



MOSTI

STANDARDS
MALAYSIA

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

SPECIFIC TECHNICAL REQUIREMENTS 1.4 (STR 1.4)

**SPECIFIC TECHNICAL REQUIREMENTS FOR
ACCREDITATION OF VETERINARY TESTING
LABORATORIES**

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(Supplementary to MS ISO/IEC 17025)



MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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INTRODUCTION

The specific requirements herein are implemented by the Department of Standards Malaysia (STANDARDS MALAYSIA) as part of its assessment criteria for the accreditation of laboratories working in the field of Veterinary Testing. They are developed in accordance with Clause 4.1.3 of ISO/IEC Guide 58, "*Calibration and testing laboratory accreditation system - General requirements for operation and recognition*". Their main purpose is to interpret and clarify the general requirements of MS ISO/IEC 17025 Document on "*General Requirements for the Competence of Testing and Calibration Laboratories*" for application in the field of Veterinary Testing.

STANDARDS MALAYSIA requires that laboratories applying for accreditation in the field of Veterinary Testing to comply with these specific requirements.

In addition to addressing the requirements of MS ISO/IEC 17025, this document is also developed to be in harmony with the requirements of SAMM policy documents SP1 to SP10.

1.0 SCOPE

These specific requirements apply to Veterinary Testing, including feed, animal products and other related areas of testing.

2.0 NORMATIVE REFERENCES

In addition to normative references in MS ISO/IEC 17025, the following are additional documents used :-

OIE Terrestrial Animal Health Code
OIE Aquatic Animal Health Code
OIE Quality Standard and Guidelines for Veterinary Laboratory for Infectious Diseases
CODEX's Code of Practice on Good Animal Feeding (CAC/RCP 54)

3.0 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, VIM, OIE Terrestrial Animal Health Code and Aquatic Animal Health Code and Codex's Code of Practice on Good Animal Feeding and the following shall apply :-

3.1 Animal

Any living or dead animal including mammal (excluding human), bird, amphibian, bees, reptile and aquatic animal.

3.1.1 Aquatic animal

Fish (including eggs and gametes), molluscs and crustaceans and does not include water-living amphibian, reptiles, birds and mammals.

3.1.1.1 Crustaceans

All life stages of aquatic animals belonging to the phylum Arthropoda, a large class of aquatic animals characterised by their chitinous exoskeleton and jointed appendages, e.g. crabs, lobsters, crayfish, shrimps, brine shrimp, prawn, isopods, ostracods and amphipods.

3.1.1.2 Molluscs

Aquatic organism belonging to the phylum Mollusca in the sub-kingdom Metazoa characterised by soft unsegmented bodies. Most forms are enclosed in a calcareous shell. The different development stages of molluscs are termed larvae, postlarvae, spat, juvenile and adult.

3.2 Approved signatory (read in conjunction with SP6)

3.2.1 The approved signatory for test reports which include diagnosis, recommended treatment, interpretations and opinions shall be a Veterinary Surgeon/Veterinarian or Veterinary Officer as defined in Section 2 of the Veterinary Surgeons Act, 1974 [Act 147].

3.2.2 Approved signatory for test reports that does not contain diagnosis, recommended treatment, interpretations and opinions shall be 3.2.1 or :-

3.2.2.1 Fisheries Officer as defined in Section 4 of the Fisheries Act, 1985 [Act 317].

3.2.2.2 Any qualified person appointed by a National Authority.

3.2.2.3 Any competent laboratory personnel registered with the Malaysian Institute of Chemistry (IKM) as defined by Chemist Act 1975 for chemical testing.

3.2.2.4 Any competent laboratory personnel who possess a minimum qualification of a degree in related area and a working experience in a veterinary/medical, or any other related laboratory for at least 1 year.

3.3 Feed or Feedstuff

Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to animals.

3.4 Specimen

The material of animal origin or material obtained from its immediate environment submitted for testing.

3.4.1 Sample

The material that is derived from a specimen and is used for testing purposes.

3.5 Veterinary Laboratory

A laboratory for testing and examination of materials derived from animal origin, feed or the environment for the purpose of disease diagnosis, monitoring/surveillance and treatment or assessment of health or disease status. This information may be used for trade certification and consultation services covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate actions. The definition also includes fisheries' laboratories.

