MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

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

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(Supplementary to MS ISO 15189)

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LABORATORY ACCREDITATION SCHEME OF MALAYSIA

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Introduction

This document describes the specific technical requirements to be complied with by medical microbiology laboratories. This document should be read in conjunction with the MS ISO 15189 *Medical laboratories - Requirements for quality and competence* and other accreditation criteria documents published by the 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 be 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 Bacteriology
1.2 Virology
1.3 Parasitology
1.4 Mycology
1.5 Mycobacteriology
1.6 Immunology

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

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

Same as MS ISO 15189 and SC 2.

4 General requirements

Same as MS ISO 15189 and SC 2.

5 Structural and governance requirements

Same as MS ISO 15189 and SC 2.

6 Resource requirements

6.2 Personnel

6.2.2 Competence requirements

a) Personnel qualifications

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

ii) A **laboratory scientist** shall hold an appropriate bachelor's degree or an equivalent as specified in the SC 2, and have had at least six (6) months of supervised training in a microbiology laboratory which may be part of the training programme during their bachelor's degree or equivalent.

iii) A **clinical microbiologist** shall be a medically qualified pathologist who has a postgraduate qualification in pathology, such as the Member of the Royal College of Pathologists (MRCPath) or Master of Pathology (MPath) or 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.

6.3 Facilities and environmental conditions

6.3.1 General

i) Sufficient and appropriate space to conduct microbiological activities shall be provided, in line with biosafety requirements.

ii) 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.

iii) The microbiological work area shall be adequately ventilated. The air should not be recirculated when dealing with organism that requires biosafety level 3 precautions.

iv) All laboratories shall conform to the requirements of good microbiological practices. Reference documents may include the Biosafety Act 678, Biosafety in Microbiological and Biomedical Laboratories (BMBL) by the CDC, Atlanta, and the WHO Laboratory Biosafety Manual.

6.3.3 Storage facilities

The provision of sufficient storage space, under the appropriate conditions, is essential for maintaining the integrity of samples, stock cultures, reagents and records.

6.3.4 Personnel facilities

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.

6.4 Equipment

6.4.2 Equipment requirements

1) Autoclaves

i) Autoclaves shall not be used to sterilise 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.

ii) 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

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

iv) The autoclave shall be operated by trained and competent personnel.

v) Biological indicators are recommended for autoclaves used for the sterilisation of media.

2) Thermometers

Thermometers shall be verified against their working temperatures. Reference thermometers and temperature loggers (if used by the laboratories) shall be calibrated by an accredited calibration laboratory.

3) Centrifuge

Sealed buckets shall be used in centrifuges (preferably refrigerated centrifuge) 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.

4) Loop steriliser

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

5) Rotator

Verification shall be conducted periodically by authorised body or trained personnel.

6) Biological safety cabinets

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

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

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

iv) Bunsen burners shall not be used in the biosafety cabinets and the use of electrical loop sterilisers in the biosafety cabinets is strongly not encouraged.

7) Microscopes

Periodic preventive maintenance (PPM) shall be conducted by trained personnel.

6.6 Reagents and consumables

6.6.1 General

Reagents/ stains/ media/ kits/ antimicrobials

1) Media (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 prepared media/solutions
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

2) Media (Purchased from manufacturers)

i) The laboratory shall obtain a comprehensive quality control report for each batch of media from the manufacturer. 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.

3) 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.

7 Process requirements

7.2 Pre-examination processes

If patient care is affected, the time of sample collection shall be documented in the request forms.

7.3 Examination processes

i) A testing algorithm should be established and shall be updated, when necessary, in respect of each clinical syndrome. (Reference may be made to e.g. Ministry of Health Syndromic Notification and Laboratory Investigation Manual or the relevant Malaysian Clinical Practice Guidelines).

ii) Cell culture and virus isolation

a. Sterility of all culture media shall be ensured following the addition of ingredients post sterilisation.

b. 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.

c. There shall be documentation of cell types, sources, passages and media used in their propagation.

d. 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).

7.3.7 Ensuring the validity of examination results

i) 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.

ii) A lineage history shall be retained of each quality control organism. These organisms are used to perform quality control, acceptance testing, method verification and validation on:

a. Culture media
b. Test kits and reagents
c. Antimicrobial susceptibility tests (manual and automated)
d. Blood culture system
e. Microbial identification system (manual and automated)

iii) 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 to:

a. demonstrate the accuracy of results;
b. calibrate equipment;
c. monitor laboratory performance;
d. validate methods; and
e. verify methods

7.4 Post-examination processes

7.4.1 Result reporting

i) Clinical interpretation of test results should be provided by a clinical microbiologist when necessary, following consultation or discussion with the clinician-in-charge. Informative and value-added comments are particularly valuable to aid the clinician in patient care.

ii) Authorised personnel who have been trained and deemed competent (e.g scientific officer, senior MLT, senior research officer) may review, evaluate and release test results in

conformity with available clinical information and provide descriptive comments e.g. reactive / non-reactive / detected / not detected / positive / negative / normal flora isolated.

iii) Medical professionals undergoing formal training in medical microbiology, such as a Master of Pathology Programme, are also qualified to provide clinical interpretation, provided they are supervised and guided by clinical microbiologists.

iv) A service medical officer can also provide clinical interpretation provided they are under direction and supervision of a designated clinical microbiologist.

v) Details of the examination methods shall be made available upon request.

vi) If applicable, the antimicrobial susceptibility results should follow the protocol for selective/cascade reporting.

vii) Interpretative comments shall be reviewed regularly and updated when necessary.

7.4.1.2 Result review and release

i) A preliminary report shall be made available when the result is critical to patient management e.g. microscopic examination of a positive blood culture or CSF.

ii) A documented procedure for obtaining preliminary reports shall be made available to the requesters (e.g. laboratory collection manual/handbook/website-laboratory service information/catalogue price list).

7.4.1.3 Critical result reports

Critical results that require immediate medical, infection control, or public health intervention, including those of a life-saving nature, shall be communicated to the appropriate healthcare providers according to the laboratory and national requirements. An escalation procedure should be documented.

8 Management system requirements

Same as MS ISO 15189 and SC 2.

Appendix 1

Classes of Test

1.1 Bacteriology

1) Microscopic examination
2) Culture and identification
3) Antibiotic susceptibility testing
4) Detection of bacterial antigens
5) Serology tests
6) Miscellaneous bacteriology tests

1.2 Virology

1) Electron microscopy
2) Viral culture and identification
3) Detection of viral antigens
4) Serology tests
5) Miscellaneous virology tests

1.3 Parasitology

1) Preparation and examination of films
2) Identification of parasites
3) Detection of parasitic antigens
4) Serology tests
5) Miscellaneous parasitology tests

1.4 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) Miscellaneous mycology tests

1.5 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) Mycobacterial susceptibility testing
7) Miscellaneous mycobacteriology tests

1.6 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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