



**STANDARDS**  
MALAYSIA

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

**STR 2.5 - SPECIFIC TECHNICAL REQUIREMENTS  
FOR ACCREDITATION OF  
MEDICAL MICROBIOLOGY LABORATORIES**

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## **SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF MEDICAL MICROBIOLOGY LABORATORIES**

### **1 Introduction**

- (a) This document describes the specific technical requirements to be complied with by medical microbiology 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 Bacteriology
- 2.2 Virology
- 2.3 Parasitology
- 2.3 Mycology
- 2.4 Mycobacteriology
- 2.5 Immunology

Please refer to Appendix 1 for specific tests under the various categories.

### **3 Terms and definitions**

As in MS ISO 15189

### **4 Management Requirement**

As in MS ISO 15189.

## **5 Technical Requirement**

### **5.1 Personnel**

#### **5.1.2 Personnel qualifications**

##### **5.1.2.1 Medical laboratory technologist**

A medical laboratory technologist shall hold such minimum qualifications as specified in the Specific Criteria 2 (SC 2) and have had at least six (6) months of supervised training in a microbiology laboratory.

##### **5.1.2.2 Laboratory scientist**

A laboratory scientist shall hold an appropriate Bachelor's Degree or an equivalent as specified in the Specific Criteria 2 (SC 2) and have had at least six (6) months supervised training in a microbiology laboratory.

##### **5.1.2.3 Clinical personnel**

A clinical microbiologist shall be a medically-qualified pathologist who has a postgraduate qualification in pathology, such as the MRCPPath, MPath and other equivalent recognised postgraduate qualifications and who has at least three (3) years of training or working experience in medical microbiology whether as part of the pathology training programme or as post-qualification experience.

### **5.2 Accommodation and environmental conditions**

5.2.1 All laboratories shall conform to the requirements of good microbiology practices. Documents which may be referred to include Biosafety Act 678 (2007), Biosafety Microbiological Biomedical Laboratories (BMBL), CDC, Atlanta and WHO Laboratory Biosafety Manual.

5.2.2 Sufficient and appropriate space, in line with biosafety requirements, shall be provided.

#### **5.2.3 Storage Facilities.**

The provision of sufficient storage space, under the correct conditions, is important in maintaining the integrity of samples, reagents and records.

The microbiological work area should be separated from the work areas of other specialties. The premises shall have separate room/space for work pertaining to viral culture.

- 5.2.4 The microbiological work area shall be adequately ventilated. The air should not be recirculated when dealing with organism that requires biosafety level 3 precautions.
- 5.2.5 Sufficient bench space should be provided for each worker at any one time as the risk of contamination and laboratory acquired infections increases with overcrowding.
- 5.2.6 For laboratories performing molecular techniques involving in-vitro nucleic acid amplification, separate rooms/spaces for nucleic acid extraction, amplification, and detection shall be provided to minimise the risk of cross-contamination.

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

#### **5.3.1 Autoclaves**

5.3.1.1 Autoclaves shall not be used to sterilize clean items and to decontaminate used items during the same sterilisation cycle. It is preferable to use separate autoclaves for these two processes. Records of autoclave operations, including temperature and time shall be maintained. Criteria for acceptance and rejection of operation conditions shall be set. Documented evidence of compliance with these criteria shall be made available.

5.3.1.2 The adequacy of each cycle shall be documented by use of an accepted method such as:

- (a) thermocouple and recorder to produce a chart or print out;
- (b) minimum-maximum thermometer;
- (c) indicators such as Browne's tubes, thermalog strips, etc.;
- (d) biological indicators, e.g. spore strips;
- (e) reading obtained from the panel of the autoclave.

5.3.1.3 A valid certification of fit-for-use of the autoclave shall be obtained from an authorised body.

5.3.1.4 The autoclave shall be operated by trained and competent personnel.

#### **5.3.2 Biological safety cabinets**

5.3.2.1 Processing materials which may contain pathogens transmissible through inhalation shall be carried out in a Biosafety cabinet Class II or higher.

