MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

STR 2.1 - SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF ANATOMICAL PATHOLOGY (CYTOPATHOLOGY) 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 by cytopathology 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 requirements for accreditation of cytopathology laboratory shall include pre-examination, examination and post-examination processes.

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

1.1 Gynaecological cytopathology (GYN cytopathology)
- i) Conventional
- ii) Liquid-based

1.2 Non-gynaecological cytopathology (Non-GYN cytopathology)

1.3 Fine-needle aspiration cytology (FNAC)

1.4 Specialised tests such as special stains, immunohistochemical stains and molecular testing (e.g. HPV DNA) if performed in the cytopathology laboratory shall be included in the scope of accreditation.

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 Abnormal gynaecological smear
Any cytological abnormality that falls under the category of epithelial cell abnormality as in The Bethesda Classification.

3.2 Anatomical pathology
Includes histopathology, cytopathology and clinical autopsy.

3.3 Anatomical pathologist
Anatomic pathologists who are involved in cytopathology laboratory operation.

3.4 CT(IAC)
Comprehensive Cytotechnology Examination (The International Academy of Cytology).

3.5 Cytopathology trainee
Is a medical practitioner working in a cytopathology laboratory under the supervision of an anatomical pathologist.

3.6 Cytoscientist
Is a scientist trained in cytopathology.

3.7 Cytoscreener
Is a person who does the screening of cytology smears.

3.8 Digital microscopy
The scanning of a whole glass slide containing cut and stained human tissue and glass slide cytology preparations, then converting into a high-resolution quality digital image, which can be viewed by an anatomical pathologist on a viewer application with panning and zooming functions which can be used to simulate the use of a conventional microscope. Images can be acquired in 2 dimensions (x- and y-axes) with the option of z-stacked (3-D).

3.9 Liquid-based cytology (LBC)
Cytologic samples collected in appropriate liquid medium for processing into smears.

3.10 Negative gynaecological smear
Any cytological changes that do not fall under the category of abnormal gynaecological smears.

4 General requirements

Same as MS ISO 15189 and SC 2.

5 Structural and governance requirements

5.4.1 General

b) The duties of anatomical pathologist(s) either resident and/or visiting includes direct supervision of personnel, processes and quality assurance activities such as, but not limited to internal quality control (IQC) and external quality assessment (EQA). It is strongly advised that the anatomical pathologist is on site to perform the above duties. The frequency and duration of visits shall be defined by the volume and scope of work undertaken by the anatomical pathologist.

6 Resource requirements

6.2 Personnel

6.2.1 General

A cytopathology laboratory shall have sufficient cytoscreeners and anatomical pathologist subject to the workload of the laboratory.

Key personnel in cytopathology laboratory shall include:

1) Anatomical pathologist;
2) Supervisory cytoscientist;
3) Supervisory cytotechnologist; and/or
4) Cytoscreener.

There shall be a written workload policy to determine the adequacy of technical personnel as follows:

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 an anatomical pathologist performs primary screening as well as reporting, he or she shall be bound by the same workload limits as for cytoscreeners. There shall be a system for re-screening.

iv) A part-time cytoscreener 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 cytopathology personnel 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.

6.2.2 Competence requirements

a) Personnel qualifications

i) Clinical personnel

   a. A qualified **anatomical pathologist** shall be a medically-qualified pathologist (i.e. a medical practitioner registered with the Malaysian Medical Council, with a postgraduate qualification in pathology approved by the Government of Malaysia). An additional certification in cytopathology is desirable.

   b. A **cytopathology trainee** is a medical practitioner working in a cytopathology laboratory under the supervision of an anatomical pathologist.

ii) Technical personnel

   a. A **qualified 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 six (6) months continuously. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.

   b. A **supervisory level cytoscientist** shall be a cytoscientist with at least three (3) years continuous working experience in cytopathology. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.

   c. 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 six (6) months continuously. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.

   d. A **supervisory level cytotechnologist** shall be a cytotechnologist with at least five (5) years continuous working experience in cytopathology. Additional certifications such as Advanced Diploma in Cytology, CT(IAC) certification or its equivalent is desirable.

e. A **cytoscreener** qualifications as stated above in ii) a.- d.

f. A **technical assistant** in cytopathology shall be a person as defined in SC 2. 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.

c) Competence assessment

The following criteria shall be fulfilled in assessing personnel competency but not limited to:

i) Anatomical pathologists:

a. Workload of 500 cases (including gynaecological, non-gynaecological and FNAC) per year. If the minimum number is not met, the laboratory should design other systems that verify the attainment of screening skill and the maintenance of diagnostic acumen of the anatomical pathologists.

b. To achieve at least 80% in Proficiency testing (PT)/EQA performance.

