



**STANDARDS**  
MALAYSIA

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

**SC 2.1 - SPECIFIC CRITERIA  
FOR ACCREDITATION IN THE FIELD OF  
MEDICAL MOLECULAR TESTING**

*Issue 1, 14 November 2017*  
(Supplementary to MS ISO 15189)



**JABATAN STANDARD MALAYSIA**  
**Department of Standards Malaysia**

## **TABLE OF CONTENTS**

		<b>Page</b>
<b>1</b>	<b>Introduction</b>	<b>1</b>
<b>2</b>	<b>Scope</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions</b>	<b>1</b>
<b>4</b>	<b>Management requirements</b>	<b>2</b>
4.1	Organisation and management responsibility	2
4.2	Quality management system	3
4.3	Document control	3
4.4	Service agreements	3
4.5	Examination by referral laboratories	3
4.6	External services and supplies	3
4.7	Advisory services	4
4.8	Resolution of complaints	4
4.9	Identification and control of non-conformities	4
4.10	Corrective Action	4
4.11	Preventive Action	4
4.12	Continual improvement	4
4.13	Control of Records	4
4.14	Evaluation and Audits	4
4.15	Management Review	5
<b>5</b>	<b>Technical requirements</b>	<b>6</b>
5.1	Personnel	6
5.2	Accommodation and environmental conditions	10
5.3	Laboratory equipment, reagents, and consumables	11
5.4	Pre-examination processes	11
5.5	Examination processes	12
5.6	Ensuring quality of examination results	12
5.7	Post-examination processes	13
5.8	Reporting of results	13
5.9	Release of results	14
5.10	Laboratory information management	14
<b>Appendix 1</b>	<b>Classes/ sub-classes of test/ test platform</b>	<b>15</b>
<b>Appendix 2</b>	<b>Table 1- Recommended calibration and performance check of equipment commonly used in the medical molecular testing laboratories</b>	<b>16</b>
<b>References</b>		<b>19</b>
<b>Acknowledgements</b>		<b>21</b>

## SPECIFIC CRITERIA FOR ACCREDITATION IN THE FIELD OF MEDICAL MOLECULAR TESTING

**1 Introduction**

- 1.1 This document describes the requirements for accreditation of medical molecular testing laboratories involved in nucleic acid testing in a broad variety of human samples.
- 1.2 This document should be read in conjunction with the MS ISO 15189 standard.
- 1.3 Clause numbers correspond to those in the standard which require elaboration.

**2 Scope of accreditation**

The areas for which accreditation offered are:

- 2.1 Inherited diseases
- 2.2 Cancer genetics
- 2.3 Infectious diseases
- 2.4 Immunogenetics
- 2.5 Pharmacogenomics

Please refer to **Appendix 1** for classes/ sub-classes of test/ test platform.

**3 Terms and definitions**

All terms and definition given in MS ISO 15189.

- (i) Medical molecular testing laboratory - any services in the molecular analysis of nucleic acid derived from human tissue or fluid or any other product of the human body.
- (ii) Result - data without clinical interpretation and may have a descriptive comment.  
Examples of descriptive comments:
  - a) Medical molecular testing
    - point mutation detected
    - deletion detected
    - xx mutation not detected
  - b) Quantitative analysis
    - 10,000 copies/ml
    - 2.4x risk of having colorectal cancer
    - normal allele detected with approximately 32 CGG repeats and no expansion in the FMR1 (NM\_002024.4) gene
- (iii) Report - interpretative report issued containing clinically relevant inferences from test results or analytical findings.  
Example:
  - Fragile X diagnosis is unlikely but not ruled out (approximately 1% possibility of point mutation or gene deletion)
  - Duchenne muscular dystrophy gene mutation with in-frame deletion of the gene

detected. Parental blood sample is required. Genetic counseling is recommended.

- (iv) Authorised requester (Clause 5.4.1 of MS ISO 15189)  
A medically-qualified practitioner or his/her authorised designee (e.g. genetic counselor, qualified staff nurse) or a person acting under a medicolegal directive (e.g. enforcement officer).
- (v) Person authorised to receive laboratory test result and report (Clause 5.8.3 of MS ISO 15189) - The person authorised to receive the laboratory test result or report shall be the authorised requester or his/her authorised designee.
- (vi) Subject Matter Experts (SME) is a person with knowledge and expertise in a specific subject or technical area.

## **4 Management requirements**

### **4.1 Organisation and management responsibility**

#### **4.1.1.4 Laboratory director (person-in-charge)**

The laboratory director shall be the person-in-charge of the services of the laboratory and should be resident to the laboratory. There may be more than one laboratory director if the scope of services provided by the laboratory extends over more than one specialty of pathology such that a single laboratory director may not have the competence to assume responsibility for all the services provided. Where national regulations apply, statutory requirements with regard to competence, qualifications and experience of the laboratory director (person-in-charge) shall be complied with.

**Note:** 'Resident' connotes that the laboratory director works in-house and the laboratory is the main place of professional practice.

