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

SPECIFIC TECHNICAL REQUIREMENTS 1.6 (STR 1.6)

SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF NUCLEIC ACID TESTING LABORATORIES

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(Supplementary to MS ISO/IEC 17025)

MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
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CLAUSE 5: **TECHNICAL REQUIREMENTS**

NOTE: Clause numbers correspond to those in the standard MS ISO/IEC 17025

5 TECHNICAL REQUIREMENTS

5.1 General

This document describes the requirements for accreditation of laboratories involved in nucleic acid testing in a broad variety of samples. The laboratory concern shall provide services in all/a particular field related to molecular biology and/or genetic analysis. The guidelines, requirement and performance criteria are intended for comparable, accurate and reproducible results. The techniques used in the laboratories cover nucleic acid amplification, sequencing and hybridization.

This document shall be read in conjunction with MS ISO/IEC 17025, STR 1.5 - Specific Technical Requirements for Accreditation of Laboratory Testing for Genetically Modified Organisms (GMO) and other specific criteria published by Department of Standards Malaysia (STANDARDS MALAYSIA).

5.2 Personnel

Skill

The testing laboratory shall have sufficient personnel having appropriate technical knowledge and proficiency. The laboratory shall have skilled and experienced signatory(ies) to validate data and troubleshoot problems. Signatory(ies) shall have sufficient experience, appropriate training and competency in nucleic acid testing methods. The training and experience received by staff shall be documented.

Requirements

- The signatory(ies) shall possess at least a bachelor of science degree in an appropriate science field such as molecular biology, chemistry, biochemistry, microbiology, genetics or biotechnology related field. They should have at least one year working experience in nucleic acid testing techniques.
- The laboratory assistant/technologist shall possess at least Sijil Pelajaran Malaysia (SPM) qualification.

5.3 Accommodation and environment conditions

Laboratories performing nucleic acid testing shall be obliged to demonstrate appropriate measures in order to minimize contamination as well as risk to personnel. The laboratory should have dedicated areas for handling samples, pre and post analysis to minimize cross-contamination. The nucleic acids testing laboratory should be flexible in meeting increased sample volumes, process changes and new technologies.

Laboratory shall comply with the relevant statutory procedures for radioactive handling and waste disposal.

5.4 Test methods and method validation

5.4.1 General

All technical procedures and methods shall be validated before being applied to routine testing. The head of the laboratory is responsible for adequate validation and shall provide all the necessary means to fulfill the task. Records of all validations shall be safely stored for future reference.

Molecular test methods can be divided into two different classes:

1. Qualitative methods (e.g. nucleic acid amplification, genomic DNA- or c-DNA sequencing, RFLP)

2. Quantitative detection methods (e.g. real time PCR, Gene-Array)

Validation of test methods should include at least:

- Specificity (e.g. the specificity of an amplicon shall be confirmed by one or more techniques such as hybridization, sequencing, restriction enzyme analysis)
- Sensitivity
- Linearity and precision within the selected range

  (e.g. for quantitative PCR)
- Reproducibility
- Stability of DNA or RNA in the sample under conditions of the assay
- Ruggedness/robustness of the method

5.4.2 Selection of methods

Whenever possible, standard methods should be used. A laboratory introducing a new method has to demonstrate and to document the performance characteristics of the method used. If new test methods are introduced, the performance characteristics of the procedures shall be verified in the laboratory. The selection and performance of test methods shall be fully documented.

5.4.3 Uncertainty of measurement

Uncertainty of measurement should be estimated for quantitative determination, by means of internationally acceptable procedure, e.g. given in the directives of European co-operation for Accreditation (EA).

5.5 Equipment

As in the standard MS ISO/IEC 17025.

5.6 Measurement traceability

Reference standards and reference material

Reference collections of data which are maintained for identification, comparison or interpretation purposes shall be documented and unequivocally identified. Reference materials shall be identified and stored separately from test samples.

5.7 Sampling

The selection and collection of sample material are important elements of nucleic acid testing methods. The general requirement for sampling shall closely follow the MS ISO/IEC 17025 document. Wherever possible, specific instructions of the CODEX product committees and/or other relevant internationally recognized sampling standards should be met.

5.8 Handling of test items

For sample handling all general and specific rules for preserving stability, safe transportation and prevention of contamination apply.

The traceability of all activities from receipt through preparation, proper analysis, reporting of results, storage to disposal of the sample shall be documented.

5.9 Assuring the quality of test results

The laboratory shall participate in proficiency testing for the tests offered. Where proficiency testing for an analyte is not available, performance assessment shall be conducted at suitable interval by appropriate procedures.

The laboratory shall design internal quality control systems that verify the attainment of the intended quality results and shall include tolerance limits and corrective action procedures when limits are exceeded.

5.10 Reporting the results

Reporting of results shall follow the requirements and recommendation of MS ISO/IEC 17025.

Terminology in reports

1. “Positive” indicates that a particular substance has been identified in accordance with the laboratory protocols. “Negative” (“not detected” would be preferable instead) indicates that particular substances were absent within the limitations of the test(s) performed.
2. Mutational nomenclature strictly follows international guidelines.
3. For gene expression profiling (expressed or repressed in a given specimen) it is recommended that reporting needs to follow the general rules.

Units shall comply with or be in reference to generally established nomenclature used in the field.

Referred tests

Results of tests performed by subcontracted laboratory may be incorporated into the laboratory report but shall be clearly indicated as such.

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