



**CANADIAN SOCIETY OF  
CYTOPATHOLOGY  
GUIDELINES FOR PRACTICE &  
QUALITY ASSURANCE IN  
CYTOPATHOLOGY**

This is the fifth revision of the document entitled "Guidelines for the Establishment of Quality Assurance Programs in Cytology" which was prepared by the Quality Control Committee of the Canadian Society of Cytology and introduced in June 1978. First revision: February 1989; second revision: September 1996; third revision: January, 2005; fourth revision, 2012; fifth revision, 2019

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## INTRODUCTION

This is the fifth revision of cytology quality assurance guidelines presented by the Canadian Society of Cytopathology. The expectations for continuous quality improvement and monitoring for all of laboratory medicine have significantly increased since the previous version. However, the practice of cytopathology has long embraced the concepts of quality management especially as it applies to gynecologic cervical cytology screening. This document expands on the quality monitoring of non-gynecological cytology. The CSC has been actively reviewing and endorsing recent international guidelines for reporting non-gynecologic cytology including urine, pancreatobiliary, salivary glands and thyroid samples. Up to date practice guidelines on these and other sites can be found at the CSC website.<sup>1</sup> ([www.cap-acp.org/cytology.cfm](http://www.cap-acp.org/cytology.cfm)) This document refers to quality practices specific to cytology and does not cover general laboratory safety and quality practices. It is assumed that a cytology laboratory must adhere to all standards expected of a medical laboratory as well as those specifically relating to the practice of cytology. The CSC QA guidelines are meant to serve as a basis for quality programs in the Canadian cytology laboratory; however, it is recognized that more specific guidelines and standards may be delivered by various accreditation bodies or regional jurisdictions and take precedence over these pan-Canadian recommendations.

### 1.0 DEFINITIONS

#### 1.1 Cytopathology

Cytopathology is the practice of medicine specializing in diagnosis through the evaluation of the cellular manifestations of disease and consulting in the decision-making related to the patient's subsequent management.

#### 1.2 Cytopathology divisions

Cytopathology is subdivided into "Gynecological" (GYN) and "Non-Gynecological" (Non-GYN) specimens according to site. The former usually relates to the evaluation of cervicovaginal cytology while the latter includes all other types of cytological specimens, even those from other regions of the female genital organs.

#### 1.3 Guidelines

Guidelines are a recommended strategy or range of strategies of laboratory practice. Variation due to patient-or laboratory-specific factors is a reasonable expectation.

#### 1.4 Standards

Standards are accepted principles of laboratory practice in which variation is not expected.



## 1.5 Quality assurance

Quality assurance is a practice aimed at achieving the highest degree of diagnostic performance by an individual laboratory. This is accomplished by the implementation of a specific and detailed quality assurance program which assesses the laboratory's performance by measuring a set of performance indicators, determines if the performance conforms to accepted standards and seeks to improve the performance when the accepted standards are not met.

1.5.1 Quality assurance practices should be documented on a continuing basis. A periodic report should be generated at least annually and its content discussed with the laboratory personnel. Further distribution is at the discretion of the individual laboratory, but should comply with local, provincial, and federal regulations.

1.5.2 The specific details of a quality assurance program are the responsibility of the laboratory director, but should include guidelines and standards related to:

1. Personnel
2. Physical facility
3. Equipment
4. Specimen collection, requisition and accessioning
5. Preparation and staining techniques
6. Pathologist responsibilities
7. Cytotechnologist responsibilities
8. Screening practices
9. Diagnostic practices
10. Reporting
11. Records
12. Gynecologic cytology utilization registry
13. Quality Assurance
14. Performance Evaluation
15. Proficiency testing
16. Continuing education

## 1.6 Compliance with relevant legislation

The laboratory should comply with all relevant federal, provincial and local legislation.