The laboratory director shall be:

- a) Medically qualified pathologist (i.e. a medical practitioner registered with the Malaysian Medical Council, with a postgraduate qualification in pathology approved by the Government of Malaysia) and a minimum of three (3) years working experience as a pathologist; or
- b) Registered medical practitioner with relevant molecular testing laboratory experience of at least seven (7) years; or
- c) Scientist with appropriate qualification and laboratory experience in molecular testing laboratory of at least seven (7) years.

The laboratory director and his designees are regarded as key personnel. Key personnel shall normally include:

- (a) Quality manager;
- (b) Technical manager;

- (c) Document controller;
- (d) Subject Matter Expert.

#### **4.1.1.4c) Sufficiency of staff to meet needs**

The appropriateness of Subject Matter Experts (SMEs) (technical or clinical personnel) engaged shall be interpreted using the following guidelines:

- (a) Where there is insufficient or no resident SME to provide the clinical input or advisory services required in Clause 4.7, the services of a visiting SME with relevant experience should be engaged.
- (b) The laboratory shall engage the services of technical personnel trained in medical molecular testing under the scope of accreditation. Where resident technical personnel are unable to cover all the services offered, suitably qualified and experienced part-time technical personnel shall be engaged.
- (c) There shall be at least one (1) technical personnel present in the laboratory, during all working hours.

#### **4.2 Quality management system**

As in MS ISO 15189

#### **4.3 Document control**

As in MS ISO 15189

#### **4.4 Service agreements**

- 4.4.1 Where a laboratory is a part of a hospital and provides in-house services to the hospital, the internal arrangement between the hospital management and the laboratory management may be considered as an agreement and the requirements of this clause apply. The agreement may be in the form of a request form, memorandum, manual, circular, letter, minutes of a meeting, etc. which shall be controlled.

#### **4.5 Examination by referral laboratories**

- 4.5.1 In exceptional circumstances where an examination is sought on an esoteric or unusual condition, and the request is urgent, one-off or ad-hoc in nature, the examination may be referred to a laboratory or a second opinion sought from an individual, without prior management evaluation. The reasons for such a referral shall be documented by the appropriate laboratory director or key personnel, to show why this referral is in the best interest of patient care.

This clause does not apply where a sample is to be examined by another laboratory, as arranged by a requester and the pathology laboratory merely acts as a handling centre on behalf of the requester. The examination results of such samples shall not be issued under the name of the pathology laboratory and the laboratory shall not make any statement on its accreditation status regarding the examination results.

#### **4.6 External services and supplies**

As in MS ISO 15189

**4.7 Advisory services**

SMEs should be available to provide relevant advice prior to test ordering and to advise on the interpretation of test results. A laboratory handbook provides guidance to authorised requester on the choice and cost of tests.

**4.8 Resolution of complaints**

As in MS ISO 15189

**4.9 Identification and control of non-conformities**

As in MS ISO 15189

**4.10 Corrective Action**

As in MS ISO 15189

**4.11 Preventive Action**

As in MS ISO 15189

**4.12 Continual improvement**

The important aspects to monitor and review are:

- (a) test repertoire, including standard testing profiles, reflex testing, procedures for follow up and confirmatory testing;
- (b) methodology which involve amplification and technical precision instrumentation considerations, including specificity, sensitivity and uncertainty of results, in relation to clinical decision making;
- (c) recent update and advances in relation to the identification of previous variants of unknown clinical significance emerging as being disease associated.

**4.13 Control of records**

4.13.1 A copy of examination results and reports issued shall be kept in the record system or it shall allow one to be reproduced upon request.

4.13.2 Minimum retention periods for patient records and specimens shall conform to relevant national guidelines / regulations where available such as College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.

**4.14 Evaluation and audits**

4.14.1 - 4.14.4

As in MS ISO 15189

**4.14.5 Internal audit**

Auditors shall have adequate knowledge in MS ISO 15189 and receive relevant training to conduct internal audit.

The elements to be audited may include but not limited to the following:

- (a) staff awareness of the quality manual;
- (b) analytical procedure selection, control and validation;
- (c) control of reagents and standards;
- (d) equipment calibration and maintenance records;
- (e) proficiency testing and inter-laboratory comparison;
- (f) audit trails in quality and technical records;
- (g) personnel training records;
- (h) handling of deficiencies and remedial action; and
- (i) laboratory housekeeping and health and safety measures.

#### **4.14.6 Risk management**

The laboratory shall identify and document potential failures in its quality management system including the pre-examination, examination and post examination work processes which affect examination results using methods such as Failure Mode and Effect Analysis (FMEA) or similar risk assessment tools. Periodic evaluation of one or more of the following indicators may be conducted:

- (a) Specimen;
- (b) Test system (Equipment and methodology);
- (c) Reagents;
- (d) Environment;
- (e) Personnel.