3.6 National Authority

The competent government body which is responsible for animal and other related fields in Malaysia.

3.7 OIE

Means *Office International des Epizooties* or World Organisation for Animal Health.

4.0 MANAGEMENT REQUIREMENTS

4.1 Organisation

The laboratory shall have a clearly defined organisational structure appropriate to the scope(s) of testing.

The scope(s) of testing may include, but not limited to, the following:

- i) Bacteriology
- ii) Mycology
- iii) Serology
- iv) Virology
- v) Parasitology
- vi) Pathology
- vii) Molecular biology
- viii) Clinical Pathology
- ix) Immunology
- x) Prions
- xi) Chemistry
- xii) Feed analysis
- xiii) Animal nutrition

4.1.1 Head of laboratory qualification

Head of laboratory shall be a practicing veterinary surgeon/veterinarian or veterinary officer, registered with the Malaysian Veterinary Council under the Veterinary Surgeons Act, 1974 [Act 147] with at least 3 years working experience or an appropriately qualified non-veterinarian who possess a minimum of any Science degree in a relevant discipline with at least 5 years of working experience in a veterinary/ medical or other related laboratory.

4.2 QUALITY SYSTEM

The quality documentation shall include all the scope(s) of testing intended for accreditation. In developing its quality system, the laboratory shall make reference to the Normative References (clause 2.0).

4.3 DOCUMENT CONTROL

There is no additional elaboration to MS ISO/IEC 17025.

4.4 REVIEW OF REQUEST, TENDERS AND CONTRACTS

There is no additional elaboration to MS ISO/IEC 17025.

4.5 SUBCONTRACTING OF TEST

There is no additional elaboration to MS ISO/IEC 17025.

4.6 PURCHASING SERVICES AND SUPPLIES

There is no additional elaboration to MS ISO/IEC 17025.

4.7 SERVICE TO THE CLIENTS

There is no additional elaboration to MS ISO/IEC 17025.

4.8 COMPLAINTS

There is no additional elaboration to MS ISO/IEC 17025.

4.9 CONTROL OF NONCONFORMING TESTING WORK

There is no additional elaboration to MS ISO/IEC 17025.

4.10 CORRECTIVE ACTIONS

There is no additional elaboration to MS ISO/IEC 17025.

4.11 PREVENTIVE ACTION

In exercising preventive action process, the laboratory may employ total quality management tools such as risk analysis, root cause analysis, brainstorming, flowcharting, Pareto charts etc. Consideration should also be given to providing staff with a formal mechanism for contributing suggestions for continual improvement.

4.12 CONTROL OF RECORDS

A number of staff may be involved in a test process or laboratory procedure. The laboratory is responsible to identify the critical step(s) and to record the identity of the person(s) involved in the test process or procedure.

4.12.1 Technical records

4.12.1.1 In general, the records shall include the following :-

- i) the specimen identification
- ii) the date of submission of specimen
- iii) the date of the test done
- iv) the test method used
- v) the test equipment used
- vi) original test observations and calculations
- vii) the identity of the personnel performing the test
- viii) an indication that calculations and manual data transfers have been checked, where appropriate
- ix) any other information specified in the test method, other contractual documents or relevant statutory regulations.

4.13 INTERNAL AUDITS

There is no additional elaboration to MS ISO/IEC 17025.

4.14 MANAGEMENT REVIEW

There is no additional elaboration to MS ISO/IEC 17025.

5.0 TECHNICAL REQUIREMENTS

5.1 GENERAL

There is no additional elaboration to MS ISO/IEC 17025.

5.2 PERSONNEL

5.2.1 All laboratory personnel shall be given adequate training opportunities such as in-house and external training and access to appropriate reference texts and journals. All training records shall have sufficient details to proof that personnel are adequately trained.

5.2.2 Personnel who are expected to work in areas other than their normal scope of work shall be adequately trained to undertake the task.

5.3 ACCOMMODATION, ENVIRONMENTAL AND SAFETY CONDITIONS

5.3.1 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 zoonotic pathogens, radioisotopes or carcinogenic chemicals) and to provide a quiet and uninterrupted work environment as required (eg. microscopy).