## 1.7 Ethics

The laboratory director and associate pathologists should comply with the rules and regulations of the provincial medical colleges and adopt the guidelines advocated by the Canadian Medical Association in regard to interactions with industry.<sup>2</sup>



## **2.0 LABORATORY PERSONNEL**

### **2.1 Director of Cytopathology**

The cytopathology laboratory should be under the direction of a legally qualified physician with specialist qualifications in pathology and cytopathology training equivalent to the training objectives of the Royal College of Physicians and Surgeons of Canada. It is recommended that the Director have extra training and/or sufficient experience in cytopathology and health care management to oversee the quality of the laboratory. The Director should be available to the laboratory at all times of operation. If possible there should be a designated Deputy Director for support and/or back-up, who also has additional training and/or sufficient expertise in cytopathology.

### **2.2 Associate Cytopathologists**

Associate cytopathologists must be legally qualified physicians with specialist qualifications in pathology, and cytopathology training equivalent to the training objectives of the Royal College of Physicians and Surgeons of Canada.

### **2.3 Cytotechnologists**

Cytotechnologists must meet the requirements for and maintain certification with the Canadian Society of Medical Laboratory Sciences in Diagnostic Cytology<sup>3</sup>, as well as necessary certification by local/provincial authorities.

### **2.4 Support personnel**

Personnel whose qualifications are appropriate to the laboratory director/hospital personnel bylaws can perform clerical and laboratory assistant functions.

### **2.5 Personnel file**

Up-to-date records including qualifications and experience should be maintained on all personnel.

## **3.0 PHYSICAL FACILITIES**

3.1 The cytopathology laboratory should comply with all safety, quality and professional requirements that pertain to medical laboratories within their jurisdiction.

### **3.2 Laboratory space**

3.2.1 Cytotechnologists must work from a designated official working site at the institution.

3.2.2 Working conditions in the laboratory should be conducive to high quality



performance. The microscopy area should be quiet, orderly and of adequate size for the number of individuals employed. Ergonomic assessment of furnishings is strongly recommended.

3.2.3 The work areas should be functionally arranged so as to minimize problems in handling specimens, screening, and reporting.

3.2.4 There must be physical separation of the microscope screening / reporting area from the specimen handling / preparatory portion of the laboratory.

3.2.5 The laboratory should meet all appropriate regulations for safety including WHMIS and local fire, safety and health precautions.

### 3.3 Equipment

3.3.1 It is strongly recommended that all laboratories be computerized to facilitate accessioning, reporting, archiving records, and quality assurance practices. A computerized laboratory should have a sufficient number of computer stations for its needs. All personnel must be appropriately trained in their use and updated as required.

3.3.2 There should be an adequate number of binocular microscopes of high optical and mechanical quality to meet screening and reporting needs. Ergonomically designed microscopes are recommended.

3.3.3 A multi-headed microscope to facilitate quality control and continuing education is strongly recommended.

3.3.4 All equipment used in the laboratory must be of high quality and satisfy Canadian manufacturing standards. There should be an active program of preventive maintenance with documentation for microscopes and all other items of equipment.

## **4.0 REQUISITION FORMS, SPECIMEN COLLECTION, AND ACCESSIONING**

### 4.1 Requisition Form:

The information required includes the following:

1. Patient names as required for proper identification
2. Provincial health number, address and/or hospital identification number
3. Date of birth (including day, month and year)
4. Name of referring health care provider
5. Anatomic site, laterality of the specimen and collection method
6. Appropriate medical history



## 7. Date of specimen collection

### 4.2 Specimen labeling

The specimen container should be clearly labeled with the patient name, identifying number and/or date of birth as well as the anatomic site and laterality of the specimen. Slides should be labeled ideally with two unique identifiers, (one identifier should include the patient's last name and initials). However, slide labeling practices may vary according to laboratory accreditation standards.

### 4.3 Specimen collection

Proper specimen collection is an important initial step to assure optimal cytological assessment. All technologists and pathologists should be aware of the recommended collection techniques and these techniques should be documented in the laboratory manual. Copies of these techniques should be provided to the Health Care Providers.

### 4.4 Specimen accessioning

4.4.1 Specimens should be accessioned by the laboratory only if ordered by an appropriate health care provider.

4.4.2 There should be a clear specimen rejection policy that is developed according to the needs of each specific laboratory. That policy should be communicated to all users of the laboratory.