Reference may be made to the following documents:

- (a) MS ISO 31000 – Risk Management – Principles and Guidelines on Implementation;
- (b) MS IEC/ISO 31010 – Risk Management – Risk Assessment Techniques;
- (c) MS ISO Guide 73 – Risk Management – Vocabulary;
- (d) MS 2370 – Medical Laboratories – Reduction of Error through Risk Management and Continual Improvement.

#### **4.15 Management review**

As in MS ISO 15189

## **5 Technical requirements**

### **5.1 Personnel**

#### **5.1.1 General**

The laboratory shall have documented procedures and maintain records that includes recruitment, appointment and assignment of all managerial, clinical, scientific and technical personnel and their performance appraisals based on predetermined individual targets. The recruitment and qualifications of laboratory personnel shall be in compliance with relevant existing laws in the country.

#### **5.1.2 Personnel qualifications**

The competency of personnel is a major aspect of each laboratory assessment as the standard of performance depends heavily on the competence of the laboratory's personnel.

Four (4) categories of personnel will be assessed. They are:

- (a) Technical personnel;
- (b) Scientific personnel;
- (c) Clinical personnel; and
- (d) Management personnel.

#### **a) Technical personnel**

A technical personnel refers to staff who perform molecular technical work. They shall have suitable qualifications and training with sufficient experience and ability to perform the required task. This shall be evidenced by:

- i) a Diploma in Medical Laboratory Technology or an equivalent, recognised by the Government of Malaysia and at least one (1) year of supervised training in the relevant area of the laboratory service (as post-diploma training); and

#### **b) Scientific personnel**

A scientific personnel refers to staff who perform and evaluate advanced and high-end technical work. They shall have suitable qualifications and training with sufficient experience and ability to perform the required task. This shall be evidenced by:

- a) Doctorate of Philosophy in a subject relevant to the field of molecular biology / molecular genetics / human genetics recognised by the Government of Malaysia with at least one (1) year experience in molecular diagnostics; or
- b) Masters of Science Degree in a subject relevant to the field of molecular biology / molecular genetics / human genetics recognised by the Government of Malaysia with at least three (3) years' experience in molecular diagnostics; or

- c) Bachelor of Science Degree or equivalent qualification in a subject relevant to the field of molecular biology / molecular genetics/human genetics recognised by the Government of Malaysia with at least five (5) years' experience in molecular diagnostics.

### **Records of evaluation of competence in the tasks assigned to the person.**

The laboratory shall ensure that technical and scientific personnel assigned to perform new or rarely used techniques undergo appropriate training. Records of training and assessments of competence shall be kept. These shall include records of results of examinations/tests performed during training and competence assessments. The validity of results produced by technical personnel, particularly in the first six months after completion of training in new techniques shall be monitored.

Personnel who are physically challenged may affect the performance of certain types of laboratory tests. It is the responsibility of the laboratory management to assign duties and take appropriate steps to ensure that validity of results and laboratory safety are not compromised.

### **c) Clinical personnel**

Clinical interpretation of test results shall be provided by a medically qualified person who has obtained post graduate qualification in appropriate specialty plus two (2) years post graduate laboratory experience in molecular genetics.

A service medical officer can also provide clinical interpretation provided they are under the direct supervision of a medically qualified person as mentioned above.

### **Visiting pathologists**

A visiting pathologist is a medically-qualified pathologist who periodically visits a laboratory and provides services in areas where the laboratory director, or other personnel of the laboratory, cannot adequately discharge the responsibilities that are appropriate to the services provided by the laboratory. These services may be supervisory or the provision of clinical interpretation of examination/test results or the performance of examinations or other services.

The visiting pathologist shall be qualified in the specialty where he/she is providing services and shall comply with the competence requirements of clinical personnel.

A formal and written arrangement between the laboratory and the visiting pathologist shall be established. The arrangement shall ensure that:

- (i) an effective working relationship between the laboratory director and visiting pathologist is established;
- (ii) advices and recommendations of the visiting pathologist are acted upon within the required timeframe;
- (iii) the frequency and duration of visits are defined and appropriate to the volume and scope of work undertaken by the visiting pathologist. This may take into account the availability of electronic links, which enable remote supervision of laboratory output;

- (iv) the functions, roles and activities of the visiting pathologist as well as his/her authorities and responsibilities are clearly defined;
- (v) records of input by the visiting pathologist are kept, the means by which the visiting pathologist can be contacted in cases when his/her advice is required urgently is established;
- (vi) an effective system to allow the provision of clinical advice as well as signing of examination reports by the visiting pathologist within a timescale appropriate to the clinical situation is in place; and
- (vii) liabilities of the examination results and their interpretations are clearly defined.

#### **d) Management Personnel**

The quality management team shall include the relevant key personnel and at least a medically qualified personnel as mentioned in para (clinical personnel) who may be a visiting pathologist.

The technical manager of the laboratory (or section) may be a medically qualified personnel, a scientist in the relevant areas, or medical laboratory technologist with specialised training and/or appropriate experience in molecular genetics.