5.3.2 A safety manual detailing the laboratory’s policies and procedures in relation to health and safety shall be readily available to all staff. Safe laboratory practice is emphasized but the review of safety during an assessment visit should not be considered to constitute a formal safety audit. It is the responsibility of the laboratory to meet the requirement of the Occupational Health and Safety Act, 1994, or other relevant laws and regulations currently enforced in the country.

Note : While safe laboratory practice forms an important part of providing a quality service and will be necessary to achieve the standards required for accreditation, assessment under SAMM does not constitute a formal safety audit.

5.4 TEST METHOD AND METHOD VALIDATION

5.4.1 The laboratory shall use test methods specified by the National Authority, otherwise modified methods shall be validated or verified.

5.4.2 The laboratory may use other methods such as in the “*OIE Manual of Standard for Diagnostic Test and Vaccines*” or as specified by the importing country.

Note : The use of manufacturer method shall be authorized and shall be the latest edition

5.5 EQUIPMENT

5.5.1 The laboratory shall ensure that the equipment used has been validated, as appropriate, for the range of species being tested.

5.5.2 Calibration of equipment shall be carried out. The laboratory may use calibration intervals recommended by the manufacturer.

5.6 MEASUREMENT TRACEABILITY

5.6.1 Reference culture

5.6.1.1 The laboratory shall maintain a collection of cultures of organisms required to verify methods and media performance.

5.6.1.2 Reference cultures shall be traceable to recognized reference culture collections such as NCTC and ATCC.

5.6.1.3 All cultures held by the laboratory shall be uniquely identified and traceable to the source.

5.6.1.4 The laboratory shall maintain procedures covering acquisition, preservation, maintenance and confirmation of cultures in the collection.

5.6.2 Culture Media and Reagent

5.6.2.1 The laboratory shall have records of traceability of the culture media and reagent to quality control results which include preparation, sterilisation batch, batch size and quantity.

5.7 SAMPLING

5.7.1 General

The specimen may be taken from animals and its environment for disease diagnosis, surveillance, health certification or monitoring of response to treatment or vaccination.

A variety of combinations of specimens from different species of animal may be collected. The specimens shall be appropriate for the purpose required and be sufficient in number and quantity. For monitoring and surveillance of animal health, sampling plans shall be based on appropriate statistical methods.

The specimen should be taken with care, to avoid undue stress or damage to the animal or injury to the operator. It is important to adopt aseptic techniques and care should be taken to avoid cross contamination between specimens.

The specimen shall be carefully packed, uniquely labelled and transported to the laboratory by the fastest practicable means, preferably with temperature control when required. Relevant shipping regulations shall be adhered to. A submission form shall accompany the specimen, indicating the name of the sender, the origin of the material, the relevant history, and the test required.

5.7.2 Specimen collection

5.7.2.1 Specimen collection by Laboratory

The laboratory shall have procedures for the collection of specimens to ensure they are both appropriate to the test being undertaken and suitable for testing. Reference may be made to sampling guides such as "*Field Guide to Submission of Specimens, Department of Veterinary Services, Malaysia*", "*OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*" and "*OIE Manual of Diagnostic Tests and Vaccines for Aquatic Animals*".

5.7.2.2 Specimen collected by client

Where specimen collection is outside the control of the laboratory, the collectors shall be informed of the laboratory's collection requirements.

5.8 HANDLING OF SPECIMEN AND SAMPLE

5.8.1 Specimen reception

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

- i) criteria for acceptance/rejection of unsuitable specimens (e.g. containers leaking or broken, specimens collected into wrong containers, specimens unsuitable for the examination requested, inadequately labelled specimen containers);
- ii) action to be taken in the event that an unsuitable specimen is received;
- iii) handling urgent specimens;
- iv) the integrity of specimens, which include transportation, receipt, handling and protection;
- v) the date and the time of receipt of specimens at the laboratory.