4.4.3 Each specimen received should be accessioned with a unique number cross referenced with the patient's name, together with all of the information from the requisition. The specimens should be easily retrievable according to any of the above data; a daily logbook may be required if the laboratory is not equipped with a computerized accessioning and reporting system.

4.4.4 The time and date of specimen receipt should be recorded.

4.4.5 The specimen accession number should be recorded on each slide by permanent marking or label.

## **5.0 PREPARATION AND STAINING TECHNIQUES**

5.1 The laboratory should carry out sufficient preparation and staining of cytologic specimens in order to maintain a high level of technical competence and quality.

5.2 Each area of the laboratory in which specimen preparation and staining are performed must have available a laboratory manual detailing the specific methodology required for the technique performed in that area. The manuals should be updated on a



regular basis, dated and signed by the director of the laboratory and circulated among the technical staff, cytotechnologists and pathologists working in the laboratory.

5.3 The Papanicolaou staining technique should be used for gynecologic cytology and fixed non-gynecological samples.<sup>3</sup> If air-dried gynecologic preparations are used, a Romanowsky-type staining technique is the preferred option.<sup>3</sup> Some laboratories may choose to use alternate methods.

5.4 Staining quality should be checked and documented daily with appropriate correction of suboptimal results. Stains should be filtered or replaced regularly to maintain potency and freedom from contamination.

5.5 All cytotechnologists should be aware of the problem of cell transfer contamination and take adequate precautions to avoid this hazard.

## **6.0 PATHOLOGIST'S RESPONSIBILITIES**

### **6.1 Director of Cytopathology**

6.1.1 The director or a deputy pathologist is responsible for all quality assurance activities, the safety and the overall performance of the laboratory.

6.1.2 Either the director or a deputy pathologist should be available to the laboratory at all times of operation to ensure appropriate laboratory performance.

6.1.3 The director should encourage all laboratory personnel to achieve the highest quality of laboratory practice.

6.1.4 The director is responsible for ensuring that the quality assurance program is followed and periodic quality assurance reports are generated, at least annually.

6.1.5 The director should ensure that the laboratory manuals are updated, at least annually.

6.1.6 The director should meet at least quarterly or more frequently if necessary with all laboratory personnel to discuss issues relating to the laboratory performance. An agenda should be generated, the proceedings minuted, and circulated.

6.1.7 The director is responsible for facilitating laboratory-based continuing education and identifying areas of deficiency amongst the personnel in terms of knowledge, attitude, and skill.



6.1.8 The director is responsible for facilitating remedial training as appropriate.

## 6.2 Associate Pathologists

6.2.1 Each pathologist should have malpractice insurance commensurate with his or her practice needs.

6.2.2 Each pathologist should be readily available for consultations with cytotechnologists, laboratory and clinical colleagues, and other allied health care providers.

6.2.3 Each pathologist is expected to participate in continuing education activities relating to cytopathology and to keep up to date with the current literature.

## **7.0 CYTOTECHNOLOGIST'S RESPONSIBILITIES**

### 7.1 Supervisory Cytotechnologist (or equivalent)

7.1.1 The supervisory cytotechnologist should have demonstrated experience in cytopathology and management skills and is responsible for the daily supervision of the laboratory.

7.1.2 The supervisory cytotechnologist is responsible, along with the director, for maintaining and updating the laboratory manuals.

7.1.3 The supervisory cytotechnologist should ensure the quality of the preparation of the specimens by supervising the responsible technical staff.

7.1.4 The supervisory cytotechnologist should train all technical staff in new cytopreparation techniques as needed.

7.1.5 The supervisory cytotechnologist should ensure that all appropriate supplies have been ordered both for the laboratory and the health care provider-clients.

7.1.6 The supervisory cytotechnologist should ensure that all maintenance contracts on equipment are being carried out at appropriate intervals.

7.1.7 The supervisory cytotechnologist should represent the interests of the cytotechnologists at all laboratory meetings.

### 7.2 All cytotechnologists



7.2.1 Each cytotechnologist is expected to participate in continuing educational activities and to document them.

7.2.2 Cytotechnologists with established competence are responsible for rescreening specimens identified for quality control review.