The suitability of personnel in performing their management shall be assessed. Aspects that will be considered include:

- (a) the qualifications and professional experience of persons with management;
- (b) the workload of the laboratory and the range of tests offered;
- (c) the contact that managers maintain with subordinate staff; and
- (d) the involvement of managers in the development of methodology and adoption of new methodology within the laboratory.

**Persons with supervisory roles** shall have sufficient authority, skills and experience to train and supervise subordinate personnel.

#### **Contracted personnel**

When a laboratory uses contracted personnel irrespective of the duration of the contract and whether the contracted personnel member is employed on a full-time or part-time basis, the laboratory shall ensure that the requirements for staff competence are met. Evaluation of the competence of these staff shall be carried out and records kept. Where necessary, training shall be provided, particularly with regard to those parts of the laboratory quality management system that are relevant to their assigned duties. Direct supervision may be required initially to ensure that the contracted personnel are competent in carrying out their duties.

#### **5.1.3 Job descriptions**

##### **Responsibilities of key personnel**

- (i) Key personnel would be expected to have:

- A position in the staff organisational chart which provides for the authority to implement necessary changes in the laboratory operation to ensure the integrity of test results is maintained.
  - A working knowledge of the quality assurance system and operation of the laboratory on a day-to-day basis.
  - A working knowledge of and commitment to the requirements for SAMM accreditation, including the quality and technical management principles embodied in MS ISO 15189 and relevant SAMM criteria/requirement.
  - The necessary expertise and experience to be aware of, and understand, any limitation of the test procedures, and to understand fully the scientific basis of the procedures.
- (ii) Key personnel can be given both the responsibility and authority to:
- Develop and implement new operational procedures.
  - Design quality control programmes, set action criteria and take corrective action when these criteria are exceeded.
  - Identify and resolve problems.
  - Take responsibility for the validity of the outputs.
- (iii) Clinical, scientific and technical personnel who are not engaged full-time could also be appointed as key personnel. However, the circumstances in which they are called upon to exercise their key personnel responsibilities and their access to and knowledge of the laboratory's operations, should be such that they are able to take full responsibility for the work they undertake, authorise or oversee.

### **5.1.6 Competence assessment**

The competency of all clinical, scientific and technical personnel to perform assigned tasks shall be reassessed, at least once in two years. Personnel who undertake duties after a significant period of absence as specified in the laboratory policy are expected to undergo reassessment and retraining if necessary. Records of training and competency attainment shall be endorsed by both trainer and trainee.

### **5.1.8 Continuing education and professional development**

Continuing education and continuing professional development are important for maintaining competence of clinical, scientific and technical personnel. These include in-house and external activities and use of appropriate reference texts and journals. Examples are:

#### External

- Attendance at professional conferences, seminars and lectures.
- Educational attachments or visits to other laboratories.
- Participation in training courses and workshops.

### Internal

- Regular educational presentations
- Journal article reviews
- Case presentations
- Participation in research activities
- Review of QAP educational material
- Review of interesting/abnormal cases

As a guideline for a minimum level of participation, all clinical personnel would be expected to spend at least 42 hours in a year and all technical personnel would be expected to spend at least 20 hours in a year participating in these activities, unless otherwise directed by the accreditation body following a peer-review assessment.

## **5.2 Accommodation and environmental conditions**

### **5.2.6 Facility maintenance and environmental conditions**

Laboratories performing medical molecular 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 testing laboratory should be flexible in meeting increased sample volumes, process changes and new technologies.

The laboratory shall comply with the relevant statutory procedures for accommodation, environmental conditions, radioactive handling and waste disposal. The laboratory should be designed to ensure a comfortable and safe working environment. Reference may be made to the following documents:

- Establishing Molecular Testing in Clinical Laboratory Environments, Approved Guideline (CLSI);
- American College of Medical Genetics – Standards and Guidelines for Clinical Genetics Laboratories 2008 Edition;
- WHO Laboratory Biosafety Manual;
- College of Pathologists, Academy of Medicine Malaysia guidelines;
- Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations);
- Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010.

## **Safety**

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

National authorities are responsible for occupational health and safety in laboratories. However, it is an expectation of the standard that all applicable standards and guidelines relating to medical laboratories in Malaysia, and recognised best practice, shall be implemented. Attention shall be drawn to any unsafe practices that are encountered. Where instruction and advice related to safety are written into test methods covered by accreditation, these shall also be observed.

A safety manual detailing the laboratory's policies and procedures in relation to health and safety shall be readily available to staff.

Due consideration shall be given to separating certain procedures from the main work area for the safety of workers, the protection of the environment and to maintaining the validity of the result. Such procedures include but are not limited to:

- (a) those that may pose a hazard to other staff (e.g. tests using potentially carcinogenic reagents, contagious specimen, volatile substances, radioactive materials); and
- (b) those procedures which may be affected or influenced by not being segregated (e.g. tissue culture, PCR work).

