

Quality Assurance Assessment Program for Anatomical Pathologists

This provincial best practice document is being developed in response to the Cochrane Report recommending a peer review program for pathology with results reported to the Health Authority Quality Committee, BC's Agency for Pathology and Laboratory Medicine and the Diagnostic Accreditation Program, when appropriate. The program has been developed with input from the provincial Anatomic Pathology Working Group, along with review of current provincial practices and peer reviewed publications, specifically the Pan- Canadian Quality Assurance Recommendations for Interpretive Pathology.

The program is designed to be proactive where quality activities are embedded directly into the clinical practice of anatomic pathologists via the Laboratory Information System (LIS), allowing standardized quality assurance data to be captured, reported, reviewed and discrepancies reported for follow up corrective action through standardized quality improvement processes.

Objective:

- Develop a standardized approach to Quality Assurance (QA) in interpretive pathology for use by all anatomic pathologists.
- Capture pathologist QA activities, and provide meaningful statistics to individual pathologists, the Laboratory quality committee, health authority medical administration and the Agency to allow year over year comparisons by pathologist, facility, HA and comparisons across the province.
- To build a provincial anatomic pathology culture based on sustainable high quality diagnostic services to enable the enhancement of patient safety.
- To ensure the public have confidence in British Columbia's anatomic pathology service regardless of geographic location or jurisdiction.

Goal:

For the activities related to all anatomic pathologists caseload be involved in a review, which is measurable and comparable to a standard baseline. Where appropriate, reviews will target surgical pathology, cytology and autopsy services, including all related ancillary testing. Reviews, reporting, and follow up actions are established using the following parameters.

- QA reports:
 - a. Specific time periods: quarterly based on calendar year
 - b. Specimen classification; surgical, cytology and autopsy
 - c. Specimen type – targeted audits: organ system (GI, Gyn, GU), method of collection (scope, surgery, punch), etc.
 - d. Reporting levels: Health Authority(HA), lab site, and pathologist
- Complete QA activities based on:
 - a. Preliminary (intraoperative consults), previous, and final report comparisons
 - b. Retroactive and proactive case status
 - c. Internal or external diagnostic consultations and reviews
- Monitor QA activity outcomes:
 - a. Level of agreement - minor or major discrepancies
- Discrepancy follow up and corrective action reporting :

- a. Investigation of cause for discrepancy and documentation of result reporting
- b. Follow up and change implementation process required to improve the overall quality

Standard Reporting Parameters:

- Reporting Period:
 - quarterly based calendar year
- Reporting Format:
 - To be determined by each site or health authority
 - Must include all reporting elements
- Reported by:
 - determined by each site or health authority
- Reported to:
 - AP Medical Director
 - Laboratory QA committee
 - HA Laboratory Medical Director
 - BC's Agency for Pathology and Laboratory Medicine as requested
 - May be used as evidence for compliance for accreditation, direct reporting to DAP not required
- Disagreement Types:
 - Minor – change from benign to benign or malignant to malignant diagnoses. ¹
 - Major – change from benign to malignant or malignant to benign diagnoses. ¹
Major disagreements are those that fill two criteria: The discrepancy must represent a significant change between the original diagnosis and the one rendered upon review, and the discrepancy must potentially have a serious impact on the patient's treatment or prognosis. Examples include reversal of a benign diagnosis to malignant, reversal of a malignant diagnosis to benign, and failure to recognize a specific treatable inflammatory condition (e.g. infectious organism). ²
- Follow up or corrective action report and documentation to include as required:
 - Anatomic Pathology revised, corrected, or addendum patient report
 - LIS internal comment
 - Patient Safety Learning System (PSLS)

¹ Prichard JW, Tomsho N, Yeager L. Quality Management of Intraoperative Consultations In. Zhai Q, Siegal GP, eds. Quality Management in Anatomic Pathology, Strategies for Assessment, Improvement, and Assurance. Northfield, Illinois: College of American Pathologist Press: 2017; chap 9.

