



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

**STR 2.3 - SPECIFIC TECHNICAL REQUIREMENTS
FOR ACCREDITATION OF
CHEMICAL PATHOLOGY LABORATORIES**

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SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF CHEMICAL PATHOLOGY LABORATORIES

1 Introduction

- (a) This document describes the specific technical requirements to be complied by chemical pathology laboratories.
- (b) This document shall be read in conjunction with MS ISO 15189 Medical Laboratories - Requirements for Quality and Competence and other specific criteria documents published by Department of Standards Malaysia (Standards Malaysia).
Note: Other accreditation criteria include SAMM Policies, Specific Criteria 2 and relevant Specific Technical Requirements documents.
- (c) The clause numbers in this document correspond to those in the standard which require elaboration.

2 Scope of accreditation

The areas for which accreditation may be offered are listed below:

- 2.1 General chemistry for blood, urine and body fluids
- 2.2 Tumor markers
- 2.3 Hormones
- 2.4 Quantitative immunology testing
- 2.5 Therapeutic drug monitoring
- 2.6 Special proteins/specific proteins
- 2.7 Biogenic amines
- 2.8 Clinical toxicology, heavy metals and trace elements
- 2.9 Drugs of abuse testing
- 2.10 Biochemical genetics testing

3 Terms and definitions

- 3.1 Special proteins/specific proteins - include but are not limited to qualitative, semi-quantitative and quantitative analysis that requires protein separation and identification.
- 3.2 Quantitative immunology testing - includes immunoglobulins, complement, CRP, and quantitative auto antibodies.
- 3.3 Drugs of abuse testing - analysis of drugs of abuse in human urine, blood, body fluids and tissues for patient management or healthcare screening. Drug of abuse is a drug that is

taken for non-medicinal reasons (usually for mind-altering effects) which can lead to physical and mental damage, and (with some substances) dependence and addiction. The drug of abuse testing methods used shall be acceptable and validated methods for both screening and confirmatory procedures. Where relevant refer to Malaysian Ministry of Health Guidelines for Testing Drugs of Abuse.

- 3.4 Biochemical genetic testing - the analysis of human proteins and certain metabolites, which is predominantly used to detect inborn errors of metabolism, heritable genotypes, or gene products of genetic variations or mutations for clinical purposes. Such purposes would include predicting risk of disease, identifying carriers, and establishing prenatal or clinical diagnoses or prognoses in individuals, families, or populations. [Tests that are used primarily for other purposes, but may contribute to diagnosing a genetic disease (e.g. blood smear, certain serum chemistries), would not be covered by this definition.] - Clinical Laboratory Improvement Amendments (CLIA) definition.

4 Management requirements

As in MS ISO 15189.

4.1 Organisation and management responsibility

4.1.2.5 Responsibility, authority and interrelationships

The laboratory management shall ensure the appointment of a resident technical manager or designee who shall be Subject Matter Expert (SME).

5 Technical requirements

5.1 Personnel

5.1.2 Personnel qualifications

5.1.2.1 Technical Manager

Technical Manager (however named) shall be:

a) Scope 2.1 - 2.4

- a medically-qualified chemical pathologist (post gazettement or equivalent); or
- a laboratory personnel with a minimum qualification of Bachelor of Science and three (3) years technical experience in chemical pathology.

b) Scope 2.5 - 2.8

- a medically-qualified chemical pathologist (post gazettement or equivalent); or
- a laboratory personnel with a minimum qualification of Bachelor of Science and five (5) years technical experience in the related scope. For drug of abuse screening only and basic clinical toxicology laboratory in the related scope such as acetaminophen, salicylate, benzodiazepines, paraquat, a laboratory personnel with a minimum qualification of Bachelor of Science and three (3) years technical experience.

c) Scope 2.9

i) For laboratories conducting screening tests for drugs of abuse

- a medically-qualified chemical pathologist (post gazettement or equivalent); or
- a laboratory scientist with a minimum qualification of Bachelor of Science and three (3) years technical experience.

ii) For laboratories conducting chemical analysis techniques for drugs of abuse confirmation tests:

- a chemical pathologist with at least three (3) years of supervised training in drugs of abuse testing or relevant area; or
- a laboratory scientist with a PhD in a related field and at least one (1) year of supervised training in the relevant area; or
- a laboratory scientist with a Masters Degree on a related subject and at least two (2) years of supervised training in the relevant area; or
- a laboratory scientist with a Bachelor of Science and a minimum three (3) years of supervised training in drugs of abuse testing or relevant area.

d) Scope 2.10

- a chemical pathologist with at least one (1) year of supervised training in the area of biochemical genetics testing; or
- a laboratory scientist with a PhD in a related field and at least one (1) year of supervised training in the relevant area; or

- a laboratory scientist with a Masters Degree on a related subject and at least two (2) years of supervised training in the relevant area; or
- a laboratory scientist with a Bachelor of Science and a minimum four (4) years of supervised training in the relevant area.

