MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

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

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(Supplementary to MS ISO 15189)

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)

LABORATORY ACCREDITATION SCHEME OF MALAYSIA

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Introduction

This document describes the specific technical requirements to be complied by chemical pathology laboratories. This document should be read in conjunction with MS ISO 15189 *Medical laboratories - Requirements for quality and competence* and other accreditation criteria documents published by Department of Standards Malaysia (JSM). The clause numbers correspond to those in the standard but since not all clauses require supplementary requirements, the numbering may not continuous.

Compliance with this document does not in any way exempt laboratories from or diminish their responsibilities in observing/complying with existing national laws and regulations/guidelines currently enforced in the country.

1 Scope

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

1.1 Blood gases and co-oximetry
1.2 General urine chemistry
1.3 General serum chemistry
1.4 Urinalysis
1.5 Hormones
1.6 Immunochemistry
1.7 Tumor markers
1.8 Heavy metals and trace elements
1.9 Biogenic amines
1.10 Protein quantitative analysis (specific protein, complement immunoglobulin, serum FLC)
1.11 Protein qualitative and semi-qualitative analysis
1.12 Special chemistry
1.13 Special lipids
1.14 Therapeutic drug monitoring
1.15 Clinical toxicology
1.16 Drug of abuse testing
1.17 Inborn errors of metabolism
1.18 Protein electrophoresis and immunofixation/immunotyping reporting

Note: For point of care testing (POCT) (e.g. glucometer, blood gas, troponin, Pro–B-type Natriuretic Peptide (proBNP), ketone, urine strip, urine pregnancy test (UPT), drug of abuse (DOA) test kit, benzodiazepine, full blood count (FBC), Human Immunodeficiency Virus (HIV) rapid test, Dengue NS1 combo rapid test, Anti-HCV Rapid Test and etc. Reference can be made to the SC 2 Specific Criteria for Accreditation in the Field of Medical Testing and national POCT guidelines.

2 Normative references

i) MS ISO 15189 - Medical Laboratories - Requirements for quality and competence.
ii) SC 2 - Specific Criteria for Accreditation in the Field of Medical 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 (MOH) 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 General requirements

Same as MS ISO 15189 and SC 2.

5 Structural and governance requirements

5.4 Structure and authority

The laboratory management shall ensure the appointment of a personnel (however named) to function as a technical manager for each laboratory.

6 Resource requirements

6.2 Personnel

6.2.2 Competence requirements

1) Technical Manager (however named) shall be for:

i) Scope 1.1 - 1.7

   a. A medically-qualified registered chemical pathologist; or

   b. A laboratory personnel with a minimum qualification of Bachelor of Science and three (3) years technical experience in chemical pathology.

ii) Scope 1.8 - 1.15 & 1.18

   a. A medically-qualified registered chemical pathologist; or

   b. A laboratory personnel with a minimum qualification of Bachelor of Science and five (5) years technical experience in the related scope.

iii) Scope 1.16

   a. For laboratories conducting screening tests for drugs of abuse:

      1. a medically-qualified registered chemical pathologist; or

      2. a laboratory scientist with a minimum qualification of Bachelor of Science and three (3) years technical experience.

b. For laboratories conducting chemical analysis techniques for drugs of abuse confirmation tests:

1. a registered chemical pathologist with at least three (3) years of supervised training in drugs of abuse testing or relevant area; or
2. a laboratory scientist with a Doctor of Philosophy (PhD) in a related field and at least one (1) year of supervised training in the relevant area; or
3. a laboratory scientist with a Master's Degree on a related subject and at least two (2) years of supervised training in the relevant area; or
4. 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.

iv) Scope 1.17

a. a registered chemical pathologist with at least one (1) year of supervised training in the area of biochemical genetics testing; or
b. a laboratory scientist with a PhD in a related field and at least one (1) year of supervised training in the relevant area; or
c. a laboratory scientist with a Master's Degree on a related subject and at least two (2) years of supervised training in the relevant area; or
d. a laboratory scientist with a Bachelor of Science and a minimum four (4) years of supervised training in the relevant area.

2) Technical Personnel may be:

i) A **medically-qualified registered chemical pathologist** 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.

ii) A **medical laboratory scientist (MLS)** also known as 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).

iii) A **medically qualified personnel** shall be a person with at least a postgraduate qualification of Master of Science (MSc) or PhD in medical laboratory sciences and at least one (1) year of working experience in chemical pathology.

iv) A **medical laboratory technologist (MLT)** 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).

After Office Hour Services

For a laboratory that performs after hours services, a technical personnel shall undergo at least 20 working days post diploma/degree supervised training and certified competent in chemical pathology for all the accredited tests listed under the out of hours testing.