² Nakhleh R, Fitzgibbons P, Quality management in Anatomic Pathology; Promoting Patient Safety Through Systems Improvement and Error Reduction: College of American Pathologists. 2005;43

Turn-Around Time (TAT):

Review of TAT data can be used to modify structures, processes and systems, which can contribute to better patient outcomes. ³

Definition of TAT:

- From time of accession or entry of the specimen into the AP Laboratory Information System (LIS).
 - Specimens should be accessioned into the LIS as soon as possible after arrival in the AP laboratory.
- To time of report sign out of the final report by pathologist.
 - AP LIS platforms should be programed to exclude weekends and statutory holidays, only working days are to be counted. If LIS cannot be programed to remove weekends and statutory holidays these should be manually removed before reporting.

TAT benchmarks exclude standard transport times for work performed off-site that is required for diagnosis (e.g. H&E slides, diagnostic IHC).

³ Middleton LP. Quality Improvement Plan Components and Monitors In. Zhai Q, Siegal GP, eds. Quality Management in Anatomic Pathology, Strategies for Assessment, Improvement, and Assurance. Northfield, Illinois: College of American Pathologist Press: 2017; chap 7.

Specimen TAT benchmarks:

Specimen Classification	Target benchmark (working days only)	Threshold benchmark – percent completed within target benchmark
Surgical Non Complex (L4E level 1-4)	72 - 96 hours 3 - 4 days	85%
Surgical Complex (L4E level 5-6)	120 - 144 hours 5 - 6 days	85%
Cytology - non GYN exfoliative	120 hours 5 days	85%
Cytology - Fine Needle Aspirate	120 hours 5 days	85%
Cytology – GYN (PAP)	360 hours 15 days	90%
Autopsy - hospital	90 days	85%
Autopsy - coroner	90 days	85%

Data collection: (by health authority, site and pathologist)

- Total number of cases (accessions) by classification: IOC, surgical, cytology, fine needle, and autopsy
- Total number of cases signed out for targeted specimen type (i.e. breast, GI biopsy, thyroid aspirate, bronchial wash, hospital or coroner)
- Total number of cases that meet TAT benchmark for targeted specimen type
- Calculate percentage of cases meeting or exceeding the threshold benchmark

Intraoperative Consultation (IOC) vs Final Diagnosis:

Correlation of the intraoperative consultation and the permanent preparations and their corresponding final diagnosis supports the measurement of individual and group diagnostic accuracy. ⁴

Definition of IOC: All specimens received without fixative for frozen section examination for which a report is prepared prior to receipt of specimen for routine formalin fixed paraffin embedded (FFPE) histological preparation. This includes samples received, examined, and deferred for FFPE.

⁴ CPAC and CAP. *Pan Canadian Quality Assurance Recommendations for Interpretive Pathology*. 2016:26

It is a best practice recommendation to be able to document the time of receipt and the time of reporting the IOC opinion to allow for auditing the IOC specimen turnaround time (TAT) as needed. Peer reviewed references recommend a benchmark TAT of twenty minutes. Document separately the TAT for each additional sample for the same specimen accession.

TAT is the time from receipt of the specimen by the pathologist to the time of reporting an IOC diagnostic report.

Data Collection: (by site and pathologists)

- Total number of surgical cases (accessions)
- Total number of surgical cases with IOC reports signed out
- Total number of cases with major discrepancy
 - Benchmark - < 2%⁵
- Number of cases appropriately deferred:
 - insufficient tissue present for adequate diagnosis at time of surgery
 - additional testing required for further classification.
 - Benchmark threshold - CAP 1.8- 4.9% of total cases (50th – 90th percentile) ⁶
- Number of cases inappropriately deferred:
 - sufficient tissue present for diagnosis at time of surgery, but diagnosis not completed
 - should there be a maximum cap for this threshold, i.e. below 1%

Follow up and Corrective Action Reporting: Required when major disagreements or inappropriate deferral are identified. Cause(s) for disagreement classified as:

- Specimen or requisition mislabelling error
- Inadequate clinical history
- Specimen:
 - Inadequate or inappropriate IOC specimen sample
 - Diagnostic tissue present in surgical specimen but not in IOC sample
- Technical:
 - Unable to prepare adequate frozen section for examination (i.e. calcium or fat)
 - Poor quality staining of section (i.e. thick or wrinkled section, poor quality reagents)
- Interpretation error
- Other – specify in writing

⁵ CAP QProbe *Arch Pathol Lab Med.* 1996;120:804–809

⁶ Towrek, et al. Q-Probe Studies in Anatomic Pathology, Quality Improvement Through Targeted Improvements. *Arch Pathol Lab Med:* 2014;138, 1156-1155.

