WCAA
Western Canada Accreditation Alliance
Alberta

Standards for Diagnostic Laboratory Accreditation: Anatomic Pathology

Version: March 2024 – v12

ISQuaEEA International Society for Quality in Health Care External Evaluation Association
Accredited Standards 2022-2026
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Developing Committee:	**Medical Facility Accreditation Committee**
Final Approval Authority:	**Council of CPSA**
Approval Date – v12:	**March 2024**
Replaces:	**v11 – April 2023**

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Introduction

Role of College of Physicians & Surgeons of Alberta (CPSA)

CPSA is mandated by legislation (Health Professions Act) to regulate the practice of medicine in Alberta and is responsible for licensing physicians, administering standards of practice and conduct, and resolving physician-related complaints. It also provides leadership and direction on issues of importance to the health care system such as access to services, quality improvement, patient safety and privacy. Authority to accredit specified medical services and facilities is one aspect of the mandate. CPSA administers accreditation programs for those services that CPSA Council determines deserve explicit standards and verification of compliance with those standards, to ensure the safety of those services to the public in the settings proposed.

Accreditation emphasizes continuous quality improvement and promotes optimum performance to ensure quality health services, and subsequently a high standard of patient care in the Province of Alberta. CPSA's accreditation programs are overseen by a standing committee, the Medical Facility Accreditation Committee (MFAC), with members appointed by the Council from diverse disciplines in clinical and diagnostic medicine. MFAC conducts a secondary review of practice standards, hears arguments on changes to accreditation standards and reviews all facility accreditation statuses.

CPSA Laboratory Accreditation Program Model

Laboratories are assessed initially when opened and subsequently on a four-year rotation. An interim assessment may also be required as a result of significant changes to the scope and/or location of services.

The key features of CPSA accreditation assessment model are as follows:

- Assessments are conducted:
  - on a 4-year rotation
  - by geographic area
  - with entire zone assessments completed within a calendar year.
- All facilities performing diagnostic laboratory testing for patient management are assessed (both public and private).
- Physician Office Laboratories are not registered or accredited by CPSA.
- Assessments are conducted by assessment teams of practicing professionals:
  - Assessment Coordinators and/or Accreditation Assessment Officers - CPSA consultants and/or staff who ensure assessments are consistent, comprehensive, accurate and lacking assessor bias; serve as a key assessment resource.
  - Assessors with subject matter expertise (selection based on size of geographical area, number of facilities, scope of services and experience of team members).
- Geographic areas receive pre-assessment notification.
- Assessment teams are vetted for approval to ensure no direct conflict of interest.
- The assessment model encompasses both a desk audit of documentation and an on-site assessment.
- Facilities are required to submit a "Pre-assessment Data Verification Form" listing key facility pre-assessment information required for assessment and are also directed to upload required desk audit documentation utilizing a secure SharePoint site.
- The focus of the on-site assessment is on high risk, patient, staff, safety elements and those activities requiring direct observation and/or validation.

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- Final accreditation reports are distributed to zone/group/facility within a specified time from the last day of the assessment via a secure SharePoint site.
- Responses to non-conformances/citations are due within a specified time of final report receipt; evidence of compliance may be requested for certain key findings for confirmation of compliance. Responses to serious safety non conformances/citations may be requested with a shorter turnaround time.
- Facilities and assessment team members receive evaluation and/or feedback surveys after each assessment to assist CPSA in process improvement and/or enhancement.
- There is no mandatory mid-cycle assessment.
- Facilities are NOT required to submit on-going self-assessment and/or audit documents.
- Spot inspections may occur without prior notice.

Standards Documents Overview

The Standards are the basis for accreditation decisions and are developed by the Medical Facility Accreditation Committee with final approval made by CPSA Council.

The Standards are evidence based and reference accepted best practices, Provincial and Canadian legislation, relevant International Organization for Standardization (ISO) standards, and other recognized provincial, national, and international standards (e.g., College of American Pathologists, CLSI, CSTM, and Canadian Standards Association). Each accreditation standard has accompanying reference citations.

All standards included in the documents are mandatory requirements for accreditation.

The Standards are process-based and incorporate a quality management system approach. The language, terms and organization of the documents are consistent with *ISO 15189, Medical Laboratories-Particular Requirements for Quality and Competence.*

A review of accreditation standards occurs on an ongoing basis, considering and incorporating stakeholder feedback. Comprehensive formal review occurs on an annual basis, with broad stakeholder review occurring every 4 years.