## 8.0 SCREENING PRACTICES

8.1 All non-GYN (including FNABs) and all GYN specimens must be screened by a cytotechnologist. Some laboratories may choose to have hierarchical screening by a senior cytotechnologist or a second mandatory screening by another cytotechnologist as routine practice for some GYN and non-GYN specimens. Approved commercial devices for automated screening may be used following protocols recommended by the manufacturer and regulatory bodies.

### 8.2 Cytotechnologists workload

Neither economic considerations alone nor expediency must determine the number of cytology slides to be screened by a cytotechnologist in a working day or 24 hour period.

The number and type of cytology slides to be screened should not, through fatigue, affect adversely the cytotechnologist's ability to find, recognize, and interpret correctly abnormal cells that may be representative of a disease process.

Precise workload limitations may be difficult to define because of variations in types of cytology specimens being screened as well as variations in other responsibilities in the laboratory. The types and complexity of specimens should determine the total number of slides screened by a cytotechnologist in an average working day.

8.3 The number of slides screened by a cytotechnologist, exclusively screening full-time without other duties or distractions may vary but preferably should not be higher than 60-80 in an average 8 hour working day.<sup>3</sup>

8.4 A cytotechnologist with other duties in addition to screening should have a proportionately reduced workload. For example, a total of 4 hours spent on slide screening should require a prorated workload no greater than  $4/8 \times (60-80) = 30-40$  slides to be screened.

8.5 A cytotechnologist must not be expected to screen more than 80 slides in a 24 hour time period (on average about 10 slides per hour devoted exclusively to screening).



8.6 A GYN conventional smear slide should be equivalent to a GYN liquid based preparation slide for screening time.<sup>1</sup>

8.7 Laboratories using automated screening devices which utilize the field of view (FOV) method should adjust the number of slides screened by the cytotechnologist. Slides with FOV only review count as 0.5 (or half a slide). Slides with full manual review (FMR) count as one slide. Slides with both FOV and FMR count as 1.5 (or 1 ½ slides).<sup>4</sup>

8.8 The total number of slides screened by a cytotechnologist may need to be reduced for practices with non-GYN cytology specimens taking into account the complexity of some non-GYN specimens. Similarly, non-routine GYN specimens (ex: follow-up post an HSIL diagnosis) may require more time to screen in comparison to routine cases.

8.9 The director and supervisory cytotechnologist should determine when circumstances for adequate screening by a cytotechnologist require that lesser numbers of slides be screened in a daily time period.

8.10 Each slide preparation should be evaluated to determine whether or not the material is satisfactory for diagnostic purposes and consistent with the stated site of origin.

8.11 Cytologic abnormalities should be dotted or otherwise appropriately marked to be adequately representative of the screened material. Interpretative notations should be made on appropriate working documents, along with the identification of the screener(s).

#### 8.12 Referral to the pathologist

8.12.1 Gynecological cytology screened as Unsatisfactory or “Negative for Intraepithelial Lesion or Malignancy” (excluding reparative changes) may be finalized by a cytotechnologist. All other Gynecologic cytology must be referred to a pathologist for reporting.<sup>5</sup> Laboratories may choose to refer some or all unsatisfactory and negative cases for screening by a second cytotechnologist or to a pathologist for sign out depending on their practice.

8.12.2 All Non-GYN cytology should be referred to a pathologist for reporting.

### **9.0 DIAGNOSTIC PRACTICES**

9.1 The director and associate pathologists should work co-operatively to establish the pathologist’s workload per usual working day and 24 hour period. The same considerations and caveats regarding workloads for cytotechnologists should apply.



9.2 The pathologist should report a sufficient variety of GYN and Non-GYN material in a year to maintain diagnostic competence.

9.3 The pathologist should obtain pertinent clinical information, when appropriate.

9.4 The pathologist should report all cytology referred to them by the cytotechnologists.

9.5 When requested, the pathologist should review any case of concern presented to them by a cytotechnologist or another pathologist.