Intradepartmental Consultation:

- Prospective (pre case sign out) peer consultation between pathologists within the same site/group via individual consultation or case conference. Discordant opinions are not classified as a disagreement, as the case has not been signed out or reported.

Data Collected: (by site and pathologist)

- Total number of cases (accessions) signed by individual pathologist
 - Total number of reviews completed. One case equals one review, regardless of the number of pathologist completing the review on the case
- Retrospective review of relevant previously signed out pathology (cytological or histological) case slides (review must include microscopic review of glass slides) related to current pathology case.
 - If slide review identifies a disagreement, the original reporting pathologist must be contacted
 - If required follow up action completed
 - corrected/revised/amended or addendum report generated
 - documentation and reporting of disagreement classification
 - documentation of corrective action completed

Data Collected: (by site and pathologist)

- Total number of cases (accessions) signed by individual pathologist
- Total number of reviews completed
- Total number of major disagreements - a retrospective review results in a difference of opinion, regardless of which interpretation is determined to be correct.
 - Classification of disagreement:
 - Initial diagnosis correct
 - Review diagnosis correct

External Consultation: Prospective (pre case sign out) or retrospective consultation with pathologist(s) outside the same site/group. This includes completion of diagnostic test with interpretation (report), expert or specialized opinion, or third opinion to resolve divergent opinions from internal consultation or external review. Discordant opinions are not classified as a disagreement as the case has not been signed out or reported.

Data Collected: (by site and pathologist)

- Total number of cases (accessions) signed by individual pathologist

- Total number of consultations completed

External Review: Reviews conducted by an outside institution/pathologist (post sign out) at the request of a clinician, pathologist, and patient or as part of established review protocol. The total reviews are sub-classified to identify disagreements (minor and major) between the original interpretation and the interpretation after second review.

Data Collected: (by site and pathologist)

- Total number of cases (accessions) signed by individual pathologist
- Total number of reviews completed
- Total number of major disagreements - a consultation review or BCCA review report results in a difference of opinion, regardless of which interpretation is determined to be correct.
 - Classification of disagreement:
 - Initial diagnosis correct
 - Review diagnosis correct

Follow up and Corrective Action Reporting:

- Required when disagreements are identified.
- Cause for disagreement to be classified and documented.
- Benchmark <2% major disagreements ²

Cytology / Surgical Pathology Correlation:

Retrospective review between follow up surgical specimen diagnosis and primary fine needle aspirate (FNA) or exfoliative cytology specimen.

Note: correlation is not required for cytology specimens that classified as unsatisfactory for diagnosis.

FNA and exfoliative cytology specimens are monitored to determine if a follow up or related surgical pathology specimen is collected within 6 months.

Data Collected: (by site, cytotechnologist and pathologist)

- Identity of person who procured or performed the FNA collection (Note: this is not the staff member assisting at the bedside)
- Total number of cytology cases (accessions)
- Total number of cases with relevant surgical pathology follow up
- Total number of disagreements – surgical diagnosis does not agree with cytology diagnosis. Note: Discrepancy due to sampling is not a major discrepancy.
 - Classification of disagreement:
 - Cytology - False negative
 - Cytology - False Positive
 - Cytology diagnosis does not correlate, specify information
 - Number of reports with change in diagnosis - review report results in a clinically significant alteration of the original diagnosis and issuing of an addendum or revised report.
- Total number of disagreements between cytotechnologist and pathologist

Follow up and Corrective Action Reporting:

- Required when disagreements are identified.
- Cause for disagreement to be classified and documented.

Cytology Specimen Adequacy: quality of the specimen after preparation (slides, smears, and blocks) classified as unsatisfactory or inadequate for evaluation.

Data Collected: (by site and pathologist)

- Total number of cytology cases (accessions)
- Total number of cases that are inadequate
 - Classification of inadequacy:
 - Insufficient specimen volume

- Insufficient diagnostic cells
- Incorrect collection procedure used
- Inappropriate specimen preparation

Cervical Cancer Screening Laboratory (CCSL): Surgical Pathology Correlation (Positive Predictive Value or PPV):

Surgical pathology data for cervical histopathology is collected, reported by the cervical cancer screening program for the entire province.