### **5.3 Laboratory equipment, reagents, and consumables**

As in MS ISO 15189

#### **5.3.1.4 Equipment calibration and metrological traceability**

Reference should be made to SAMM Policy 2. Test or calibration equipment that has a significant effect on the reported results and associated uncertainties of measurement (including, where relevant, instruments used for monitoring environmental conditions) shall be calibrated by (one or more) of the following:

- (a) Standards Malaysia accredited calibration laboratories.
- (b) Calibration laboratories accredited by one of Standards Malaysia's Mutual Recognition Agreement (MRA) partners.

**Note:** An endorsement relating only to ISO 9001 certification is not acceptable.

Standards Malaysia may expect reduced, or accept extended, calibration intervals based on such factors as history of stability and accuracy and precision requirements. It is the responsibility of the laboratory to provide clear evidence that its calibration and maintenance system ensures confidence that the equipment is maintained. Recommended calibration and/or performance check interval are available in **Appendix 2: Table 1**. Reference may also be made to ILAC G 24- Guidelines for the Determination of Calibration Intervals of Measuring Instruments.

### **5.4 Pre-examination processes**

The selection and collection of sample materials are important elements in medical molecular testing methods. The general requirement for sampling shall closely follow the MS ISO 15189 document.

- 5.4.3 All specimens accepted by the laboratory for testing shall be labeled in accordance with procedures defined. As a minimum, the specimen label shall carry the following:

- Two unique identifiers (e.g. name of patient and patient identification number);
- Type of sample (e.g. body fluid, tissue) and anatomic site of origin; and
- Date and time of sampling (if applicable).

5.4.4 Each sample received shall be uniquely identified and matched to the accompanying request form by at least two unique identifier. Where two or more samples accompany a request form, these shall be distinguishable from each other in both the labels and request form.

5.4.6 Sample identification should be traceable constantly at all stages of sample processing (e.g. specimen receipt, nucleic acid extraction, endonuclease digestion, amplification, electrophoresis, photography and storage).

## **5.5 Examination processes**

### **5.5.1 Selection, verification and validation of examination procedures**

#### **5.5.1.1 General**

Each procedure shall be authorised and dated by the responsible key personnel.

Review of methods shall be documented. Where there are no changes, a date and signature will be sufficient. Some manufacturers provide method documentation (product inserts) with their product and these may be included in method manuals. These shall be authorised as above. Where this information is not sufficiently detailed to cover all required elements it shall be supplemented by the laboratory. Inserts for new batches received shall be checked for changes in procedure and a copy of the new insert placed in the manual.

Where a test may be performed by more than one method, there shall be documented criteria for method selection. Where relevant, the degree of correlation between the methods shall be established and documented.

#### **5.5.3 Documentation of examination procedure**

In addition to Clause 5.5.3 a) - t) of the MS ISO 15189 standard, this information shall be included:

- (a) Type of sample (e.g. body fluid, tissue and blood) and anatomic site of origin, where applicable; and
- (b) Limitation of the examination procedure. Reference may be made to Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations).

## **5.6 Ensuring quality of examination results**

### **5.6.2 Quality control**

Positive (including low positive) and/or negative controls shall be run for every batch of analysis. Its performance shall be reviewed based on acceptance or rejection criteria and the analytical problems rectified.

**Note:** For panels with multiple targets, systematic rotation of controls may be acceptable.

### **5.6.3 Interlaboratory comparisons**

5.6.3.1 The laboratory shall subscribe to at least one external quality assurance programme or inter-laboratory comparison (national or international) for each test or related group of test or test method where relevant under the scope of accreditation.

The order of preference for choosing an ILC programme should be:

- i) An EQA programme accredited to ISO/IEC 17043;
- ii) Recognised EQA programme;
- iii) Interlaboratory comparison between accredited labs;
- iv) Interlaboratory comparison between non-accredited labs.

Where such ILC programmes are not available, the laboratory shall develop appropriate quality control activities in compliance to MS ISO 15189 Clause 5.6.3.2.

### **5.6.3.2 Alternative approaches**

The frequency of participation in the interlaboratory comparison (ILC) shall be referred to SAMM Policy 4.

## **5.7 Post-examination processes**

All samples shall be retained in accordance with national guidelines e.g. College of Pathologists, Academy of Medicine Malaysia Guidelines.

### **5.7.2 Storage, retention and disposal of clinical samples**

#### **Storage of Nucleic Acids Extract**

Nucleic acids should be processed promptly and stored appropriately to minimize degradation. Samples should be reassessed for integrity before use if stored for prolonged periods of time at any temperature.

## **5.8 Reporting of results**

### **5.8.1 General**

Approvals for providing interpretations and signing *Skim Akreditasi Makmal Malaysia* (SAMM) endorsed reports containing interpretations will be granted to those personnel who are found to fulfill the relevant requirements. The responsibility for interpretation of the laboratory's test results remains with the approved person(s). This responsibility cannot be delegated to other persons. The person giving the interpretations shall authorise the release of the report containing his/her interpretation personally.