CPSA Laboratory Accreditation program currently maintains the following standards documents for the assessment of diagnostic laboratory facilities:

- General
- Anatomic Pathology
- Chemistry
- Fertility Assessment – Semen Analysis
- Flow Cytometry
- Hematology
- Microbiology
- Molecular Diagnostics & Genetics
- Transfusion Medicine

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The 'General Standards' document includes ALL standards common to ALL disciplines. To eliminate redundancy, the discipline-specific standards include ONLY those standards specific and relevant to each discipline. For example, general quality control, proficiency testing, calibration, validation, and procedure manual standards are not repeated in each discipline specific standard.

Prior to each assessment, accreditation standards, tailored to the scope of testing of a facility, and are made available to:

- Facilities for self-assessment and/or to prepare for an on-site accreditation assessment.
- Assessors for on-site assessments.

Document Format:

- Standard number
- Patient or staff safety risk category (where applicable)
  Each standard has been reviewed to determine if it represents a direct and/or immediate patient or staff safety risk.
  - Those with either a patient safety (PS) or staff safety (SS) designation indicates that any non-compliance may have direct and/or immediate impact on safety.
  - PS/SS standards are 'shaded' for ease of detection.
  - Assessors must ensure that ALL standards with either a PS or SS designation are directly assessed at the time of the on-site assessment.

Safety Risk Category		
PS	**Patient Safety**	non-compliance may have direct and/or immediate impact on patient safety
SS	**Staff Safety**	non-compliance may have direct and/or immediate impact on staff safety

- Description of standard requirement
- Specific reference(s) (e.g., CLSI, ISO, AABB, College of American Pathologists)
- Interpretation guidance where relevant regarding the application of requirements
- Assessment of compliance questions (AOC) that provide specific guidance and practical direction for evaluation of compliance with the standard.
  - Although the AOC questions address the key evidence required to meet the intent of each standard, they are not meant to be all encompassing.
  - In addition to the AOC questions, there may be other evidence that demonstrates compliance with the standard. Individual assessors apply their own expertise in determining compliance with each standard.
  - Where AOCs state, "all of the following", compliance with all elements is expected to achieve compliance with the standard.
  - Compliance with the standard may be assessed by review of documents and records, observation, interviews, or a combination of these techniques.
  - Upon assessment of the objective evidence, failure to meet the intent and/or requirement of the standard will result in an assessment of non-compliance.
  - "In Progress" citations require submission of future evidence of compliance based on direction from the assessor.

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- "Exceeds Requirement" citations are for those situations where a facility exceeds the intent of the standard and employs commendable practice. The intent of capturing these occurences is to promote and focus on quality initiatives.
- Receipt of "FULL" accreditation status is contingent upon satisfactory resolution of all non-compliances (N and P).

Compliance Assessment Category:	
C	meets intent and requirements of standard
P	in progress (working towards meeting intent and requirements of standard; assessor notes evidence of progress towards full compliance)
E	exceeds requirements of standard
N	does not meet intent and/or requirements of standard
N/A	not applicable to scope of service or testing

- Compliance Assessment Category checkboxes
- Observation field for recording of objective evidence (field is expandable in electronic document)

References

A detailed reference list is provided at the end of this document. The references support the content and intent of each standard. It should be noted that all components of the cited references may not always be relevant and/or applicable. Compliance is expected with CPSA standards.

Terms and Definitions

See Diagnostic Laboratory General Standards document for all terms and definitions.