5.1.2.2 Technical Personnel

Technical personnel may be:

- a) A **medically-qualified chemical pathologist** shall be a medical practitioner registered with the Malaysian Medical Council with a postgraduate qualification in pathology recognised by the Government of Malaysia and at least three (3) years of training or working experience in chemical pathology whether as part of the pathology training programme or as post-qualification experience. He/She shall be registered with National Specialist Register (NSR) when enforced.
- b) A **laboratory scientist** shall be a person with at least a Bachelor of Science Degree in Biochemistry, Biomedical Science, Chemistry or equivalent recognised by the Government of Malaysia and at least six (6) months of supervised training in chemical pathology/clinical biochemistry (whether as part of the degree programme or as post-degree training). He/She shall be registered with Allied Health Professionals Registry when enforced.
- c) A **medical laboratory technologist** shall be a person with at least a Diploma in Medical Laboratory Technology or an equivalent, recognised by the Government of Malaysia and at least six (6) months of supervised training in chemical pathology/clinical biochemistry area of the laboratory services (whether as part of the diploma programme or as post-diploma training). He/She shall be registered with Allied Health Professionals Registry when enforced.

After Office Hour Services

For a laboratory that performs after hour services, a technical personnel shall undergo at least one (1) month post diploma/degree supervised training and certified competent in chemical pathology for all the accredited tests listed under the out of hours testing.

5.1.2.3 Supervisory personnel

- (a) Supervisory personnel for laboratory performing chemistry testing for scope 2.1- 2.4 shall be:

- a medically-qualified chemical pathologist (post gazettement or equivalent); or
 - a laboratory scientist with at least two (2) years working experience in chemical pathology; or
 - a medical laboratory technologist with at least three (3) years of experience in chemical pathology.
- (b) Supervisory personnel for laboratory performing chemistry testing for scope 2.5 - 2.10 shall be:
- a medically-qualified chemical pathologist (post gazettement or equivalent); or
 - a laboratory scientist with relevant qualification and training in the specific area and at least two (2) years of experience in the relevant area.

5.2 Accommodation and environmental conditions

5.2.2 Laboratory and office facilities

The laboratory area shall be well ventilated.

5.2.3 Storage facilities

Inflammable and dangerous substances should be handled and stored in a separate chemical store and shall comply with relevant national regulations. Reference may be made to the following documents:

- i) Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations);
- ii) Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations);
- iii) Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010.

5.2.6 Facility maintenance and environmental conditions

The laboratory environment shall be clean and tidy and not overcrowded, to ensure the quality of the work carried out and the safety of personnel are not compromised. This includes division of the laboratory into “non-chemical” areas for sample reception and storage, weighing and instrumental measurements, etc; and “chemical” areas for sample preparation, extraction, reagent and measurement standard preparation, and other chemical reactions.

The temperature of all freezers, refrigerators and cold rooms used to store samples, reagent and reference materials shall be monitored regularly to ensure integrity of the materials and records kept.

The temperature of all equipments involved in analytical procedures shall be monitored regularly and before use (e.g. water bath, oven, incubator).

5.3 Laboratory equipment, reagents and consumables

5.3.1.4 Equipment calibration and metrological traceability

Analytical equipment shall be calibrated using reference materials and should be verified at regular intervals. Recommended calibration and/or performance check interval are available in Appendix 1 of SC 2 and ILAC G 24- Guidelines for the determination of calibration intervals of measuring instruments.

Reference shall be made to SAMM Policy 2 for traceability.

5.4 Pre-examination processes

As in MS ISO 15189

5.5 Examination processes

5.5.1 General

5.5.1.2 Verification of examination procedures

Method verification:

Examination procedures from method developers that are used without modification shall be subject to verification before being introduced into routine use. The verification shall confirm, through provision of objective evidence (performance characteristics) that the performance claims for the examination method have been met. Performance characteristic examination procedure may include:

- i) Precision
- ii) Accuracy
- iii) Analytical sensitivity
- iv) Analytical specificity
- v) Detection limit, linearity and reportable range
- vi) Diagnostic specificity and sensitivity.
- vii) Recovery

- viii) Reference interval
- ix) Interference

5.5.1.3 Validation of examination procedures

Method validation:

When performing validation of methods, reference may be made to national and international guidelines and guidance documents available from other accreditation/professional bodies e.g. NATA Technical Note 17, Guidelines for the Validation and Verification of Quantitative and Qualitative Test Methods, CLSI, Eurachem, Westgard Method Validation etc.