9.6 There should be timely and adequate feedback on case material by the pathologists to the cytotechnologists.

## **10.0 REPORTING**

10.1 If the report form is separate from the requisition form, it should include all the information as on the requisition form and the date of the report.

10.2 Reports on negative GYN cytology (not including repair) may be finalized by the screening cytotechnologist if that is the practice of the laboratory. All other cases must be finalized by a pathologist.

10.3 The report should document the name(s) of pathologist(s) who reviewed and interpreted the case, and the signature (which can be electronic) of the pathologist who finalized the report. The initials, name or identifier of the cytotechnologist screening the case may appear internally or externally on the report. If the cytotechnologist finalized the report, their initials, name or identifier should appear on the report. In addition, some laboratories may decide to routinely include the name of the laboratory director in the final report.

10.4 Each report should have a clearly stated diagnosis that represents the highest degree of abnormality present. Other abnormalities can be documented/described in the microscopic/comment section.

### **10.5 Reporting terminology**

10.5.1 It is recommended that the most current version of The Bethesda System (TBS) should be used as the primary diagnosis for gynecologic cytology.<sup>5</sup>

10.6 For non-gynecologic cytology, the report should provide clear communication



using interpretive terminology and published classification systems. (see also<sup>1</sup>)

## 10.7 Specimen adequacy

10.7.1 If the specimen cellularity or preparation is unsatisfactory, interfering with the interpretation, this should be stated and recommendations provided for the submission of an adequate specimen.

10.7.2 Specimens considered to be non-representative of the stated tissue site should result in a report that indicates such concern.

## 10.8 Critical/alert values/diagnoses

10.8.1 Critical diagnoses (or critical values, alert values) are those requiring expedited notification of the most responsible physician or delegate. Reasons may include: 1) a clinically unusual diagnosis; 2) a significant diagnosis; or 3) an unexpected result (see Appendix A).<sup>6-13</sup> Some may require urgent patient management or a change in management.

10.8.2 There should be a policy outlining critical diagnoses for cytopathology as well as a procedure for communication of these diagnoses in a timely fashion to the most responsible physician or delegate.

## 10.9 Management recommendations

Each gynecological cytology report should include a management recommendation if that is the expected practice.<sup>14-15</sup> ([www.cancercare.on.ca/pcs/screening/hcpresources](http://www.cancercare.on.ca/pcs/screening/hcpresources)) Ideally, management recommendations should be developed in association with stakeholders from Family Medicine, Obstetrics and Gynecology, provincial screening programs and other involved groups. The presence/absence of a population based information system (cytology registry) and its impact on management recommendations should be taken into consideration.

10.10 The accession file should be monitored at frequent intervals to ensure that all accessioned cases have a finalized report.

## **11.0 RECORDS**

11.1 All slides, cell blocks and reports for the previous 2 years should be stored on site. Material from other years should be easily retrievable.

11.2 The laboratory should retain all slides, cell blocks and reports as currently recommended by this society<sup>1</sup> and as local regulations dictate. At a minimum, all



negative gynecologic and non-gynecologic cytology slides should be retained for five years. All slides on abnormal gynecologic and non-gynecologic material should be retained for twenty years. Cell blocks should be retained for 20 years. Reports should be kept indefinitely.

## **12.0 GYNECOLOGICAL CYTOLOGY UTILIZATION REGISTRY**

In provinces without an organized cervical screening information system (GYN cytology registry), it is recommended that each laboratory maintain a database of GYN cytology specimens to include patient demographics, referring physician, diagnosis, management recommendation, and date of test. The database should be searched at set intervals to determine if the management recommendations pertaining to at least HSIL, AIS and malignancy were followed. If no record is found, a reminder letter should be sent to the physician or patient, depending on what the local legislation allows.

## **13.0 QUALITY ASSURANCE (QA)**

Assuring the quality of slide preparation, screening and the interpretation of detected abnormalities is an integral part of cytology practice. QA guidelines and standards must be adapted to a range of laboratory situations with varied volumes, types of specimens and personnel. There should be continuing effort for development and improvement of quality assurance practices beyond what is outlined in this document.

