1. Purpose

This Supplement requirements are specific requirements for Cytopathology Laboratory.

2. Application

This supplement requirements are specified the requirements that the Cytopathology Laboratory shall establish the policy and procedure to ensure that the Cytopathology Laboratory comply with this supplement requirements and ISO 15189.

3. References

3.1 Cytopathology Checklist for CAP Accreditation Program: in conjunction with the all common and laboratory general checklists to inspect a cytopathology laboratory section or department. The College of American Pathologists (CAP), U.S.A., 2017.

☞ 3.2 Cytopathology Checklist for CAP Accreditation Program: in conjunction with the all common and laboratory general checklists to inspect a cytopathology laboratory section or department. The College of American Pathologists (CAP), U.S.A., 2024

3.3 Canadian Society of Cytopathology. Guidelines for practice & quality assurance in cytopathology [Internet]. Canadian Society of Cytopathology; 2019.

4. Definition and abbreviation

4.1 Cytopathology is a diagnostic technique that examines cells from various body sites to determine the cause or the nature of disease.

5. Associated Documents

5.1 N 07 15 001	Policy and requirements for acceptance the measurement result of calibration equipment
5.2 N 07 15 011	Supplement requirements for medical laboratory

6. Procedures

Supplement Requirements

6.1 Personnel

6.1.1 Personnel Responsible for Cytopathology

The personnel responsible for cytopathology shall include, at a minimum, the following:

1) Cytotechnologists, including cytological screeners and certified senior cytotechnologists.

1.1) For gynecologic cytology (conventional and/or liquid-based preparations), the screening workload shall not exceed 60 slides within 8 hours, and shall not exceed 100 slides within 24 hours. If the cytotechnologist is additionally assigned to other cytopathological tasks such as specimen registration, slide preparation, staining, data entry, or reporting of cytopathology results, the cytopathology screening workload shall be proportionally reduced.

1.2) Cytologists or medical science personnel responsible for cytology slide screening shall possess appropriate qualifications in cell biology or other equivalent qualifications, such as a Certificate in Cytology issued by the Royal College of Obstetricians and Gynaecologists of Thailand.

1.3) Cytologists or medical science personnel performing gynecologic cytology diagnosis shall have undergone calibration or proficiency assessment in gynecologic cytodiagnosis by a recognized organization, such as the Royal College of Obstetricians and Gynaecologists of Thailand.

2) Pathologist

There shall be an adequate number of pathologists to ensure the quality and quantity of cytopathological services. Each pathologist who is responsible solely for pathological diagnosis, without any additional administrative or academic duties, shall not exceed a working period of 6 hours per day. If the pathologist is additionally engaged in other professional responsibilities — such as teaching, training, management, quality control,

continuing education, or research — the pathological diagnostic workload shall be proportionally reduced to maintain the accuracy and quality of work.

☞ 6.1.2 Competency Evaluation of Personnel under Clause 6.1.1

Personnel listed in Clause 6.1.1 shall undergo periodic assessment of knowledge and competency to ensure they remain qualified for their assigned responsibilities, as follows:

1) Pathologists are required to participate in Continuing Medical Education (CME) activities in accordance with the regulations of the Medical Council of Thailand.

2) Other relevant personnel shall participate in appropriate continuing professional development (CPD) or academic activities to maintain and enhance their professional competence.

☞ 6.1.3 Position and Responsibilities

The laboratory shall have clear appointment or assignment of duties, including designation of deputies to act on behalf of responsible personnel in cases of absence. The structure shall include key positions that perform major functions; however, not all of the positions listed are required to be present in every laboratory. The details are as follows:

1. Laboratory Director

The Laboratory Director is responsible for the overall management, quality, and compliance of the cytopathology laboratory with applicable standards and regulations. The Director authorizes test methods, ensures adequacy of personnel qualifications, approves reports, and oversees the implementation of quality and safety systems. The Director delegates technical and administrative responsibilities as appropriate but maintains ultimate accountability for laboratory operations.

2. Technical Director

The Technical Director provides expert oversight of all technical aspects of cytopathology testing. This includes validation and verification of test methods,

ensuring accuracy and reliability of results, and supervising the training and competency assessment of laboratory personnel. The Technical Director authorizes testing procedures and monitors corrective and preventive actions related to technical performance.