5.5.1.4 Measurement uncertainty of measured quantity value

The measurement uncertainty should be determined at clinical decision level, where possible.

5.6 Ensuring quality of examination results

5.6.3 Inter-laboratory comparisons

All tests shall be consistently enrolled in at least one external quality assessment (EQA) programme or inter-lab comparison (ILC) that uses matrix matched samples e.g.: urine electrolytes and serum electrolytes, urine cortisol and serum cortisol.

5.6.4 Comparability of examination results

Comparability studies shall include but not limited to the following:

- a) Using a minimum of 20 patient samples analysed preferably in duplicate and where possible sample concentration to cover the entire reportable range of the method and represent the clinically appropriate intervals.
- b) The data shall be analysed using valid statistical methods to provide acceptable estimates of the slope and intercept.

When performing comparability reference may be made to the following guidelines:

- i) Clinical & Laboratory Standard Institute (CLSI - E P09-A2)
- ii) Westgard Reference Materials and Resources

The laboratory shall review and endorse the acceptance of the comparison study.

Once comparability study is established, periodic comparability checks shall be carried out.

5.7 Post-examination processes

5.7.1 Review of results

The authorisation for review of results shall be by the following personnel:

- (a) For scope 2.1: at least a medical laboratory technologist who has met the requirement of 5.1.2.2 (c) and has a minimum of three (3) months working experience in the related scope.
- (b) For scope 2.2-2.8: at least a laboratory scientist who has met the requirement of 5.1.2.2 (b) and has a minimum of six (6) months working experience in the related scope.
- (c) For scope 2.9:
 - i) Drugs of abuse for clinical purposes
 - A medically-qualified chemical pathologist who has met the requirement of 5.1.2.2 (a) and has a minimum of six (6) months working experience in the related scope.
 - A laboratory scientist who has met the requirement of 5.1.2.2 (b) and has a minimum of six (6) months working experience in the related scope.
 - ii) Drugs of Abuse tests under Dangerous Drug Act 1952 (Act 234)
 - Biochemist with related PhD or a related Master's Degree with at least one (1) year of technical training inclusive of six (6) months working experience in the related scope or a Bachelor of Science with at least two (2) years technical training inclusive of six (6) months working experience in the related scope. Training in giving court testimony is required.
- (d) For scope 2.10: Biochemical Genetics Testing
 - Chemical pathologist or laboratory scientist with related PhD with at least one (1) year supervised training or a related Master's Degree with at least three (3) years supervised training or a Bachelor of Science and at least five (5) years supervised training can release both normal and abnormal results.
 - Chemical pathologist or laboratory scientist with related PhD with less than one (1) year supervised training or a related Master's Degree with at least one (1)

year supervised training or a Bachelor of Science and at least two (2) years supervised training can only release normal results.

5.8 Reporting of results

As in MS ISO 15189.

5.9 Release of results

Refer to 5.7.1 requirements of this document and SAMM Policy 3, Policy on the Use of SAMM Accreditation Symbol and Combined ILAC MRA Mark or Reference to SAMM Accreditation.

5.10 Laboratory information management

As in MS ISO 15189.

References:

1. Clinical & Laboratory Standard Institute (CLSI - E P09-A2)
2. Dangerous Drug Act 1952 (Act 234)
3. Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010 (http://www.moh.gov.my/images/gallery/Garispanduan/Guidelines_on_Chemical1.pdf)
4. ILAC G 24- Guidelines for the determination of calibration intervals of measuring instruments.
5. MS ISO 15189 'Medical Laboratories - Requirements for Quality and Competence'
6. NATA Technical Note 17, Guidelines for the Validation and Verification of Quantitative and Qualitative Test Methods
7. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations) (<http://www.dosh.gov.my/index.php/en/legislation/regulations-1/osha-1994-act-154/522-pua-131-2000-1/file>)
8. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH 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%20pelabelan%20dan%20helaian%20data%20keselamatan%20bahan%20kimia%20berbahaya%29%202013.pdf)
9. SAMM Policy 2 – Policy on the Traceability of Measurement Results
10. SAMM Policy 3 - Policy on the Use of SAMM Accreditation Symbol and Combined ILAC MRA Mark or Reference to SAMM Accreditation
11. SC 2 'Specific Criteria for Accreditation in the Field of Medical Testing'
12. Westgard Reference Materials and Resources

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17. Ms. Rohasmizah Ismail Standards Malaysia
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