13.1 A small proportion of slides from each batch prepared should be reviewed on a daily basis, for adequacy of preparation, including fixation, staining quality and coverslip quality.

### 13.2 Gynecological cytology

#### 13.2.1 Rescreening/prescreening of negative GYN cytology

Rescreening practices include 1) Prospective - Targeted, Random, Rapid or Prescreening and; 2) Retrospective. All manual rescreening should be conducted by a cytotechnologist with established competence. The laboratory should document details of the rescreening/prescreening practices used.

##### 13.2.1.1 Prospective Rescreening

A total of 10% of negative GYN cytology shall be rescreened prospectively. Slides shall be selected by a combination of random and targeted methods for a total of 10% of all cases. The use of prospective rapid rescreening or prescreening precludes the 10% rescreen.

13.2.1.1.1 Targeted rescreening is a strategy whereby a slide is rescreened if the patient



belongs to a high-risk group. This may include the following:

1. History provided by clinician of vaginal bleeding or spotting.
2. History of cervical/ vaginal/vulvar carcinoma.
3. Previous cytology reported as  $\geq$  atypical squamous or glandular cells within last two years.
4. Abnormal cervix on speculum examination.
5. History of DES exposure.

13.2.1.1.2 Random rescreening involves rescreening a randomly selected proportion of negative GYN cytology. This has been a widely practiced technique, but its value in the detection of false-negative screening has been shown to be less effective than other measures.<sup>16-24</sup> Therefore the CSC discourages from using the 10% random rescreening as the sole quality assurance measure in a laboratory.

13.2.1.1.3 Rapid rescreening involves reviewing all negative GYN cytology using a specified time period ( $<1$  minute). The use of this method precludes the 10% rescreen. There is increased detection of false negatives with this technique.<sup>21, 24-28</sup>

13.2.1.1.4 Prescreening involves reviewing all GYN cytology for abnormal cells, followed by a full screen. The use of this method precludes the 10% rescreen. There is increased detection of false negatives with this technique.<sup>29-33</sup>

#### 13.2.1.2 Retrospective rescreening

All negative GYN cytology from at least the previous 3 years (or up to six years if the screening interval is 3 years) in a woman with current cytology showing  $\geq$  HSIL or AIS should be rescreened by a cytotechnologist and then referred to a pathologist<sup>34</sup>. Corrected reports should be issued only when additional findings change the current management of the cases. The findings should be used for educational feedback, if the review is not blinded, recognizing that this form of rescreening is biased and does not simulate normal screening practices.

#### 13.2.2 Follow-up program

Gynecological diagnoses should be correlated with follow up biopsy material. As a minimum, follow up on diagnoses of HSIL, AIS and malignancy should be sought to determine the correlation rates. This information may be available from the laboratories' own files or another source, e.g., provincial Cytology Registry. In some cases cytological and histological tissue sampling may be at variance requiring further follow-up to resolve an apparent discrepancy.<sup>35-39</sup> The data should be used to streamline and standardize diagnostic criteria in the laboratory.



### 13.2.3 Comparison of colposcopic Pap test and histological sampling

Comparison of diagnoses of concurrent colposcopic Pap test and histological sample (cervical or vaginal biopsy, or endocervical curettage) should be performed to monitor non-correlation rates. Some labs may choose to retrospectively review the slides from non-correlating samples to identify reasons for non-correlation (sampling error, interpretation differences, screening error). As a minimum, HSIL non-correlating diagnoses should be compared. However, some labs may choose to compare other non-correlating diagnoses (LSIL, ASC-H).

## 13.3 Non-gynecological cytology (see also <sup>1</sup>)

13.3.1 Follow up program Positive Non-GYN cytology should be correlated with the corresponding biopsy or autopsy material at regular intervals, recognizing that in some cases cytological and histological tissue sampling may be at variance requiring further follow-up to resolve what at first may appear to be a biopsy discrepancy.<sup>36-42</sup>

### 13.3.2 Retrospective review

Retrospective review of a percentage of Non-GYN samples may aid in the identification of report discrepancies, terminology irregularities, and interpretation differences, some of which may require a corrected report.<sup>40-42</sup>

### 13.3.3 Site specific review

Selected sample types may be reviewed to assess diagnostic reporting criteria and follow-up outcomes. This form of review may be useful for new procedural techniques, or unusual sites.<sup>40-42</sup>

## 14.0 PERFORMANCE EVALUATION

All measures used to evaluate performance should be uniformly applied and documented. If possible, laboratory and individual performance should be separately measured. A system of annual peer comparison of performance indicators and proficiency testing results should be established.