5.3.2.2 Laboratories shall establish a program to ensure the proper functioning of the cabinets and to maintain the appropriate records.

5.3.2.3 The biosafety cabinets shall be maintained by trained and competent personnel.

### **5.3.3 Thermometers**

5.3.3.1 Thermometers shall be verified against their working temperatures. Reference thermometers shall be calibrated by an accredited calibration laboratory.

### **5.3.4 Centrifuge**

5.3.4.1 Sealed buckets shall be used in centrifuges when airborne pathogens are present or are likely to be present. Where infection may be acquired by aerosolisation, the bucket shall be unloaded in a biological safety cabinet after waiting for a suitable time before opening the sealed buckets.

### **5.3.5 Loop steriliser**

5.3.5.1 The use of Bunsen burners for loop sterilisation in microbiology laboratory is not encouraged. Wherever possible, use an electrical loop steriliser.

### **5.3.6 Reagents/ stains/ media/ kits/ antimicrobials**

5.3.6.1 Media

#### **(A) In-house media**

- (i) The laboratory shall maintain the procedure for media preparation. Records shall be kept of the details of preparation. All media produced in-house shall be checked for performance. Quality control tests using known positive and negative control strains should be included on each new batch of media. Records of performance testing shall be maintained and be traceable.
- (ii) Preparation, storage and quality control of media shall be performed in accordance with the documented method from suitable manuals. Modifications from the standard method shall be validated. Each unit of medium or reagent prepared in-house, shall be clearly labelled with:
  - (a) Type of medium or reagent
  - (b) Batch number
  - (c) Expiry date

- (iii) Standard organisms shall be used to perform quality control for in-house media. An appropriate range of organisms from a reliable source shall be kept. The stock of organisms shall be maintained under appropriate long-term storage conditions. Refer Clause 5.6.1 of this document.
  - (iv) Records shall be kept of the preparation details for all types of media including:
    - (a) Name of media
    - (b) Batch number for unique identity
    - (c) Personnel responsible for preparation
    - (d) Date of preparation
    - (e) Expiry date
    - (f) Volume of media/solutions made
    - (g) Media ingredients, manufacturer, manufacturer's batch number and quantity of each component
    - (h) Initial pH (pre-sterilisation) where indicated
    - (i) Final pH (post-sterilisation) where indicated
    - (j) Method of sterilisation, including time and temperature as appropriate
  - (v) All media produced shall be checked for performance and the following information recorded:
    - a) Physical appearance
    - b) Sterility results after incubation
    - c) Performance checks using positive and negative control organisms
    - d) Records of performance testing must be traceable to batch preparation records
- (B) Media purchased from manufacturers**
- (i) The laboratory shall obtain a customer report from the manufacturer with a comprehensive quality control report for each batch of media. The report shall include:

- (a) Name and code of media
  - (b) Quality control result (e.g. organisms, pH, etc.)
  - (c) Shelf life and expiry date
- (ii) The laboratory shall continue to test the batches irrespective of whether they were previously quality controlled.
  - (iii) Laboratories shall periodically review the reliability of purchased media and document the results of this review.

#### 5.3.6.2 Stains

Each new batch of stains (Gram stain, special stains, and fluorescent stains) shall be checked with known positive and negative control organisms for intended reactivity and results recorded.

#### 5.4 Pre-examination processes

As in MS ISO 15189.