5.8.2 Specimen Retention

The laboratory shall have documented procedures for retention and disposal of specimen. The following minimum retention times for specimens shall apply, unless specified by the regulatory authority : -

Haematology

Samples of blood, serum, plasma	7 days
Blood film	14 days

Biochemistry

Samples of serum, plasma and other body fluids	7 days
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Immunology

Samples of material examined	7 days
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Serology

Samples of material examined	7 days
For samples where retesting and/or referral is likely	30 days

Microbiology

Cultures and stained slides	7 days
Swabs, specimens or other material examined	7 days

Parasitology

Samples of material examined	3 days
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Histology

Slides	2 years
Blocks	5 years
Unblocked, fixed tissue	30 days

Cytology and Pathology

Slides	1 year
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Necropsy

Necropsy tissue after sample collection	14 days ($\leq -20^{\circ}\text{C}$)
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Virology/Molecular Biology

Specimens collected for tissue culture work, virus isolation should be as fresh as possible and kept frozen at -20°C to -80°C

7 days ($\leq -20^{\circ}\text{C}$)
3 months ($\leq -80^{\circ}\text{C}$)

Feed Samples

Fresh or dried feed for analysis
Dried and grounded feed
(dried to a stable weight in electric oven at 60°C, samples must be kept in sealed container at room temperature)

3 months ($\leq -20^{\circ}\text{C}$)
1 month

5.9 ASSURING THE QUALITY OF TEST RESULTS

5.9.1 General

- i) Quality control protocols initiated by the laboratory shall take into account the many factors that can influence the frequency with which quality control is performed. Guidance on quality control issues should be sought from publications of the relevant professional organizations.
- ii) Quality control shall be performed, where relevant.
- iii) The quality control material used shall cover the analytical concentrations encountered; low/normal/high, normal/abnormal, positive/negative, reactive/non-reactive controls, as appropriate for the test and species. Where appropriate, acceptable ranges shall be defined for internal quality control material.
- iv) Quality control material shall be analysed for each batch/lot of prepared media, reagents and test kits.
- v) The laboratory shall have procedures for actions to be taken when quality control results fall outside the acceptable range. Details of action taken shall be recorded.
- vi) Internal quality control results shall be recorded and shall be retained for a sufficient period to allow retrospective review. The laboratory shall have a programme for monitoring quality control results to assess test performance.

5.9.2 Specific quality control guidelines for various scopes of testing

5.9.2.1 Bacteriology

5.9.2.1.1 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.

5.9.2.1.2 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.

5.9.2.1.3 Quality control on antimicrobial susceptibility testing must be performed in accordance with the documented method. Departures from recognized international standard methods must be validated.

5.9.2.1.4 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.

iii) 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.

5.9.2.2 Mycology

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

5.9.2.3 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.

5.9.2.4 Serology

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

5.9.2.5 Histopathology

5.9.2.5.1 When using special stains, control slides shall be available for reference.

5.9.2.5.2 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.

5.9.2.6 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.

5.9.2.7 Immunology

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

5.9.2.7.2 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.

5.9.2.7.3 The appropriate working concentration of every new batch of fluorescein labelled Immunoglobulin conjugate shall be determined by checkerboard titration with each different substrate with which it will be used. 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. If using conjugate from one manufacturer and slides from another or in-house slides, then the conjugate will need to be optimized for individual substrates.

5.9.2.8 Virology

5.9.2.8.1 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.

5.9.2.8.2 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.

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

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

5.9.2.9 Molecular biology

5.9.2.9.1 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.

5.9.2.9.2 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.

5.9.3 Proficiency testing

5.9.3.1 When proficiency testing programmes are available locally, the laboratory shall participate in those programmes. When it is not available, alternative measures such as exchange of samples with other laboratories may be considered.

5.10 REPORTING THE RESULTS

5.10.1 Test reports

5.10.1.1 The laboratory may use photographic, electronic and mechanical means for the reproduction of signatures or names of signatories. Test results may be electronically issued provided that the reports have been appropriately authorized for release. Copies of test results shall be retained by the laboratory. The laboratory shall exercise appropriate controls over the electronic generation, access, storage and back-up of results and reports and programme controls such as password protection or downloading into a protected format.

5.10.1.2 Preliminary test reports may be released to the client. The laboratory shall have a documented procedure for issuing preliminary test results, if this applies.

5.10.2 Interpretations and opinions

5.10.2.1 Interpretations and opinions constitute a diagnosis or actions stipulated as practice of veterinary medicine as defined in the Veterinary Surgeons Act, 1974 [Act 147] may be included in the test report.