c. To screen 20 abnormal gynae smears per month. If the 20 abnormal gynae cases reported in a month is insufficient, the laboratory shall take part in documented supplementary activities designed to maintain expertise.

d. To perform cytopathology /histopathology correlation (gynaecological, non-gynaecological and FNAC).

e. To have regular update in cytopathology.

ii) Cytotechnologists/cytoscientists:

a. Workload of 3000 gynaecological smears per year. This includes either primary screening and full manual re-screening of gynaecological smears. If the minimum number is not met, the laboratory should design other systems that verify the attainment of screening skill of the cytotechnologists.

b. Concordant rates of at least 80% for gynaecology smears.

c. To screen 20 abnormal gynaecological smears per month. If the 20 abnormal gynaecological cases reported in a month is insufficient, the laboratory shall take part in documented supplementary activities designed to maintain expertise.

d. To achieve at least 80% in PT/EQA performance for gynaecological cytology.

e. To have regular updates in cytopathology.

Note: Anatomic pathologist and cytotechnologist/cytoscientist performance may be evaluated through pick up rate, ASC rate, ASC-SIL ratio and HPV in ASC-US.

6.2.3 Authorization

b) In addition to standard requirements, technical personnel shall be authorised to perform the following laboratory activities but not limited to:

i) Reception of samples.

ii) Cytopreparation of cytology samples.

iii) Screening and reporting of gynaecological/non-gynaecological smears/FNAC smears.

iv) Screening, reporting, review and release of negative gynae smear.

v) Assist in Fine-needle aspiration (FNA) procedure.

6.3 Facilities and environmental conditions

6.3.1 General

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

i) A procedure on how to handle medical emergencies.

ii) Trained personnel to handle medical emergencies.

iii) Simple resuscitation equipment such as Artificial Manual Breathing Unit (AMBU bag) and intravenous drip set.

Availability of a resuscitation trolley is recommended.

6.3.2 Facility controls

i) Cytoscreening shall be carried out in a separate room, free from noise and distraction that can affect the concentration of the staff. The room shall be well-lit, have sufficient space and personnel should be provided ergonomically designed work benches for microscopic work due to the repetitive nature of the process.

ii) An appropriate extraction system shall be in place in the specimen processing area to minimise the level of noxious vapours.

iii) When the laboratory is responsible for operating a FNAC clinic, appropriate safety instructions shall be provided to the sample collectors and operators if biosafety cabinet is not installed at the sites where the aspirate to be collected. This is to ensure safety by requiring appropriate personal protective equipment shall be worn during operation and precautionary measures to protect other personnel in the surrounding area.

6.4 Equipment

i) Essential equipment shall be furnished for the provision of cytopathology service. These include the following:

   a. High quality binocular microscopes (4x, 10x and 40x objectives) for screening and reporting.
   b. Biosafety cabinet for all cytopathology specimen preparation including infectious sample to provides protection for the operator and the environment.
   c. Fume cabinet for manual preparation of smears which include staining, clearing and mounting.
   d. Cytocentrifuge for laboratories offering non-gynaecological cytopathology services.
   e. Universal centrifuge.
   f. Specimen refrigerator.

ii) Additional equipment should be made available based on workload and training needs. These include the following:

   a. Automated stainer
   b. Multi headed microscope
   c. Dual viewing microscope
   d. Cover slipper machine
   e. LBC system
   f. Slide labeler
   g. Laboratory Information System (LIS)
   h. Automated screening devices

7 Process requirements

7.2 Pre-examination processes

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

b) Information needed in the request form for gynaecological cytopathology shall include the following:

i) Last menstrual period (LMP)
ii) Previous surgery (GYN)
iii) Type of contraceptive (where applicable)
- Hormonal
- Intrauterine Contraceptive Device (IUCD)
iv) Hormonal therapy (where applicable)
v) Chemo/radiation therapy (where applicable)

7.2.4 Primary sample collection and handling

FNAC sampling shall be carried out by anatomical pathologist or competent medical personnel.

7.2.4.3 Patient consent

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

7.3 Examination processes

7.3.1 General

7.3.6 Documentation of examination procedures

a) Documentation of examination procedures

i) Laboratory which uses digital microscopy for diagnostic purposes shall have relevant documents, procedures, training and verification in place. Reference can be made to national or international guidelines.

7.3.7 Ensuring the validity of examination results

7.3.7.2 Internal quality control (IQC)

a) The laboratory shall establish a procedure to conduct the following:

i) The laboratory shall carry out internal quality control activities which may include but not limited to cytopreparatory procedures such as staining quality and its criteria, slide preparation (including source of IQC material) and steps to prevent cross contamination.

ii) Staining solutions are filtered, covered when not in use and changed in accordance with a written procedure. It includes frequency stains changed, circumstances stains are filtered.

iii) All QC slides shall show the date when the staining was performed on the slide label.