#### 5.5 Examination processes

- 5.5.1 A testing algorithm should be established in respect of each clinical syndrome. (e.g. Ministry of Health Syndromic Notification and Laboratory Investigation Manual or Malaysian Clinical Practice Guideline).
- 5.5.2 The laboratory shall indicate the extent to which the following examination procedures are carried out:
  - (a) Direct examinations
  - (b) Culture
  - (c) Antimicrobial susceptibility tests
  - (d) Identification: limited or definitive
  - (e) Screening methods used
  - (f) Confirmatory methods used



### 5.5.3 Nucleic Acid Amplification Method

Adequate measures shall be taken to prevent cross contamination of material between samples. This shall include but not limited to the following:

- (i) There shall be no sharing of reagents and general instruments (micropipettes, vortex mixers, heating block and micro-centrifuges) utilised for performing the various stages of such tests. In particular, no nucleic acid samples are to be taken into the reagent preparation area. Equipment from other areas should never be taken into the reagent preparation area.
- (ii) Samples shall be stored separately from reagents.
- (iii) The movement of specimens and equipment shall be unidirectional, i.e. from pre-amplification to post-amplification areas. Only sealed nucleic acid amplification tubes and tube racks shall be carried between the pre-amplification area and the post-amplification area.
- (iv) Should there be a need to move equipment from post-amplification to pre-amplification area, adequate decontamination procedures shall be instituted.

### 5.5.4 Cell culture and virus isolation

- (i) Sterility of all culture media shall be ensured following the addition of ingredients post sterilisation.
- (ii) Animal sera for use in culture media shall be tested to exclude toxicity to cells. Appropriate media must be available to support all the services offered by the laboratory.
- (iii) There shall be documentation of cell types, sources, passages and media used in their propagation.
- (iv) All cell cultures maintained in the laboratory shall be tested for mycoplasmal contamination immediately upon receipt, after recovery from the deep freezer and at regular intervals (at least annually).

## 5.6 Ensuring quality of examination results

5.6.1 The laboratory shall have policies and procedures for purchase, handling, storage, preservation, maintenance and use of reference cultures and stocks. Appropriate controls shall be performed and recorded using reference strains [e.g. National Collection of Type Cultures (NCTC), American Type Culture Collection (ATCC) and Institute of Medical Research

Culture Collection (IMRCC)] or reference standards of appropriate range. Microorganisms for standard protocols should be used within five passages of the original reference culture. A reference strain obtained from a commercial source may be already one or more passages away from the original reference culture. The information on the passage number is available in the product certificate.

5.6.2 A lineage history shall be retained of each quality control organism. These organisms are used to perform quality control on:

- (a) Culture media
- (b) Test kits and reagents
- (c) Antimicrobial susceptibility tests

5.6.3 Reference materials

Reference materials which may be in-house, but preferably certified reference materials shall be used to provide essential traceability in measurements. They may be used:

- (a) to demonstrate the accuracy of results;
- (b) to calibrate equipment;
- (c) to monitor laboratory performance;
- (d) to validate methods; and
- (e) to enable comparison of methods.

## **5.7 Post-examination processes**

As in MS ISO 15189.

## **5.8 Reporting of results**

5.8.1 A clinical interpretation of test results should normally be provided by a clinical microbiologist preferably after consultation or discussion with the clinician in-charge with exception of simple interpretation (See Clause 5.8.2 of this document).

5.8.2 Any authorised personnel may evaluate test results in conformity with clinical information available and provide simple interpretation e.g. “normal flora isolated”, “no enteric pathogen isolated”, “mixed growth-suggest repeat culture”, “no recognised pathogen”.

- 5.8.3 The clinical interpretation of viral diagnostic test results shall be provided by a clinical microbiologist who has at least six (6) months of supervised training in medical diagnostic virology.
- 5.8.4 Medical practitioners who are undergoing formal training in medical microbiology, such as a Master of Pathology Programme, can also provide clinical interpretation, provided that they are under the direction and supervision of a clinical microbiologist.
- 5.8.5 A service medical officer can also provide clinical interpretation provided they are under direction and supervision of a clinical microbiologist.