Department of Standards Malaysia (Standards Malaysia) shall be informed of departure or changes in the availability of the persons approved for giving interpretations as soon as possible. Standards Malaysia will take the necessary actions such as amendment of the

scope of accreditation of the laboratory regarding the availability of consultation and interpretation services, or suspension of the laboratory's accreditation, depending on the circumstances.

### **5.8.3 Report content**

For medical molecular testing report shall follow international guidelines such as:

- i) Human Genome Variation Society (HGVS) nomenclature;
- ii) EMQN Best Practice;
- iii) ACGS General Genetic Laboratory Reporting Recommendations;
- iv) Recommendations for Reporting Results of Diagnostic Genetic Testing (Biochemical, Cytogenetic and Molecular Genetic), M Claustres et al., European Journal of Human Genetics (2014) **22**, 160–170.

### **5.9 Release of results**

Even though, transcription of results are not encouraged, when data are transcribed manually into an electronic database or otherwise, there shall be a means of checking the accuracy of transcriptions and entries. Wherever relevant, checking should be performed by an independent operator.

#### **Electronic transmission of results**

It is essential that the integrity of data and confidentiality requirements are met during the transfer of results by any electronic system.

Where the clinician requests the electronic transmission of results from the laboratory to a remote location, the responsibility for ensuring the integrity of data transfer to the referring clinician and other designated addressee, rests with the laboratory.

### **5.9.3 Revised reports**

Additional information may be added as an addendum to the original report, if necessary/required.

### **5.10 Laboratory Information System**

As in MS ISO 15189.

**CLASSES/ SUB-CLASSES OF TEST/ TEST PLATFORM**

- i) Sanger sequencing
- ii) Prenatal genetic testing (excludes Non-invasive prenatal screening)
- iii) Pre-implantation genetic testing
- iv) Genetic testing for constitutional gene variants (diagnostic and carrier testing)
- v) Predictive genetic testing
- vi) Pharmacogenetic testing
- vii) Genetic testing for mosaic gene variants (cancer and somatic mosaicism)
- viii) Screening for an unknown mutation
- ix) Assay for a defined mutation or polymorphism
- x) Assaying heterozygous loci
- xi) Calculated estimate of risk of inheritance of an unknown mutation (Bayesian and linkage calculations)
- xii) Massively parallel sequencing
- xiii) Non-invasive prenatal screening
- xiv) Detection and characterisation of cell free DNA in cancer screening
- xv) Infectious disease
- xvi) Miscellaneous tests

**TABLE 1: RECOMMENDED CALIBRATION AND PERFORMANCE CHECK OF EQUIPMENT  
COMMONLY USED IN THE MEDICAL MOLECULAR TESTING LABORATORIES**

S/N	Type of Instrument or Equipment	Maximum Period Between Successive Calibrations or Performance Checks
1.	Anaerobic jars and cabinets	Each use: Check using indicators, vacuum gauge or control cultures.
2.	Analyzers <ul style="list-style-type: none"> <li>• Automated</li> <li>• blood gas</li> <li>• electrolyte</li> <li>• glucose</li> <li>• oxygen</li> <li>• protein</li> </ul>	Check using appropriate controls and standard materials with frequency depending on the particular use of the equipment and manufacturer's recommendation.
3.	Atomic absorption spectrophotometers	6 monthly: Check for sensitivity, baseline variation, background correction, and optimisation parameters.
4.	Autoclaves	(a) When used: Check for temperature and pressure on display. (b) Use autoclave tape to check performance; use biological indicator where appropriate. (c) Every 2 years: Calibrate gauges. (d) Register with the Ministry of Manpower.
5.	Balances and scales	(a) When used: Zero point check. (b) Yearly: Calibration by accredited calibration laboratory for repeatability, linearity and accuracy. Use 10 weighing of a mass having a value close to the maximum load of balance.
6.	Biological Safety Cabinet & Laminar flow	Yearly: Certified to ensure filters are functioning properly and that airflow rate meet specifications.
7.	Centrifuges	Yearly: <ul style="list-style-type: none"> <li>(a) Check temperature using a calibrated thermistor, or more frequently if required, and</li> <li>(b) Check speed using a calibrated tachometer.</li> </ul>
8.	Chromatography, Gas	Instrument must be routinely monitored during use with standard reference materials. System components (e.g. integrators, ovens, electronic amplifiers and detectors) must also be checked periodically, and records kept.
9.	Chromatography, Liquid & (HPLC)	Liquid chromatography, including high performance (or high pressure) liquid chromatography (HPLC) and ion chromatography :  The total system must be monitored during use with reference standards. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e.g. pumping system and detectors) must be subject to periodic checks and details must be recorded.
10.	Counter <ul style="list-style-type: none"> <li>• beta</li> <li>• cell</li> <li>• gamma</li> </ul>	Each use: Check using appropriate controls and standard materials