### 14.1 Performance indicators

Performance indicators listed below and productivity rates for each cytotechnologist and pathologist should be documented on at least an annual basis. Individual performance indicator feedback should be done confidentially, while overall laboratory performance indicators should be shared with all laboratory personnel. If desired, the pertinent results may be communicated to the individual health care providers (e.g. specimen adequacy). Details of the methodologies should be documented. There are presently no national performance standards, however, it is suggested that individual laboratories should aim to equate their results with performance indicators from comparable laboratories and published data. Performance indicators and other QA data should be collected under the



perview of a properly constituted Quality Assurance Committee per provincial legislation in order to protect disclosure of identifiable information.

#### 14.2 Gynecological cytology: performance indicators

14.2.1 The total number and rates of unsatisfactory GYN cytology cases should be measured for the laboratory, and each cytotechnologist, pathologist and health care provider-client.

14.2.2 The total number and rates of the major GYN diagnoses should be measured for the laboratory, and for individual cytotechnologists, and individual pathologists.

14.2.3 The false-negative rate of the laboratory and individual cytotechnologists should be separately measured<sup>20, 40</sup> A false-negative result is identified through prospective rescreening and is defined as a screening error of an abnormality  $\geq$  LSIL. The laboratory may also choose to document screening misses including ASC-H or AGC or other abnormality which changes clinical management. There should be documentation that the original cytotechnologist has reviewed their false negative cases.

14.2.4 The cyto-histological correlation rates for HSIL, ASC-H, AIS and malignancy on GYN cytology should be measured against the results of the follow-up surgical material, or clinical outcome (if more appropriate).

14.2.5 The ASC:SIL ratio of the laboratory, individual cytotechnologists and individual pathologists should be separately measured. The ASC includes ASC-H and ASC-US, while the SIL includes LSIL, HSIL and SIL, not graded.

14.2.6 Discrepancy between cytotechnologist and pathologist diagnoses should be measured separately for the laboratory and each cytotechnologist. The laboratory should define minor and major discrepancies. There should be documentation that the cytotechnologist has reviewed cases with major discrepancy<sup>42</sup>

14.2.7 The turnaround time (from the date the specimen is received in the laboratory to the date the finalized report is issued) for the laboratory and individual pathologists should be separately measured.<sup>43, 44</sup>

#### 14.3 Non-Gynecological cytology: performance indicators (see also <sup>1</sup>)

14.3.1 The total number of Non-GYN cases categorized by anatomic site and type of specimen, must be documented.

14.3.2 The total number and rates of unsatisfactory Non-GYN cytology cases must



be measured for the laboratory, and should be measured for each cytotechnologist and pathologist.

14.3.3 The rates of major diagnostic categories (e.g. unsatisfactory, negative, atypical, suspicious, malignant) for the laboratory must be calculated overall and for major groups of Non-GYN cytology (e.g. Breast, Thyroid, Respiratory). The rates of major diagnostic categories should be calculated for individual cytotechnologists and individual cytopathologists.

14.3.4 Correlation of the results of fine needle aspirates (especially those of commonly aspirated sites) with their corresponding surgical material is recommended. When possible, unsatisfactory, sensitivity, and specificity rates should be calculated. Of the remaining Non-GYN material, at least the malignant diagnoses should be correlated with the tissue results or clinical outcome (if more appropriate).