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#	Standard	Reference	Assessment of Compliance
The following standards are discipline-specific and are to be used in conjunction with CPSA General Standards			
AP.1.0 ANATOMIC PATHOLOGY (AP) - GENERAL			
AP.1.2 AP - General - Examination Policies, Processes and Procedures			
AP.1.2.1	The laboratory ensures appropriate handling of original slides and blocks referred for consultation.	CAP[1] – ANP.10260 CAP[3] – 3:16	Is there a record of the location of original slides and blocks that have been referred for consultation at all handling phases, including all of the following: • receipt? • use? • circulation? • referral? • transfer? C □ P □ E □ N □ N/A □ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.1.3 AP - General - Safety			
AP.1.3.1 **SS**	Formalin and xylene vapor concentrations are maintained below maximum acceptable exposure levels.	CAP[1] - ANP.08216 CAP[4] – GEN.76720 CLSI[9] - GP17-A3 – 9.1.4 GOA[1] – Schedule 1; p. 382, 409	Are formaldehyde and xylene vapor concentrations monitored in all areas where these reagents are used? Are appropriate action limits defined in laboratory policy? Does the initial monitoring: • identify all employees who may be exposed at or above the action level or at or above the short-term exposure level (STEL)? AND • accurately determine the exposure of each employee identified? Are results of the formaldehyde monitoring made available to personnel when available? Is further periodic formaldehyde monitoring mandated if results of the initial monitoring equal or exceed the acceptable exposure level? Is initial monitoring repeated any time there is a change in production, equipment, process, personnel, or control measures; which may result in new or additional exposure to formaldehyde for any employee involved in the activity? Is there evidence of corrective action when exposure limits are exceeded? Are there appropriate criteria for the discontinuation of periodic formaldehyde monitoring? If any personnel report signs or symptoms of respiratory or skin conditions associated with formaldehyde exposure, does the laboratory promptly monitor the affected person's exposure?

