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

STR 2.4 - SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF HAEMATOLOGY LABORATORIES

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MS ISO 15189

JABATAN STANDARD MALAYSIA
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SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF HAEMATOLOGY LABORATORIES

1 Introduction

1.1 This document describes the specific technical requirements to be complied by haematology laboratories.

1.2 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 and relevant Specific Technical Requirements documents.

1.3 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 Routine haematology may include:

a) Full blood count and differential count
b) Peripheral blood film examination
c) Reticulocyte count
d) Erythrocyte sedimentation rate
e) Prothrombin time / International Normalised Ratio
f) Activated partial thromboplastin time
g) Thrombin time
h) D-dimer / Fibrinogen degradation products
i) Fibrinogen
j) Glucose-6-phosphate dehydrogenase deficiency (G6PD) screening

2.2 Specialised haematology may include tests other than those listed in 2.1 above. This may include but not limited to the following:

a) Full blood picture with clinical interpretation
b) Haemoglobin analysis
c) Bone marrow examination
d) Special haemostasis e.g. factor assays, lupus anticoagulant testing, thrombophilia screening
e) Flow cytometric examination e.g. CD4/CD8 enumeration, CD34 enumeration, leukemia/lymphoma immunophenotyping, paroxysmal nocturnal haemoglobinuria (PNH) testing
f) Molecular testing

2.3 Blood transfusion tests may include;

a) Blood grouping and phenotyping
b) Antibody screening and identification
c) Compatibility testing
d) Investigation of transfusion reaction
e) Direct Antiglobulin Test (DAT)

Note: The scope of blood transfusion includes storage and release of blood and blood products to patients. It excludes blood procurement, production of blood components and activities prior to supply of blood stock to a transfusion testing laboratory.

3 Terms and definitions

3.1 Subject matter experts (SME) - is a person who is an authority in a particular area or topic. SME is a technical personnel trained for specific task.

4 Management requirements (Clause 4.1 – 4.15)

As in MS ISO 15189 and Specific Criteria.

5 Technical requirements

5.1 Personnel

5.1.2 Personnel qualifications

a) A **Haematologist** shall be a medically qualified pathologist who has obtained a postgraduate qualification in pathology, such as Master of Pathology or its equivalent and at least 3 years of training or working experience in haematology and blood transfusion laboratory whether as part of the pathology qualification training programme or as post-qualification experience and should be registered with the National Specialist Register.

b) A **Transfusion Medicine Specialist** shall be a medically qualified doctor who has obtained a postgraduate qualification in transfusion medicine, such as Master of Transfusion Medicine and at least 3 years of training or working experience in transfusion medicine as part of the post graduate training programme and should be registered with the National Specialist Register.

c) A **Medical Officer** shall be a medically qualified doctor with at least 2 months of supervised training/working experience in haematology/ blood transfusion.

d) A **Laboratory Scientist** shall be a person with at least a Bachelor of Science Degree or equivalent recognised by the Government of Malaysia and at least 6 months of supervised training in haematology and/or blood transfusion (whether as part of the degree programme or as post-degree training). He/She should be registered with Allied Health Professionals Registry.

e) 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 6 months of supervised training in haematology and/or blood transfusion laboratory (whether as part of the diploma programme or as post-diploma training). He/She should be registered with Allied Health Professionals Registry.

f) **Technical Manager** (however named) is the key personnel responsible for technical operation in the scope of:

i. Routine haematology

- a Haematologist; or
- a laboratory personnel with a minimum qualification of Bachelor of Science and at least 3 years technical experience in haematology laboratory; or
- a Medical Laboratory Technologist with at least 5 years technical experience in haematology laboratory.

ii. Specialised haematology

- a Haematologist; or
- a laboratory personnel with a minimum qualification of Bachelor of Science and at least 5 years technical experience in particular area of specialised haematology; or
- a Medical Laboratory Technologist with at least 8 years technical experience in particular area of specialised haematology.

iii. Blood transfusion

- a Haematologist; or
- a Transfusion Medicine Specialist; or
- a laboratory personnel with a minimum qualification of Bachelor of Science and at least 5 years technical experience in transfusion. Exception can be made for laboratories performing ABO and RhD grouping only in which 3 years minimum experience is acceptable; or
- a Medical Laboratory Technologist with at least 8 years technical experience in transfusion. Exception can be made for laboratories performing ABO and RhD grouping only in which 5 years minimum experience is acceptable.

5.1.5 Training

The training of a medical officer for blood film morphology shall include:

a) reporting under supervision at least 20 normal Full Blood Picture (FBP) of which 10 cases with differential white cell blood count;
b) reporting under supervision at least 50 abnormal FBP (eg: hypochromic microcytic anaemia, nutritional anaemia and reactive leukocytosis etc); and
c) recognising 30 abnormal cases of various pathology requiring Haematologist review (eg: cytopaenias, acute and chronic leukemia, haemolysis, MAHA pictures, and thrombocytopaenia etc).

