (e.g. presumptive test/tentative diagnosis versus confirmatory tests/definitive diagnosis).

Interpretations and opinions constitute a diagnosis or actions stipulated as practice of veterinary medicine as defined in the Veterinary Surgeons Act [Act 147] may be included in the test report.

Interpretations and opinions of results shall only be given by a practicing veterinary surgeon/veterinarian or veterinary officer with a current Annual Practicing Certificate (APC). This information may be used for consultation services, disease and laboratory investigation.

7.9 Complaints

Same as in MS ISO/IEC 17025.

7.10 Nonconforming work

Same as in MS ISO/IEC 17025.

7.11 Control of data and information management

Same as in MS ISO/IEC 17025.

8.0 Management system requirements

Same as in MS ISO/IEC 17025.

Appendix 1

Scope of Veterinary Testing

No.	Field of Testing	Type of Test & Test Method
1.	**PATHOLOGY**	
	(a) Gross Pathology	• Necropsy and morphological diagnosis/interpretation
	(b) Histopathology	• Tissue trimming and processing of fixed specimens for histopathology • Processing of frozen sections • Histochemistry • Immunohistochemistry (IHC) • Histopathological interpretation • Characterisation by molecular techniques • Characterisation by in-situ hybridization • Special stains • Others
2.	**CLINICAL PATHOLOGY**	
	(a) Haematology	• Diagnostic haematology - complete haemogram, examination of blood films, and etc. • Basic coagulation screening tests • Bone marrow microscopy • Cell markers • Others
	(b) Biochemistry	• Diagnostic biochemistry - analytes for organ systems, analysis of proteins and electrolytes • Blood gas tensions, pH • Hormone assays • Pregnancy diagnosis • Urine biochemistry • Analysis of calculi • Trace element analysis • Vitamin assays • Others
	(c) Urinalysis	• pH, S.G., examination of calculi • Cytology • Dipstick Test • Bences Jones Protein • Others

No.	Field of Testing	Type of Test & Test Method
	(d) Cytology	• Diagnostic cytology • Quantitative cytology • Cytochemistry • Immunocytochemistry • Others
3.	**BACTERIOLOGY & MYCOLOGY**	• Diagnostic bacteriology - microscopy, cultural methods of detection, isolation and identification of organisms • Antibiotic susceptibility test (antibiograms) • Immunological methods / Serological methods • Quantitative methods • Molecular methods • Rapid tests • Others
4.	**VIROLOGY**	• Diagnostic virology - non-cultural /immunological methods • Diagnostic virology - cultural methods of detection and identification of organisms • Immunological methods / Serological methods • Quantitative methods • Molecular methods • Rapid tests • Others
5.	**PARASITOLOGY** (including helminths, arthropods and protozoa)	• Diagnostic parasitology - detection and identification using morphological methods • Anthelmintic resistance testing • Immunological methods / Serological methods • Quantitative methods • Molecular methods • Others
6.	**TOXICOLOGY**	• Heavy metals • Poisons • Pesticides • Toxins • Others
7.	**FEED ANALYSIS** (a) Raw feed ingredients (e.g. Fish meal, Bone meal, Blood meal)	• Proximate analysis • Mycotoxins • Drugs and chemical • Pesticide • Heavy metals

No.	Field of Testing	Type of Test & Test Method
	(b) Feed/ Feed additive/ Feeding material	• Melamine • Malachite Green • Dioxin • Growth Promoter • Antioxidants • Others
8.	**WATER QUALITY ANALYSIS**	• pH • Salinity • Dissolved Oxygen • Nitrogen, Ammonia • Nitrite • Nitrate • Phosphorus, Reactive (Orthophosphate) test • Total iron • Heavy metal • Free chlorine • Alkalinity • Total hardness • Biochemical Oxygen Demand (BOD) • Chemical Oxygen Demand (COD) • Turbidity • Others
9.	**BIOLOGICAL**	• Planktons (zooplankton/phytoplankton) • Zoonotic parasites • Chlorophyll • Macro benthos (composition and abundance) • Others

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