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			Is xylene exposure monitored initially? Is repeat xylene monitoring performed when there is a change in production, equipment, process, personnel or control measures likely to increase exposure levels?
			C □ P □ E □ N □ N/A □
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.1.3 AP - General – Safety continued			
AP.1.3.3 **SS**	Microtome knives and/or disposable blades are appropriately stored to avoid personnel injury or equipment damage.	CAP[1] – ANP.24100 CLSI[9] - GP17-A3 – 9.1 CSMLS[1] – 16.8	Are microtome knives and/or disposable blades appropriately stored? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.1.3.4 **SS**	The laboratory has procedures for the special handling of tissues in the histology laboratory from cases in which prion disease is suspected.	CAP[1] – ANP.24300 CLSI[9] - GP17-A3 – 9.2.1, 9.2.2	Are neuropathology tissues from cases of suspected Creutzfeldt-Jakob disease treated with formic acid? If tissue has not been treated with formic acid, are paraffin blocks and slides hand-processed and treated as containing potentially transmissible prions? Are all of the following precautionary methods taken when handling such tissue: • double gloves are worn? • all solutions, including water washes, are collected and treated with equal volumes of fresh undiluted household bleach for 60 minutes before disposal? • disposables, glassware, tools, etc. are handled appropriately? • all scraps of paraffin and unused sections are collected on a disposable sheet? • broken slides are decontaminated and discarded? • paraffin blocks are stored in a bag or box and labelled as infectious or the cut surface of the blocks is resealed with paraffin? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.1.3 AP - General – Safety continued			
AP.1.3.5 **SS**	Microwave devices in the histology laboratory are used and maintained appropriately.	CAP[1] – ANP.27170, .28290, .28860, .29430 CLSI[4] QMS01 – 3.6 CSA[1] Z316.5-20	Do microwave devices meet all of the following criteria: • used in accordance with manufacturer's instructions? • monitored for reproducibility at defined intervals? • tested for radiation leakage if there is visible damage to the device? • properly vented if required by the manufacturer? • placed in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents? Is the effectiveness of ventilation monitored at least annually? Are all containers used in microwave devices appropriately vented? Is there evidence that the laboratory reviews the SDS received with reagents and stains to assist in determining proper handling requirements and safe use in the microwave device?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.0 SURGICAL PATHOLOGY			
AP.2.1 Surgical Pathology - Personnel			
AP.2.1.1	Macroscopic tissue gross examinations are performed by pathologists or appropriately trained and monitored staff.	CAP[1] - ANP.11600, .11605, .11610, .11640 CAP[3] – 3:13	Do non-pathologists performing grossing meet all of the following criteria: • are there minimum education and training requirements? • are there clear guidelines that outline the types of specimens that can be grossly described, dissected and sampled? • is the nature of the pathologist supervision (physically present or available by phone or electronic means) clearly defined for each type of specimen and for each non-pathologist? • is competency ensured with proper sign-off? • is there ongoing competency assessment? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.2 Surgical Pathology - Quality Management System (QMS)			
AP.2.2.1	The laboratory has a defined and documented quality management system for surgical pathology.	CAP[5] – COM.04000 ISO[1] – 5.4.2, 8.9	Is there evidence of a defined and documented quality management system for surgical pathology? Does AP laboratory management have the responsibility for the design, implementation, maintenance and improvement of the QMS? Does the AP QMS meet the needs of patients and all personnel responsible for patient care? Does the AP QMS clearly define the responsibilities, authority and interrelationships of all personnel? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.2 Surgical Pathology - Quality Management System continued			
AP.2.2.2 **PS**	The laboratory documents and investigates sentinel events in which there is significant patient harm or where there is significant breach of known policies, processes and procedures.	ADASP[2] CAP[3] - 5:44 CAP[4] – GEN.20310, .20318	For sentinel events, is there evidence of all of the following: • criteria defining a sentinel event? • documentation of sentinel events? • investigation of sentinel events? • implementation of corrective and preventative measures?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.2 Surgical Pathology - Quality Management System continued			
AP.2.2.3	The laboratory has a designated AP quality improvement (QI) committee.	ADASP[2] CAP[3] – 2:6	Does the AP QI committee include the following: • the majority of the AP and/or surgical and/or autopsy pathologists? • selected residents or fellows? • key laboratory and clerical staff? Are there defined terms of reference and clearly defined roles and responsibilities for committee members? Is there evidence of regular meetings? Is there documentation of all of the following: • review of quality improvement data? • revisions to the QI plan or changes in practice? • management of diagnostic discordances? For sentinel events, does the QI committee review all of the following: • documentation of the investigation? • policy and procedure changes resulting from the investigation? • documentation of referral of sentinel events to institutional QI and/or risk management committees?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.3 Surgical Pathology - Physical Facilities			
AP.2.3.1 **SS**	The laboratory has sufficient and appropriate space and utilities for the performance of surgical pathology activities.	CAP[1] – ANP.11250, .23700 CAP[3] - 4 CAP[4] – GEN.60000 Guidance: Facilities may be considered inadequate if there is clear evidence of a safety risk to staff and/or patients or operational deficiencies indicated by quality monitoring records, data derived from complaints or concerns, turnaround time and error statistics etc.	Is sufficient space allotted for all of the following where applicable to the scope of service: • surgical specimen examination? • frozen sections? • histological preparation? • stain preparation? • administration, clerical and/or dictating functions? • technical functions? • photographic facilities? • storage? Is there sufficient and appropriate: • water and drainage? • electrical power? • refrigerated storage for large or unfixed specimens? AND • lighting? Do slides and paraffin blocks meet all of the following criteria: • stored in an organized manner? • accessible for retrieval? • stored in a manner to prevent contamination from blood or other fluids or tissues? • stored in a pest free, temperature-controlled area to prevent blocks from melting together? Is there adequate space for all of the following frozen section activities: • gross dissection? • storage of supplies and reagents? • microscopy? • result reporting? Is there adequate ventilation in the frozen section area? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.3 Surgical Pathology - Physical Facilities continued			
