



STANDARDS
MALAYSIA

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

**STR 2.1 - SPECIFIC TECHNICAL REQUIREMENTS
FOR ACCREDITATION OF
ANATOMICAL PATHOLOGY (CYTOPATHOLOGY)
LABORATORIES**

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MS ISO 15189

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SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF ANATOMICAL PATHOLOGY (CYTOPATHOLOGY) LABORATORIES

1 Introduction

- (a) This document describes the specific technical requirements to be complied by cytopathology 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 and 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 minimum requirement for accreditation of cytopathology laboratory shall include reception of sample and request form, slide preparation, staining, screening, reporting and release of report.

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

- 2.1 Gynaecological Cytopathology (GYN Cytopathology)
 - i) Conventional
 - ii) Liquid based
- 2.2 Non-Gynaecological Cytopathology (Non-GYN Cytopathology)
- 2.3 Fine Needle Aspiration Cytology (FNAC)
- 2.4 Specialised tests such as special stains, immunohistochemical stains and molecular testing (HPV DNA) if performed in the cytopathology laboratory shall be included in the scope of accreditation.

3 Terms and definitions

- 3.1 Anatomical pathology - includes histopathology, cytopathology and clinical autopsy.

- 3.2 Cytoscientist - is a scientist trained in cytopathology.
- 3.3 Cytoscreener - is a person who does the screening of cytology smears.
- 3.4 Liquid-based cytology (LBC) - cytologic samples collected in appropriate liquid medium for processing into smears.
- 3.5 CT(IAC)- Comprehensive Cytotechnology Examination (The International Academy of Cytology)
- 3.6 Abnormal gynaecological smear - any cytological abnormality that falls under the category of epithelial cell abnormality as in the Bethesda classification.
- 3.7 Negative gynaecological smear - any cytological changes that do not fall under the category of abnormal gynaecological smears.

4 Management requirement

As in MS ISO 15189 and Specific Criteria 2 (SC 2).

4.13 Control of records

The laboratory shall maintain statistics of the number of samples handled in the laboratory classified under the following headings:

- a) Gynaecological;
- b) General (non-gynaecological) cytology;
- c) Fine needle aspirations.

If any relevant records or slides are removed from a file, this shall be traceable.

5 Technical requirements

5.1 Personnel

5.1.1 General

A cytopathology laboratory shall have at least a cytoscreeener and a cytopathologist.

Key personnel in cytopathology laboratory shall include cytopathologist, supervisory cytoscreeener and/or supervisory cytotechnologist.

5.1.2 Personnel qualifications

- a) Clinical personnel
- i) A **qualified cytopathologist** (hereafter referred to as cytopathologist) shall be a medical practitioner registered with the Malaysian Medical Council and an anatomical pathologist with additional training or working experience in cytopathology for at least 6 months. Registration with the National Specialist Register and additional certification in cytopathology are desirable.
 - ii) A **cytopathology trainee** is a medical practitioner working in a cytopathology laboratory under the supervision of a cytopathologist.
- b) Technical personnel
- i) A **qualified cytoscientist** (hereafter referred to as cytoscientist) shall have a Bachelor of Science Degree or an equivalent and have undergone additional supervised training and evaluation in cytopathology for a minimum of 6 months.
 - ii) A **supervisory level cytoscientist** shall be a cytoscientist with at least 3 years continuous working experience in cytopathology. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.
 - iii) A **qualified cytotechnologist** (hereafter referred to as cytotechnologist) shall have a Diploma in Medical Laboratory Technology (MLT) or its equivalent and have undergone additional supervised training and evaluation in cytopathology for a minimum of 6 months. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.
 - iv) A **supervisory level cytotechnologist** shall be a cytotechnologist with at least 5 years continuous working experience in cytopathology. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.
 - v) A **technical assistant** in cytopathology shall be a person with at least Sijil Pelajaran Malaysia (SPM) or equivalent. The person shall have appropriate practical experience and specific training and authorised to assist the cytotechnologist/cytoscientist in the reception, registration and processing of specimens, labeling, automated staining, arranging stained slides prior to

screening and archiving of slides and reports. The above processes shall be monitored by a cytotechnologist/cytoscientist.