3. Head of Cytology Unit

The Head of Cytology Unit is responsible for coordinating day-to-day cytology operations, including specimen processing, screening, staining, and reporting workflows. The Head ensures that cytotechnologists follow approved procedures, monitors workload and turnaround times, and reports directly to the Technical Director. Authorization for cytology examinations and reporting is performed under the supervision of the Technical Director and/or Laboratory Director.

4. Cytotechnologists

Cytotechnologists perform microscopic screening and preliminary evaluation of cytological specimens under the supervision of a pathologist. They identify abnormal cells, record findings, and mark areas of interest for pathologist review. Cytotechnologists perform tasks within their authorized scope of practice as assigned and are required to maintain competency through periodic training and proficiency assessment.

5. Pathologists

Pathologists are responsible for the final interpretation and diagnosis of cytopathology specimens. They review all abnormal or suspicious cases identified by cytotechnologists, issue final diagnostic reports, and provide clinical correlation and consultation. The pathologist supervises the cytotechnologists' work and authorizes the release of cytology results.

☞ **Accommodation and Environmental Conditions**

The cytopathology laboratory shall provide appropriate accommodation and environmental conditions to ensure the accuracy, safety, and

efficiency of work processes. The working areas should include, at a minimum, the following designated spaces:

1.Cytotechnologist and/or Pathologist Office – for the interpretation, reporting, and documentation of cytological findings.

2.Cytopathology Laboratory Area – for specimen processing, staining, slide preparation, and microscopy.

3.Document Control Office – for the storage and management of records, quality documents, and administrative files.

4.Storage Area for Blocks and Slides – for the proper preservation, archiving, and retrieval of cytology slides, cell blocks, and related materials under controlled environmental conditions.

6.2 Laboratory equipment, reagents, and consumables

6.2.1 Pre-Pre-examination processes

6.2.1.1 The laboratory shall be equipped with all necessary items of equipment, instruments, consumables, reference materials, and reagents required for the provision of services. Purchased items must consistently meet the laboratory’s requirements. There shall be procedures for handling, storage, maintenance, and a regular monitoring program.

6.2.1.2 The laboratory is responsible for ensuring that manufacturers' performance claims are met, and that calibration services provided by manufacturers fulfill the laboratory's requirements. The suitability for the intended use must also be verified.

6.2.1.3 When laboratories use different equipment or examination methods, the comparability of these various examination systems must be ensured.

6.2.1.4 The laboratory shall have firefighting equipment, chemical and hazardous materials protection equipment, and a first aid kit readily available in case of accidents, where necessary and appropriate.

6.2.2 Pre-examination processes

6.2.2.1 The laboratory shall establish a procedure for customers to follow. This procedure shall include details on the test analysis, patient preparation, sample collection, sample container requirements, sample handling, completion of request forms, turnaround times, criteria for acceptance or rejection of primary samples, safety protocols for collection and handling of samples, and the receiving/sending of test reports.

6.2.2.2 The laboratory shall provide such documents to the customers, and records of the handling or receipt of these documents shall be maintained by the laboratory.

6.2.2.3 Laboratory staff may not collect all or any samples for examination. However, the laboratory is still responsible for ensuring that the samples received are not compromised.

☞ **6.3 Examination processes**

6.3.1 Cytotechnologists shall work under the direct supervision and authorization of a pathologist. They are responsible for evaluating and screening cytology specimens to detect the presence of abnormal cells, which may be cancerous, precancerous, or indicative of other pathological conditions.

6.3.2 Cytotechnologists shall identify and mark abnormal cells and issue a preliminary interpretation. The pathologist must review and confirm all abnormal Pap smear results that fall into the following categories:

1.Malignant or suspicious for malignancy

2.Low- or high-grade squamous intraepithelial lesions (LSIL/HSIL)

3.Atypical squamous cells (ASC-US or ASC-H)

4.Atypical glandular cells (AGC)

If the laboratory does not have an in-house pathologist, it shall maintain an updated list of qualified pathologists or a designated pathology department (e.g., from the College of Pathologists) to review and verify all abnormal Pap smear reports.

6.3.3 or non-gynecologic cytology specimens, diagnostic interpretation shall be performed exclusively by qualified medical pathologists.

6.3.4 The laboratory shall establish and maintain all examination procedures that have been accredited in compliance with ISO 15189:2022. All such procedures shall be applied and controlled in accordance with the BLQS procedure N 0715011 Supplement requirements for medical laboratory.