S/N	Type of Instrument or Equipment	Maximum Period Between Successive Calibrations or Performance Checks
	• particle size	
11.	Deionizers	(a) Daily or when used: Check for conductivity using conductivity meter. (b) 6 monthly: Check for sterility
12.	Densitometers	6 monthly: Check for linearity.
13.	DNA-sizing equipment	Instrument performance must be routinely monitored during use with control samples.
14.	Electrophoresis	Instrument performance must be routinely monitored using the appropriate controls. System components (e.g. electrodes, tank and power supply), must be checked periodically.
15.	Flame photometers	Each use: Check using appropriate controls and standard materials.
16.	Freezers	(a) Daily: Check temperature using a thermometer. (b) Yearly: Check temperature with a reference thermometer.
17.	Glassware	(a) Volumetric glassware (burettes, pipettes, and volumetric flasks). Once – before first use. (b) Volumetric glassware for general use. Need and extent of calibration to be appropriate for intended use.
18.	Haematocrits	Yearly: Check speed using a calibrated tachometer.
19.	Haemoglobinometers	Twice weekly: Check using the appropriate controls and standard materials.
20.	Heating Baths	Daily or When used: Check temperature with a thermometer.
21.	Heating Blocks	For use analytical measurement or critical procedure: each day of use - by thermometer.
22.	Incubators	(a) Daily: check for temperature, using a calibrated thermometer. To maintain temperature to accuracy of $\pm 2^{\circ}\text{C}$ or within a given range as stipulated in methods. (b) Yearly: temperature checks, using a reference thermometer. (c) Carbon dioxide incubator (microbiology): check carbon dioxide content daily using built-in gauge; 6 monthly using fyrite device or equivalent device.
23.	Manometers	(a) Reference: 10 years (complete) and check fluid every 3 years. (b) Working : 3 years (Check against reference)
24.	Masses	Reference: 3 years initial, 6 years subsequent.
25.	Microscopes	(a) Regular cleaning and maintenance. Clean stage and lenses after use. (b) Yearly: Service maintenance.
26.	Microscopes, Fluorescent	(a) Check for the used time of UV bulb. Bulb should be changed when time reaches 200-300 hours or depending on life-span of bulb. (b) Yearly: Service maintenance.
27.	Ovens	(a) Drying oven. By thermometer – frequency appropriate to use. (b) Sterilizing oven (Hot air oven). Daily using thermometer.
28.	pH Meters	Daily or When used: Check for accuracy. Bracket pH value expected as closely as possible with buffers.
29.	Piston-operated volumetric apparatus • Pipettes and	Every 6 months: For gravimetric checks, volume delivery and weighing under specified conditions must be repeated at least 10 times. For adjustable devices check volume delivered at several

S/N	Type of Instrument or Equipment	Maximum Period Between Successive Calibrations or Performance Checks
	Dispensers	settings. Delivery of volumes less than 100uL may be verified by spectrometry using a dye solution.
30.	Refrigerators	(a) Daily: Temperature checks, using calibrated thermometer. (b) Yearly: Temperature checks, using reference thermometer.
31.	Spectrophotometers <ul style="list-style-type: none"> <li>• UV–visible Spectrophotometer / colorimeter</li> </ul>	6 monthly: (a) Wavelength accuracy and reproducibility. Run two spectra. (b) Photometric accuracy and reproducibility.
32.	Sterilizers, gas	Each use: Using biological indicators.
33.	Stop Watches	Yearly: Calibration by accredited calibration organisation.
34.	Tachometers	(a) Reference: 5 years (b) Working : Once a year
35.	Thermocouples	Yearly: calibration by accredited calibration organisation.
36.	Thermometers	(a) Reference : <ul style="list-style-type: none"> <li>• 2 Yearly: Specific points check by accredited calibration organisation.</li> </ul> (b) Working : <ul style="list-style-type: none"> <li>• Yearly: Temperature is checked at specific point using reference thermometer.</li> </ul>
37.	Timing Devices	Yearly: Verification.
38.	Temperature-controlled equipment	<p>The performance of water baths, incubators, ovens and refrigerators must be monitored continuously to ensure compliance with the temperature requirements of test methods.</p> <p>Accordingly, daily-recorded checks of the temperature within the load space of these items of equipment must be maintained.</p> <p>The thermometers used to monitor the performance of temperature-controlled equipment must be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods.</p> <p>The spatial distribution of temperature throughout the load space of temperature-controlled equipment may be checked following installation of equipment and at appropriate intervals thereafter.</p> <p>Temperature recording devices must be checked at yearly intervals against a reference thermometer and the results recorded.</p>
39.	Water Bath	<p>Daily or when used: Check the temperature using a calibrated thermometer contained in water bath.</p> <p>Maintain the accuracy of <math>\pm 1^{\circ}\text{C}</math> of the requirement. Record water bath thermometer correction factor and attach to water bath.</p>
40.	Water purifiers	(a) Daily or When used: In-line check for conductivity. For instruments without in-line checks: weekly off-line check for conductivity. (b) 6 monthly: Check for sterility.