5.1.3 Job descriptions

Given the duties of a cytopathologist (resident and visiting) includes direct supervision of personnel, processes and quality control, it is strongly advised that the cytopathologist is on site to perform the above duties. The frequency and duration of visits are defined by the volume and scope of work undertaken by the cytopathologist.

5.1.6 Competence assessment

Personnel Competency

- a) A cytoscreener shall perform screening of at least 3000 gynaecological smears per year to maintain competency.
- b) A cytopathologist/ cytoscientist/ cytotechnologist shall screen a minimum of 20 abnormal gynaecological smears per month to maintain competency. If the number of abnormal cases reported is insufficient, the laboratory shall take part in documented supplementary activities designed to maintain expertise.
- c) A cytopathologist shall report no less than 750 cases (gynaecological and/or non-gynaecological and/or FNAC) per year to maintain competency.

Workload policy

- i) A cytoscreener with no other duties shall screen:
 - a) no more than 70 conventional gynaecological smears per 24 hours. For screening of gynaecological smears, the maximum rate shall not exceed 10 smears per hour.
 - b) no more than 100 liquid-based gynaecological smears per 24 hours.
 - c) no more than 140 slides per 24 hours for smears prepared by liquid-based method and pre-screened using automated devices.
- ii) A cytoscreener performing full re-screening shall screen no more than 20 conventional gynaecological smears per hour or no more than 25 smears per hour for LBC.
- iii) If anatomical pathologist performs primary screening as well as reporting, he or she shall be bound by the same workload limits as for cytotechnologist screeners. There shall be a

system for re-screening.

- iv) A part-time cytotechnologist shall observe the same workload limits.

Note: The number of slides screened by an individual should be governed by the relative skill and experience of the screener.

All cytology staff using liquid-based method and automated screening techniques shall be trained and qualified to operate the device, and to interpret results obtained from those technologies.

5.2 Accommodation and environmental conditions

5.2.2 Laboratory and office facilities

For laboratories providing FNAC services, the following shall be in place:

- a) a procedure on how to handle medical emergencies;
- b) trained personnel to handle medical emergencies; and
- c) simple resuscitation equipment such as AMBU bag and intravenous drip set.

For safety and security of personnel in health care facilities, 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

- a) Cytoscreening shall be carried out in a separate room, free from noise and distraction.
- b) An appropriate extraction system shall be in place in the specimen processing area to minimise the level of noxious vapours.

5.3 Laboratory equipment, reagents and consumables

5.3.1.1 General

All cytopathology specimen preparation shall be carried out in a biosafety cabinet that provides protection for the operator and the environment.

Manual preparation of smears which include staining, clearing and mounting shall be carried out in a fume cabinet.

High quality binocular microscopes shall be available to all cytoscreeners. Microscope should include 4x, 10x, 20x and 40x objectives.

Multi-headed microscope or other similar devices should be available for teaching and training.

5.4 Pre-examination processes

5.4.3 Request form information

Information needed in the request form for gynecological cytopathology should include the following:

- (a) Last Menstrual Period (LMP)
- (b) Previous surgery (GYN)
- (c) Hormonal/Oral Contraceptive (OCP)

5.4.4 Primary sample

5.4.4.1 In laboratories that provide FNAC services, a signed consent from the patient shall be obtained by the person performing the procedure.

5.5 Examination processes

5.5.1 Selection, verification and validation of examination procedures

There shall be a hierarchical system for gynaecological and non-gynaecological cytology screening.

All technologies using liquid-based method and automated screening devices shall have approval from the national authority e.g. Medical Device Authority.

5.6 Ensuring quality of examination results

5.6.1 General

There shall be a mechanism for feedback to the cytoscreener when the final diagnosis in the report is different from the cytoscreener's interpretation.