5.1.6 Competence Assessment

Competency for blood film reporting

a) Competency assessment for technical personnel performing blood film reporting (as in 5.8 (A)) shall be made by at least a competent senior MLT or scientific officer or Haematologist.
   (Competency of the senior MLT or scientific officer performing the assessment shall be assessed and verified by a Haematologist)
b) Competency assessment for medical officers performing blood film reporting shall be made by a Haematologist.

5.2 Accommodation and environmental conditions

5.2.1 For molecular haematology, the laboratory shall have a separate area for each of the following:

a) nucleic acid extraction;
b) preparation of PCR reagents (including dispensing of master mix); and
c) contained area for amplification and product detection.
   References MJPATH 2015; 37 (2):165-173

5.2.2 Laboratory and office facilities

The design of the area and work top should permit efficient cleaning and should not contain features that are incompatible to activities performed.

Blood transfusion testing shall be carried out in an appropriately controlled environment, separated from activities related to blood collection and processing.

5.2.3 Storage facilities

The temperature and humidity (where appropriate) in storage areas for materials, blood and blood components should be appropriately controlled, monitored and checked to demonstrate compliance with specifications and equal distribution throughout the storage facilities. The checks shall be recorded.

Storage areas should provide for suitable and effective segregation of blood stock according to screening, cross matching and blood group type status. There should be a separate area for reagents, materials and rejected products.

For storage of reagents, there should be an alarm system in place, audible and/or visible, to indicate when the storage temperature is outside acceptable limits. This alarm system should also cover the time period out of working hours. Regular checks of the alarm system should be performed and recorded at least daily.

For blood and blood products, storage device shall have a system to monitor the temperature continuously, and shall have an alarm system to alert abnormal storage conditions.

There should be a written procedure describing the actions to be taken in response to alarms.

5.2.6 Facility maintenance and environmental conditions

Access to temperature and pressure controlled areas should be restricted and controlled. Environmental monitoring should be performed to demonstrate that the appropriate classification is consistently achieved. Records of the monitoring should be maintained.

5.3 Laboratory equipment, reagents and consumables

Procedures to assure and verify the proper functioning of equipment, reagents and consumables shall meet acceptable professional standards. For molecular testing, there shall be dedicated equipment for each activity e.g. micropipettes, vortex mixture, micro-centrifuges among the designated areas.

5.4 Pre-examination processes

5.4.4 Primary sample collection and handling

Primary sample collection and handling procedures shall comply with national or internationally accepted guidelines such as:

i) Transfusion Practice Guidelines for Clinicians and Laboratory Personnel produced by Ministry of Health, Malaysia
ii) British Committee for Standards In Haematology (BCSH)
iii) Clinical and Laboratory Standards Institute (CLSI)

Any deviation from the above guidelines shall be validated.

5.5 Examination processes

5.5.1.4 Measurement of uncertainty of measured quantity values

The laboratory shall review and recalculate measurement of uncertainty (MU) at minimum once a year. A more frequent review should be performed if significant changes occur within a measurement system. Examples include, but are not limited to, change of equipment, upgrade of equipment, test method change and other changes that may be noted from trends in the laboratoryôs own internal controls. Quantitative tests that are operator dependent require a review of MU whenever the staff changes.

The test parameters for determination of MU shall include at least the following.

i) FBC ï haemoglobin, haematocrit, total white blood cell count and platelet
ii) Haemostasis - Prothrombin time, activated partial thromboplastin time, thrombin time, quantitative D-dimer and fibrinogen.

iii) Haemoglobin analysis ï Hb A2 and Hb F

iv) Flow cytometric examination ï CD4/CD8 enumeration, CD34 enumeration

v) Special haemostasis- Protein C, Protein S and Antithrombin

vi) Quantitative G6PD enzyme assay

vii) Molecular testing ï Quantitative BCR/ABL analysis

5.5.3 Documentation of examination procedure

A) Special Haemostasis

Mixing test shall be included as part of the investigation of prolonged PT/APTT.

Laboratories shall have mechanism to verify results that are affected by interferences such as polycythaemic, lipaemic and icteric samples.

B) <u>Blood Transfusion</u>

All blood transfusion tests and procedures shall be performed in accordance with the current version of the Transfusion Practice Guidelines for Clinical and Laboratory Personnel, National Blood Center, Ministry of Health Malaysia or any internationally recognised guidelines.

i) For the laboratory performing ABO grouping, both forward and reverse method shall be carried out simultaneously from the same sample for all patients except for neonates. Tile method shall not be used.

ii) For pre transfusion testing, the laboratory shall perform:
- ABO grouping;
- Rh (D) typing;
- antibody screening; and
- compatibility testing (if transfusion is required).

iii) The laboratory shall record the grade of reactions for all transfusion testing.

iv) The laboratory shall have a mechanism to resolve samples with positive antibody screening or incompatible cross match.

v) The laboratory shall have a system to review the previous blood group and transfusion record for every request for blood and blood products.

vi) The procedure for testing and issue of blood during emergency situations shall include details on handling and testing of the pre-transfusion sample.

vii) Blood and blood component shall have traceability, from source to final fate. This shall also apply to all uncross-matched blood used in emergency circumstances (e.g. ósafe Oôin emergency department).