☞ **6.4 Ensuring quality of examination results**

6.4.1. At least 10% of all negative screening slides from each cytotechnologist shall be randomly selected and reviewed by a senior cytotechnologist or a pathologist as part of retrospective rescreening quality control. If any discrepancies or inconsistencies are identified between the original and the review findings, the department shall follow the established policy and corrective action procedure to amend or correct the reported results and document the outcome of the review.

6.4.2. For all current screening results interpreted as High-Grade Squamous Intraepithelial Lesion (HSIL) or higher, the laboratory shall review the original slides of patients with previously negative results within the past five (5) years. If discrepancies are found between the previous and current interpretations, an amended or supplementary report shall be issued to clarify and document the revised findings.

6.4.3. Cyto-Histopathological Correlation (CHC) shall be performed routinely, particularly for all cases with cytological findings of HSIL or higher. If corresponding histopathology (biopsy) results are not available from the same laboratory, efforts shall be made to obtain such results for correlation.

In cases where Pap smear findings are not concordant with the biopsy results, the Pap smear slides shall be re-evaluated, and the review findings shall be documented as evidence for quality assurance and continual improvement.

☞ **6.5 Post-examination processes**

The laboratory shall ensure that all medical records, specimens, and examination materials are properly documented, retained, and preserved for the specified

retention period to support traceability, result verification, and medico-legal requirements. The minimum requirements are as follows:

1.Specimen Log Book – Records of specimen receipt, accessioning, and reporting shall be retained for at least 10 years.

2.Gross Specimens and Effusion Fluids (including cases where no specimen container remains) – Shall be retained for a minimum of 2 weeks after the report has been issued.

3.Paraffin Blocks – Shall be stored for a minimum of 5 years in an appropriate storage area under controlled environmental conditions to maintain the integrity and retrievability of the material.

4.Glass Slides – Shall be retained for at least 5 years following the date of reporting.

5.Duplicate Copies of Reports and Request Forms – Shall be maintained for at least 10 years to ensure continuity of patient and test record traceability.

6.Cytology Reports – Including both internal and external consultation reports. A complete copy of the final report, together with the original, shall be kept for 10 years.

All the above materials and records may be preserved in electronic format, such as scanned reports, digitized slides, or secure digital archives, provided that accessibility, integrity, and confidentiality are ensured throughout the retention period.

☞ **6.6 Reporting of results**

All cytology reports shall be reviewed, authorized, and signed in accordance with the laboratory's reporting policy and applicable regulatory requirements.

1.Cytotechnologist Signature

Each cytotechnologist shall sign or apply a legally recognized electronic signature on all screening reports for which they are responsible.

2.Pathologist Review and Authorization

All diagnostic cytopathology results, as specified in Section 6.3, shall be reviewed, verified, and co-signed by a pathologist prior to report release. This includes all cases

interpreted as abnormal, suspicious, or malignant.

3.Electronic Reporting and Authentication

The use of a secure digital or electronic signature by cytotechnologists and/or pathologists is permitted, provided that:

- the signature is legally valid and identifiable,
- the system ensures traceability, confidentiality, and integrity, and
- the signature is applied to the final verified report before issuance.

4.Inclusion of Supporting Materials:

Reports may include digital images, photomicrographs, or report attachments as supporting documentation where applicable.

5.Restriction on Printed Name Only:

Reports that contain only a typed or printed name without a corresponding manual or electronic signature are not considered authorized.

Each report must bear a valid signature or digital authentication from the responsible cytotechnologist and/or pathologist.

7. Data record and Used document

-

8. Supplementary notes

-

9. History of change

Revision	Document Changes	Prepared / Revised by	Date Issued
00	Initial document	Ms. Sirimas Khamsai	31 August 2018
01	- Add Reference in clause 3.4 - Edited wording of clause 6.5 - Page 4/5 Edit wording in clause 6.5 all records and documents mentioned in this section may be stored electronically.	Ms. Sirimas Khamsai	7 January 2025

Revision	Document Changes	Prepared / Revised by	Date Issued
	- Change format and updated approver		
02	- Add Reference in clause 3.5 - Added Clause 6.1.3 Position and Responsibilities. -Edited the text to be concise and academically accurate in Clause 6.1.1, Personnel Responsible for Cytopathology 6.1.2. Competency Evaluation of Personnel under Clause 6.1.1 Accommodation and Environmental Conditions 6.3 Examination processes 6.4 Ensuring quality of examination results 6.5 post-examination processes 6.6 Reporting of results	Ms. Sirimas Khamsai	