**References:**

1. ACGS General Genetic Laboratory Reporting Recommendations ([http://www.acgs.uk.com/media/949852/acgs\\_general\\_genetic\\_laboratory\\_reporting\\_recommendations\\_2015.pdf](http://www.acgs.uk.com/media/949852/acgs_general_genetic_laboratory_reporting_recommendations_2015.pdf)).
2. American College of Medical Genetics – Standards and Guidelines for Clinical Genetics Laboratories 2008 Edition.
3. College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.
4. EMQN Best Practice (<https://www.emqn.org/emqn/Best+Practice>).
5. Establishing Molecular Testing in Clinical Laboratory Environments, Approved Guideline (CLSI).
6. Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010 ([http://www.moh.gov.my/images/gallery/GarisPanduan/Guidelines\\_on\\_Chemical-1.pdf](http://www.moh.gov.my/images/gallery/GarisPanduan/Guidelines_on_Chemical-1.pdf)).
7. Human Genome Variation Society (HGVS) Nomenclature (<http://www.hgvs.org/mutnomen/>).
8. ILAC G 24- Guidelines for the Determination of Calibration Intervals of Measuring Instruments.
9. MS 2370 – Medical Laboratories – Reduction of Error through Risk Management and Continual Improvement.
10. MS ISO 15189 – Medical Laboratories – Requirements for Quality and Competence.
11. MS ISO 31000 – Risk Management – Principles and Guidelines on Implementation.
12. MS IEC/ISO 31010 – Risk Management – Risk Assessment Techniques.
13. MS ISO Guide 73 – Risk Management – Vocabulary.
14. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations) (<http://www.dosh.gov.my/index.php/en/legislation/regulations-1/osha-1994-act-154/522-pua-131-2000-1/file>).
15. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations) ([http://www.federalgazette.agc.gov.my/output/pua\\_20131011\\_P%20U%20%20%28A%29%20310-peraturan-peraturan%20keselamatan%20dan%20kesihatan%20pekerjaan%20%28pengelasan%20pela%20belan%20dan%20helaian%20data%20keselamatan%20bahan%20kimia%20berbahaya%29%202013.pdf](http://www.federalgazette.agc.gov.my/output/pua_20131011_P%20U%20%20%28A%29%20310-peraturan-peraturan%20keselamatan%20dan%20kesihatan%20pekerjaan%20%28pengelasan%20pela%20belan%20dan%20helaian%20data%20keselamatan%20bahan%20kimia%20berbahaya%29%202013.pdf)).
16. Recommendations for Reporting Results of Diagnostic Genetic Testing (Biochemical, Cytogenetic and Molecular Genetic), M Claustres et al., European Journal of Human Genetics (2014) **22**, 160–170.
17. SAMM Policy 2 – Policy on the Traceability of Measurement Results.

18. SAMM Policy 4 – Policy for Participation in Proficiency Testing Activities.
19. WHO Laboratory Biosafety Manual (<http://www.who.int/en/>).

---

### Acknowledgements

1. Prof. Dr. Yasmin Abdul Malik (Chairman) Standards Malaysia
2. Ms. Noraidah Hj. Subakin (Secretary) Standards Malaysia
3. Ms. Fariza Wan Abdullah Standards Malaysia
4. Dr. Zubaidah Zakaria Institut Penyelidikan Perubatan (IMR)
5. Dr. Wong Yong Wee DNA Laboratories Sdn. Bhd.
6. Dr. Roziana Ariffin Hospital Kuala Lumpur
7. Ms. Yusnita Yakob Institut Penyelidikan Perubatan (IMR)
8. Prof. Dato' Dr. Mohd Zaki Salleh iPROMISE, UiTM
9. Dr. Tengku Shahrul Anuar Tengku Ahmad Basri iPROMISE, UiTM
10. Prof. Dr. Zulqarnain Mohamed Universiti Malaya
11. Prof. Dr. Roslan Harun KPJ Ampang Puteri Specialist Hospital
12. Prof. Datin Dr. Zahurin Mohamed Universiti Malaya
13. Assoc. Prof. Dr. Abhimanyu Veerakumarasivam Universiti Perdana
14. Dr. Baizurah Mohd Hussain Hospital Ampang
15. Dr. Arni Talib Hospital Kuala Lumpur
16. Prof. Dr. Rosline Hassan Hospital Universiti Sains Malaysia (HUSM)
17. Dr. Masita Arip Institut Penyelidikan Perubatan (IMR)
18. Dr. Lim Chun Ren GeneNews (M) Sdn. Bhd.
19. Dr. S. Geetha Subramaniam Geneflux Molecular Diagnostics Centre
20. Ms. Rohasmizah Ismail Standards Malaysia
21. Ms. Siti Norehan Ishak Standards Malaysia
22. Ms. Norsheda Mohd Bahari Standards Malaysia