5.6.2 Quality control

The laboratory shall also carry out internal quality control activities which may include the following:

- i) slide staining quality
- ii) steps to prevent cross contamination

5.6.3 Interlaboratory comparison

The laboratory shall participate in an Interlaboratory Comparison Programme (ILC) such as External Quality Assurance (EQA) (national and/or international programme) which addresses its diagnostic and technical activities. The laboratory shall monitor individual and overall performance and implement corrective action where necessary. Records of these activities shall be maintained.

Where a cytopathologist is providing service in more than one laboratory, he/she is required to participate in the appropriate module(s) of the EQA programme.

Gynaecological cytopathology

- a) The laboratory shall establish criteria for review of cases by the cytopathologist. The criteria shall include but not limited to abnormal and unsatisfactory smears.
- b) The rates of unsatisfactory smears and those without endocervical or squamous metaplastic cells shall be monitored, and feedback given to smear takers at least every 6 months.
- c) Cyto-histopathologic correlation of High Grade Squamous Intraepithelial Lesion (HSIL) and more severe lesions is recommended.
- d) There shall be a system to review the previous cytology smears of current abnormal smears. The recommendation for review is slide/s within preceding 3 years.

- e) Laboratories shall establish a system of re-screening of negative gynaecological smears (manual and automated system). A minimum of 10% re-screening of negative smears and all targeted cases shall be carried out. The laboratories are encouraged to achieve 100% re-screening.
- Note:** Targeted cases means with positive clinical history e.g. per vaginal bleeding, discharge, lesions or “negative” smears with positive clinical history.
- f) Laboratories shall monitor (at least annually) its performance as a whole, these activities shall include the following :
- i. Rate of unsatisfactory smears
 - ii. Rate of negative smear
 - iii. Rate of abnormal smears (for each category)
 - iv. False positive and false negative rates
- g) Laboratory shall monitor the performance of individual screeners and cytopathologists.

Non-gynaecological cytopathology

- a) There shall be a system to review the previous cytology smears of current abnormal smears.
- b) Cyto-histopathologic correlation should be carried out in laboratories that provide both cytology and histopathology services.

FNA cytopathology

- a) Cyto-histopathologic correlation should be carried out in laboratories that provide both cytology and histopathology services.

5.7 Post-examination processes

- 5.7.1 In the event of discrepancy in diagnosis with prior samples examined by the laboratory, previous cytopathologic and histopathologic results shall be reviewed.

5.8 Reporting of results

Peer consultation of difficult cases should be encouraged before the final report is issued.

Gynaecological cytopathology

- a) Negative smears may be reported by authorised cytoscientist, cytotechnologist or pathology trainee in cytopathology. All other smears shall be reported by a cytopathologist.
- b) The current Bethesda System shall be used for reporting.

Non-gynaecological cytopathology

- a) Negative sputum smears may be reported by authorised cytoscientist or cytotechnologist or pathology trainee in cytopathology. All other smears shall be reported by a cytopathologist.

FNA cytopathology

- a) All cases shall be reported by a cytopathologist.

5.9 Release of results

The laboratory shall establish an “alert” or “critical” result e.g. high grade lesion in Pap smear from an asymptomatic woman.

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.

References:

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. Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010 (http://www.moh.gov.my/images/gallery/Garispanduan/Guidelines_on_Chemical-1.pdf)
4. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations) (<http://www.dosh.gov.my/index.php/en/legislation/regulations-1/osha-1994-act-154/522-pua-131-2000-1/file>)
5. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations) (http://www.federalgazette.agc.gov.my/outputp/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)
6. The Royal College of Pathologists Guidelines on staffing and workload for histopathology and cytopathology departments (4th edition), September 2015
7. HOKLAS Supplementary Criteria No. 24 'Medical Testing' Testing Category- Cytopathology, Issue 5, 24 June 2015
8. SANAS TR 32-04 Technical requirements for the accreditation of cytology in medical laboratories, 5 February 2010
9. SAC-SINGLAS Technical Notes Med 002- Specific criteria for cytopathology section, August 2013
10. National Pathology Accreditation Advisory Council (NPAAC)- Requirements for Gynaecological (Cervical) Cytology, Second Edition 2014

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