C) Molecular Haematology Test

Molecular haematology procedures should follow national or international guidelines. Reference may be made to the following documents:

i) AMERICAN College of Medical Genetics - Standards and Guidelines for Clinical Genetics Laboratories
ii) Clinical and Laboratory Standards Institute of USA - Nucleic Acid Amplification Assays for Molecular Haematopathology: Approved Guideline
iii) National Pathology Accreditation Advisory Council of Australia - Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis
iv) Any other guideline documents published by College of Pathologist and Standards Malaysia.

D) Flow cytometric examination

Flow cytometry procedures should follow national or international guidelines. Reference may be made to the following documents:

i) Clinical and Laboratory Standards Institute of USA - Enumeration of Immunologically Defined Cell Populations by Flow Cytometry: Approved Guideline.

ii) Clinical and Laboratory Standards Institute of USA - Clinical Flow Cytometric Analysis of Neoplastic Haematolymphoid Cells.

For the diagnosis of haematological malignancies, there shall be written policies and procedures to compare morphology and flow cytometry data before the release of flow cytometry report.

5.6 Ensuring quality of examination results

5.6.2 Quality control

A) Routine Haematology

i) Automated blood cell counting

(a) A multilevel control shall be run at least once per day. For laboratories providing 24 hours service, an additional multi-level control(s) shall be run at appropriate frequency and time.

(b) There shall be protocols for common interferences that may affect the accuracy of blood count data such as lipaemia, in-vitro haemolysis, etc. Patientôs results exceeding laboratory defined counts shall be verified (e.g. cytopenic samples shall be checked against haemocytometry or blood film estimates) and recorded.

ii) Routine coagulation test

At least two levels of appropriate controls shall be performed for all procedures.

B) Specialised Haematology

i) Haemoglobin analysis

Abnormal bands or peaks detected during screening should be verified by at least another method.

ii) Specialised haemostasis

At least two levels of controls (normal and abnormal, positive and negative controls, as appropriate) shall be performed for all procedures.

iii) Cerebrospinal fluid (CSF)

CSF preparations with suspected malignant cells shall be reviewed by a Haematologist or cytopathologist.

C) Blood Transfusion Test

The laboratory shall perform and document daily QC for blood grouping and antibody screening test.

5.6.3 Interlaboratory comparisons

Specialised tests

Interlaboratory comparison for specialised test shall be conducted at least 2 times per year in laboratory choosing options iii) and iv) of Clause 5.6.3 of SC 2.

5.7 Post examination processes

As in MS ISO 15189.

5.8 Reporting of results

A) Morphological examinations which are only descriptive and not accompanied by a clinical interpretation may be reported by suitably qualified and competent technical personnel e.g. hypochromic microcytic anaemia: common causes include iron deficiency anaemia and thalassaemia. Representative slides shall be periodically reviewed by a Haematologist.

B) Peripheral Blood Film Morphology interpretation may be carried out by a competent medical officer who is credentialled to report certain cases as determined by Haematologist in charge. Representative slides shall be periodically reviewed by a Haematologist.

C) Transfusion laboratory reports which have direct bearing on clinical management i.e. clinically relevant antibody, transfusion reaction investigations shall be made by a Haematologist or Transfusion Medicine Specialist.

Medical officers working in transfusion laboratory or undergoing formal training in pathology / transfusion medicine can also provide report under the direction and supervision of a Haematologist/ Transfusion Medicine Specialist. A system shall be in place to verify the medical officerôs interpretations. The supervising Haematologist/Transfusion Medicine Specialist is responsible for the reports made by the medical officers.

D) Reporting and interpretative of molecular haematology and flow cytometry shall be made by a Haematologist. Reports for flow cytometric quantitation of CD4, CD8 and CD34 cells may be made by suitably qualified and competent technical personnel.

E) **Bone marrow reporting**

If trephine sections and aspirates are independently evaluated by different sections of the laboratory, there shall be written policies and procedures to compare data and interpretations before release of trephine section report by Histopathologists or Haematologists.

5.9 Release of results

As in MS ISO 15189

In exceptional circumstances the Haematologist may authorise another competent Haematologist to release his/her report. This information shall be indicated in the report. There shall be a clear procedure for such practices to safeguard the integrity of the report.

5.10 Laboratory information management

If the LIS does not meet the requirements of Clause 5.10 MS ISO 15189 or the system has limitation (e.g. traceability, accessibility) laboratory is required to have appropriate procedure to address the limitation.

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