3) Supervisory personnel

i) Supervisory personnel for laboratory performing chemistry testing for scope 1.1-1.4 shall be:

a. a medically-qualified chemical pathologist (post gazettement or equivalent); or
b. a laboratory scientist with at least two (2) years working experience in chemical pathology; or

c. a medical laboratory technologist with at least three (3) years of experience in chemical pathology.

ii) Supervisory personnel for laboratory performing chemistry testing for scope 1.5-1.18 shall be:

a. a medically-qualified chemical pathologist (post gazettement or equivalent); or

b. a laboratory scientist with relevant qualification and training in the specific area and at least two (2) years of experience in the relevant area.

6.3 Facilities and environmental conditions

6.3.2 Facility controls

i) The laboratory performing drug of abuse testing, reference should be made to Pekeliling Ketua Pengarah Kesihatan Malaysia Bil 1 Tahun 2021: Garis Panduan Bagi Ujian Pengesanan Penyalahgunaan Dadah Dalam Air Kencing Versi 2.0.

ii) The temperature of all freezers, refrigerators and cold rooms used to store samples, reagent and reference materials shall be monitored and reviewed regularly to ensure integrity of the materials and records kept. Any abnormal or persistent out of range temperature recorded, laboratory shall troubleshoot and fix the problem.

iii) The temperature of all equipment (e.g. water bath, oven, incubator) involved in analytical procedures shall be checked before use and to ensure the temperature is maintain throughout the procedure.

7 Process requirements

7.3 Examination processes

7.3.2 Verification of examination procedures

The laboratory shall independently perform the method verification. The data shall be analysed using the appropriate statistical analysis. The use of valid statistical analysis will provide accurate estimates of the error.

7.3.7.4 Comparability of examination results

b) When sample size is small (<20), the laboratory may use other statistical methods such as non-parametric test.

Sample concentration should cover the clinical/medical decision limit/range. When performing comparability, reference may be made to the following guidelines:

i) Clinical & Laboratory Standard Institute
ii) Westgard Reference Materials and Resources

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

7.4 Post-examination processes

7.4.1 Result reporting

7.4.1.2 Result review and release

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

i) For scope 1.1 - 1.4:

   a. At least a laboratory technologist who has met the requirement of 6.2.2 2) iv) and has a minimum of three (3) months working experience in the related scope.

   b. For laboratory that is offering 24 hours testing or special request other than those scopes 1.2, 1.4, 1.5 and 1.17, the laboratory management shall have a policy and procedure to handle the release of results after office hours. The results shall be first verified by the authorised personnel before the results can be released. Records shall be kept.

ii) For scope 1.1 - 1.17: at least a laboratory scientist or medical officer who has met the requirement of 6.2.2 2) ii) / 6.2.2 2) iii) and has a minimum of six (6) months working experience in the related scope.

iii) For scope 1.1 - 1.18: at least a chemical pathologist who has met the requirement of 6.2.2 2) i) and has a minimum of six (6) months working experience in the related scope.

iv) For scope 1.16: Drugs of Abuse

   a. Drugs of abuse for clinical purposes

      A medically-qualified chemical pathologist who has met the requirement of 6.2.2 2) i) and has a minimum of six (6) months working experience in the related scope.

   b. Drugs of abuse tests under Dangerous Drug Act 1952 [Act 234]

      Laboratory scientist 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.

   c. Drug of abuse testing not related to Dangerous Drug Act 1952 [Act 234]

      Example cases:
      - Employment screening
      - Workplace testing (other than government personnel)
      - Students entrance requirements

      A medically-qualified chemical pathologist who has met the requirement of 6.2.2 2) i) and has a minimum of six (6) months working experience in the related scope.

      A laboratory scientist who has met the requirement of 6.2.2 2) ii) and has a minimum of six (6) months working experience in the related scope.

   Note: Reference may be made to Akta Penagih Dadah (Rawatan dan Pemulihan) 1983 [Akta 283].

v) For scope 1.17: Biochemical Genetics Testing

   a. 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.

   b. 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.

7.4.1.3 Critical result reports

The laboratory shall have a policy and procedure on the management of critical results which shall include the tests that may require acute medical management.

7.4.1.5 Automated selection, review, release and reporting of results

The LIS configuration shall be reviewed for its functionality at least yearly and after LIS/middleware breakdown/database maintenance or changes made to the parameters (e.g. results transfer, calculation formula, delta check, HIL and alarms).

Validation of the auto verification shall be performed and reviewed regularly, as determine by the laboratory.

8 Management system requirements

Same as MS ISO 15189 and SC 2.

Bibliography

1. MS ISO 15189 - Medical Laboratories - Requirements for Quality and Competence.
2. SC 2 - Specific Criteria for Accreditation in the Field of Medical Testing.
3. Clinical & Laboratory Standard Institute guidelines.
4. Dangerous Drug Act 1952 [Act 234].
5. Westgard textbook and website.

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