14.3.5 Discrepancy between cytotechnologist and pathologist diagnoses should be measured separately for the laboratory and each cytotechnologist. The laboratory should define minor and major discrepancies. There should be documentation that the cytotechnologist has reviewed cases with major discrepancy.<sup>45</sup>

14.3.6 The turnaround time (from the date the specimen is received in the laboratory to the date the finalized report is issued) must be measured for the laboratory and should also be measured for individual pathologists.<sup>43, 46</sup>

#### 14.3.7 FNAB Adequacy Assessment/Preliminary Diagnosis

14.3.7.1 At the time of FNAB adequacy assessment/preliminary diagnosis, patient identifiers should be confirmed by the cytotechnologist and/or pathologist according to the institution's policy on patient identification.

14.3.7.2 A comparison of Adequacy Assessment/Preliminary Diagnosis to the Final Diagnosis may be performed with feedback to the cytotechnologist and/or pathologist.

#### 14.3.8 Aspirator Outcomes

14.3.8.1 FNAB unsatisfactory rates may be measured for clinician and pathologist aspirators.

14.3.8.2 FNAB complication outcomes may be documented for clinician and pathologist aspirators.



14.3.9 Service satisfaction may be monitored for pathologists and cytotechnologists participating in FNAB services.<sup>47, 48</sup> For example, a survey of clinician satisfaction with on-site adequacy assessments.

#### 14.4 Other: Performance Indicators

##### 14.4.1 Workload

The number of GYN, non-GYN and total cytology cases and slides should be monitored for each cytotechnologist and ideally for each pathologist.

##### 14.4.2 Corrected and Supplemental Reports

The number and reasons for corrected and supplemental cytology reports should be monitored.<sup>49, 50</sup>

##### 14.4.3 Second Opinions

The number of internal and external cytology consultations as well as external review requests should be monitored. Reasons for external cytology consultations and external review requests should be monitored. Discrepancies between original and external opinions should be documented.<sup>51-53</sup>

#### 14.5 External proficiency testing

A review of both normal and abnormal cytology exchanged between co-operating laboratories on a national, provincial or regional basis is a valuable contribution to the field of performance assessment. Several established programs are available (Institute for Quality Management in Healthcare, Checkpath Program of the American Society of Clinical Pathologists, PAP Program of the College of American Pathologists.) and if not already mandated by provincial regulations, each laboratory is strongly encouraged to participate in some form of external proficiency testing.

14.5 A mechanism for taking remedial and corrective action should be in place when the performance indicators and proficiency testing results are considered suboptimal.

### **15.0 CONTINUING EDUCATION PRACTICES**

15.1 Each laboratory should have a subscription or online access to one or more of the cytology journals, e.g. Cancer Cytopathology, Acta Cytologica or Diagnostic Cytopathology. There should be a good supply of appropriate, current cytology textbooks. Books and journals should be easily accessible.

15.2 Each cytotechnologist and pathologist is expected to independently pursue continuing education in the specialty. They should participate in scientific meetings, review courses, or specialty conferences, and should update his/her knowledge of



cytology practice by reading the current literature.

15.3 Performance evaluations should be used to identify those with deficiencies in knowledge and skills who would benefit from a more directed educational program.

15.4 The laboratory director should facilitate continuing education by ensuring an appropriate educational environment.

15.5 There should be a regular schedule of lectures, or symposia, particularly in the larger laboratories. The staff should be relieved of their duties to take advantage of these educational opportunities.

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APPENDIX A: EXAMPLES OF CYTOLOGY CRITICAL/ALERT  
VALUES/DIAGNOSES

- 1) Any unusual or unexpected cytology result, which may include an unexpected malignancy in a GYN, non-GYN or FNA specimen.
- 2) A malignancy involving a critical anatomic site in a non-GYN or FNA specimen.

Examples: a malignancy causing superior vena caval syndrome or paralysis.

- 3) Identification of possible pathogenic organisms in a non-GYN or FNA specimen from an immunosuppressed patient or in any orbital or CSF sample.

Examples: finding bacteria, pneumocystis, fungi, mycobacteria or viral (CMV, Herpes) cytopathic effect.

- 4) Identification of Herpes Simplex viral changes in a cervical/vaginal sample of near-term pregnant patient.
- 5) Any corrected report, where the diagnosis is significantly changed and will result in a significantly different patient management.