Retrospective review between follow up surgical specimen diagnosis and primary gynecological cytology specimen for all cases in which a colposcopic examination was recommended (persistent atypical squamous cells of undetermined significance / low-grade squamous intraepithelial lesions (ASC-US/LSIL), high grade squamous intraepithelial lesions (ASC-H), atypical glandular cells (AGC) and high grade squamous intraepithelial lesions (HSIL) or more severe.

Note: correlation is not required for cytology specimens that are classified as unsatisfactory for diagnosis.

Retrospective data:

- Evaluated quarterly for a one year period of cervical cytology reports.
- Reported from the prior 18 to 6 months to allow at least 6 months for subsequent follow up and data collection.

Data Collected: (by site, cytotechnologist and cytopathologist)

- Identity of person who procured or performed the cervical cytological sample collection
- Total number of cytology cases (accessions) with a colposcopy referral recommendation.
- Total number of cases with relevant surgical pathology follow up
- A positive predictive value (PPV) for cervical intraepithelial neoplasia (CIN 2+ and CIN 3+) is calculated and stratified:
 - Persistent ASC-US/LSIL
 - ASC-H, AGC (NOS) and HSIL (Moderate Dyskaryosis)
 - HSIL or more severe, AIS and AGC (Favour neoplasia)

Follow up and Corrective Action Reporting:

- Document discrepancies and follow up actions.

- Each pathologist gets an individualized PPV report with comparative peer data.

Specimen Adequacy: quality of the specimen after preparation (slides, smears, and blocks) classified as unsatisfactory or inadequate for evaluation.

Data Collected: (by site and pathologist)

- Total number of cytology cases (accessions)
- Total number of cases that are inadequate⁷
 - Classification of inadequacy:
 - Inadequately labeled
 - Insufficient specimen cellularity
 - Cellular material poorly preserved or obscured

Discrepancy Rates: Number of undercall and overcall discrepancies for all gynecological cytology slides read more than once.

Data collected

- Random Prospective review – prior to sign out of cytology report
 - 10% of cases reported as negative for intraepithelial lesion or malignancy (NILM) are reviewed by a second cytotechnologist
 - Discrepancies levels are weighted based on a standardized grid
 - overall classification if the second review is reported as a less severe category
 - undercall classification if the second review is reported as a more severe category
 - discrepancy rate is reported each quarter for each cytotechnologist
- Retrospective review previous 5 year of patient cases where:
 - current cytological diagnosis is HSIL or more severe or a current histological diagnosis of CIN 2 or more severe.
 - Retrospective review of all NILM or unsatisfactory cervical samples in the preceding 5 year period.
 - Discrepancy rates are calculated in the same way as for random retrospective review.
- Review of cases subject to mandatory second review
 - All ASC-US or more severe abnormalities that are reviewed by pathologists

⁷ Nayar R, Wibur D. The Bethesda System for Reporting Cervical Cytology: A Historical Perspective. Acta Cytologica: 2017;61:359-372

- Discrepancy rates are calculated in the same way as for random retrospective review

Follow up and Corrective Action Reporting:

- Based on the individual discrepancy rate for cytotechnologists:
 - If the discrepancy rate is less than 1 Standard Deviation (SD) of the lab average 10% of cases undergo random review
 - If the discrepancy rate is more than 1 but less than 2 SD of the lab average 30% of cases undergo random review
 - If the discrepancy rate is more than 2 SD of the lab average 50% of cases undergo random review
- Pathologists
 - Corrective action to be documented if more than 1 major undercall discrepancy per year

Review History:

Date	Version	Revision / Correction	Completed by
September 3, 2019	2.0	Addition of Turnaround Time statement Font change to Calibri Addition of page numbers Page 5- first paragraph change from required to complete, to be able to document and audit. Page 5 addition of TAT definition Page 5 Follow up and corrective action – remove minor and from the first line. Page 8 Cytology data collected – add note Page 9 Cervical cancer data collection – remove note.	J Tunnicliffe