## **5.9 Release of results**

- 5.9.1 A preliminary report shall be made available when the result is crucial to patient management e.g. microscopic examination of a positive blood culture or CSF.
- 5.9.2 A policy shall be made between the laboratory and the requesters of tests clearly describing the procedure for obtaining preliminary reports. This shall be spelt out in the laboratory collection manual/handbook.
- 5.9.3 Results shall be immediately communicated to the requester of tests when a result warrants a notification of a communicable disease under the Notifiable Communicable Disease of Malaysia via Prevention and Control of Infectious Disease Act 1998.
- 5.9.4 For certain laboratory results, it is important to notify the authorised requester as soon as possible. The laboratory shall in consultation with the requesters establish the conditions where it is necessary for such urgent notification and the time frame within which such notifications should be made. Examples of these laboratory results may include but not limited to the following:
- (a) Positive direct smear for acid fast bacilli
  - (b) Multi-resistant nosocomial pathogens
  - (c) Positive blood film for malarial parasites
  - (d) Positive microscopic examination of CSF in a case of meningitis

## **5.10 Laboratory information management**

As in MS ISO 15189.

## Classes of Test

### **Bacteriology**

1. Microscopic examination
2. Culture and identification
3. Antibiotic susceptibility testing
4. Detection of bacterial antigens
5. Serology tests
6. Detection and characterisation of DNA/RNA
7. Miscellaneous bacteriology tests

### **Parasitology**

1. Preparation and examination of films
2. Identification of parasites
3. Detection of parasitic antigens
4. Serology tests
5. Detection and characterisation of DNA/RNA
6. Miscellaneous parasitology tests

### **Mycology**

1. Microscopic examination of clinical specimens
2. Culture of specimens
3. Identification of fungi
4. Antifungal susceptibility tests
5. Detection of fungal antigens
6. Serology tests
7. Detection and characterisation of DNA/RNA
8. Miscellaneous mycology tests

### **Mycobacteriology**

1. Microscopic examination of clinical specimens
2. Culture of mycobacteria
3. Limited identification of isolates
4. Definitive identification of isolates
5. Serology tests
6. Detection and characterisation of DNA/RNA

7. Mycobacterial susceptibility testing
8. Miscellaneous mycobacteriology tests

### **Virology**

1. Electron microscopy
2. Viral culture and identification
3. Detection of viral antigens
4. Serology tests
5. Detection and characterisation of DNA/RNA
6. Miscellaneous virology tests

### **Immunology**

1. Immunoglobulin assays
2. Specific immunoglobulin assays
3. Complement assays
4. Autoantibodies assays
5. Tests of cellular immunity
6. Immunotyping
7. Miscellaneous immunology tests

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12. Dr. B. Vijayamalar Standards Malaysia
13. Datin Dr. Salbiah Hj. Nawar Hospital Kuala Lumpur
14. Ms. Zaidatul Azmi Abdul Rahman Standards Malaysia
15. Dr. Zubaidah Abdul Wahab Hospital Sungai Buloh
16. Dr. Masita Arip Institut Penyelidikan Perubatan
17. Mr. Khairul Azan Hashim Makmal Kesihatan Awam Kebangsaan
18. Dr. Mangalam Sinniah Clinipath (M) Sdn. Bhd.
19. Dr. Siti Norlia Othman Pusat Perubatan UKM
20. Mr. Mustafah Md. Nor Bahagian Sains Kesihatan Bersekutu, Kementerian Kesihatan Malaysia
21. Ms. Suguna A/P Rasamaniam Gribbles Pathology (M) Sdn. Bhd.
22. Ms. Jamuna Jairaman Sunway Medical Centre Berhad
23. Prof. Dr. Zamberi Sekawi Universiti Putra Malaysia
24. Prof. Madya Dr. Fauziah Mohamad Idris Universiti Sains Malaysia
25. Ms. Rohasmizah Ismail Standards Malaysia
26. Ms. Siti Norehan Ishak Standards Malaysia
27. Ms. Norsheda Mohd Bahari Standards Malaysia