7.3.7.3 External quality assessment (EQA)

a) The laboratory shall participate in an EQA which addresses its diagnostic and technical activities.

c) i) The laboratory shall monitor individual and institutional EQA performance with a recommended target of minimum 80% and implement corrective action where necessary. Records of these activities shall be maintained.

ii) Where an anatomical pathologist is providing service in more than one laboratory, he/she is required to participate in the appropriate module(s) of the EQA programme. Records of these activities shall be available.

7.4 Post-examination processes

7.4.1 Reporting of results

7.4.1.1 General

a) For reporting of cytopathology examination results, the laboratory shall comply to the following requirements:

i) Explanatory note shall accompany any unsatisfactory or equivocal reports.

ii) Anatomical pathologists reporting slides using digital microscopy shall have evidence of training and are credentialed to use this diagnostic method.

iii) There shall be a hierarchical system for cytopathology screening and reporting of gynaecological, non-gynaecological and fine needle aspiration.

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

7.4.1.2 Result review and release

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

For result review and release, the following shall be followed:

i) Gynaecological cytopathology

a. Negative smears shall be reported by authorised cytoscientist, cytotechnologist or pathology trainee in cytopathology. All other smears shall be reported by an anatomical pathologist.

b. The current Bethesda System shall be used for reporting.

c. The laboratory shall establish criteria for review of cases by the anatomical pathologist. The criteria shall include but not limited to abnormal and unsatisfactory smears.

d. 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.

e. There shall be a system to review the previous and current abnormal cytology smears. The recommendation for review of the slide(s) is within preceding 3 years.

f. Laboratories shall establish a system of rescreening of negative gynaecological smears (manual and automated system). A minimum of 10% rescreening of negative smears and all targeted cases shall be carried out. The laboratories are encouraged to achieve 100% rescreening.

Note: Targeted cases means with positive clinical history e.g. per vaginal bleeding, discharge, lesions or “negative” smears with positive clinical history.

ii) Non-gynaecological cytopathology

a. All cases shall be reported by an anatomical pathologist.

b. There shall be a system to review the previous cytology smears of current abnormal smear from the same site or organ.

iii) FNAC

a. All cases shall be reported by an anatomical pathologist.
b. Cyto-histopathologic correlation shall be carried out in laboratories that provide both cytology and histopathology services.
c. If significant disparities exist between histologic and cytologic diagnosis that may affect patient management, these shall be reconciled in the report with appropriate recommendations or actions.

7.4.1.3 Critical result reports

The laboratory shall establish critical decision limits e.g. unexpected high-grade lesion or malignancy in gynaecological smears, unexpected malignancy in non-gynaecological and FNAC smears, organisms in cerebrospinal fluid (CSF).

8 Management system requirements

8.4 Control of records

The laboratory shall have procedure and retain records but not limited to, as follows:

i) To handle slides with proper identification and storage to ensure readily retrievable.
ii) To retain specimens including slides and paraffin blocks according to the national and/or international guidelines.
iii) To retain original request forms and final report (hard/electronic copies) according to the national and/or international guidelines.
iv) To release slides and/or cell blocks to third parties e.g. other laboratories or other clinicians.
v) To archive records, residual samples, slides and/or blocks.
vi) To archive samples or slides for academic purposes (teaching and research).
vii) To dispose records, residual samples, slides and/or blocks.

8.8 Evaluations

8.8.2 Quality indicators

1) Accuracy

i) Gynaecological

Laboratories shall monitor (at least annually) its performance as a whole, these activities shall include the following:

a. Rate of unsatisfactory smears
b. Rate of negative smear
c. Rate of abnormal smears (for each category)
d. False positive and false negative rates
e. HR-HPV Records - If available, records are maintained for high-risk HPV tests performed on ASC-US cases including:
   - Total number of HR-HPV tests performed on ASC-US cases
   - Total number of positive HR-HPV ASC-US cases

Cyto-histopathologic correlation shall be carried out in cases with High-grade Squamous Intraepithelial Lesion (HSIL) or above with performance defined as in Ministry of Health or

international standard, monitored, with statistical calculation and record of the action taken if required or not achieved.

ii) Non-gynaecological and FNAC

Cyto-histopathologic correlation shall be carried out in cases with positive cytologic findings with performance defined as in Ministry of Health or international standard, monitored, with statistical calculation and record of the action taken if required or not achieved.

2) Timeliness

The laboratory shall establish an appropriate time frame for reporting urgent and non-urgent cytology samples to facilitate patient management.

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