AP.2.3.2 **SS**	Adequate ventilation systems are present in the examination and storage areas.	CAP[4] – GEN.76600 CLSI[9] - GP17-A3 – 9.1.3, 9.1.4 CSA[1] Z316.5-20	Are the adequate ventilation systems present in examination and storage areas? Are fumes from tissue processors and stainers adequately vented? Are exhaust fans or fume hoods adequate to remove noxious fumes and odors?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.2.4 Surgical Pathology - Equipment, Reagents & Supplies			
AP.2.4.1	Tissue processor solutions are changed at defined frequencies based on workload.	CAP[1] – ANP.23100 ISO[1] 15189 – 6.4.5 Guidance: Solutions must be entirely replaced with new solution and not just 'topped off'.	Is there evidence that tissue processor solutions are changed at defined frequencies?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.4 Surgical Pathology - Equipment, Reagents & Supplies continued			
AP.2.4.2	The laboratory appropriately maintains and monitors paraffin baths and dispensers.	CAP[1] – ANP.23350 CAP[3] – 7:78 ISO[1] 15189 – 6.4.5	Are paraffin dispensers clean and well-maintained? Is the temperature of the paraffin dispensers: • checked regularly and documented? AND • adjusted for the type of paraffin used? Is there evidence that the temperature of the paraffin baths is checked regularly? Is there evidence of corrected action when temperature tolerance limits are exceeded? C □ P □ E □ N □ N/A □ Observation:
AP.2.4.3	The laboratory appropriately maintains flotation baths.	CAP[1] – ANP.23350, .21397 CAP[3] – 7:84 ISO[1] 15189 – 6.4.5	Are flotation baths clean and well-maintained? Is there a procedure for preventing cross-contamination of paraffin sections in the bath? C □ P □ E □ N □ N/A □ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.4 Surgical Pathology - Equipment, Reagents & Supplies continued			
AP.2.4.4	The laboratory appropriately maintains microtomes.	CAP[1] – ANP.23400 CLSI[9] - GP17-A3 – 9.1 ISO[1] 15189 – 5.3.1.5	Are microtomes: • clean and well-maintained? AND • properly lubricated and without excessive play in the advance mechanism? Are microtome knives sharp and free of nicks? Is decontamination of the microtome performed when an infective case is sectioned? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.4 Surgical Pathology - Equipment, Reagents & Supplies continued			
AP.2.4.5	Stains and reagents are appropriately maintained and replaced.	CAP[1] – ANP.10041, .11756, .21360 CAP[5] – COM.30300, .30400	Is there evidence that stains and reagents are maintained and replaced according to a defined schedule? Are records of all solution changes, filtering, or addition to solutions available? Does the laboratory assign an expiration date to any reagents that do not have a manufacturer-provided expiration date? Are assigned expiration dates based on known stability, frequency of use, storage conditions and risk of contamination or deterioration? Is the quality of formalin monitored by: • performing pH checks on new batches of formalin prepared by the laboratory? OR • maintaining records of manufacturer's QC of pH or performing pH spot checks on purchased ready to use formalin? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.5 Surgical Pathology - Pre-examination Policies, Processes and Procedures			
AP.2.5.1	For surgical pathology specimens, the examination request includes appropriate specific clinical information.	AHS[1] CAP[4] – GEN.40750 CLSI[1] – GP15-A3 – 6.2	Does the examination request for surgical pathology specimens include appropriate specific clinical information where applicable? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.5.2	The laboratory provides guidelines for the appropriate collection of surgical pathology specimens.	ADASP[1] CAP[3] - 3:11; 6:45 CAP[4] – GEN.40115	Has the laboratory provided guidelines on the collection of surgical pathology specimens, including: • descriptions of containers? • any required additives, fixatives? • amount of specimen? • special handling or transport? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.5.3	The laboratory has policies, processes and procedures for the receipt and handling of surgical pathology specimens.	AHS[1] ADASP[1] CAP[3] - 3:11; 6:46	Are multiple specimens received from the same patient, on the same day, from the same procedure, all identified with the same accession or surgical case number and further subcategorized? Is there evidence that the laboratory documents the date and time of delivery of histology slides and electronic images or prints to the pathologist? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.5 Surgical Pathology - Pre-examination Policies, Processes and Procedures continued			
AP.2.5.4	The laboratory has a tissue exclusion list that defines the types of tissues not requiring examination by the surgical pathology department and/or requires only gross examination.	CAP[1] - ANP.10016, .10032 CAP[3] – 3:12	Is there a tissue exclusion list that defines the types of tissues not requiring: • examination by the surgical pathology department? • microscopic examination? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.5.5	There are criteria for acceptance or rejection of primary specimens.	CAP[3] - 3:12 CAP[5] – COM.06300	Are there defined acceptance and/or rejection criteria for primary specimens? Is there evidence of assessment of specimens for acceptability in accordance with the established criteria? Are specimens assessed for appropriate type and amount of fixative? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.6 Surgical Pathology - Quality Assurance of Pre-examination Procedures			
AP.2.6.1	The laboratory monitors defined pre-examination quality indicators and adherence to established targets.	AHS[1] CAP[3] - 6:46-49	Are all of the following quality indicators monitored: • percentage of specimen identification errors? • percentage of specimens with inadequate history? • percentage of specimens with improper fixation? Has the laboratory established additional pre-examination quality indicators relevant to the outcome of patient care and scope of laboratory services? Is there evidence that quality indicator benchmarks are being achieved? Where quality indicator targets are not achieved, is there evidence of investigation and corrective action? Does the laboratory provide regular feedback to submitting physicians on inadequate pre-examination elements?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures			
AP.2.7.1	There are detailed gross room protocols and procedures for the proper dissection, description, and histologic sampling of various specimen types readily available in the laboratory.	AHS[1] CAP[1] – ANP.10038, .11670, 11680, .21397	Are there detailed gross room protocols and procedures for the proper dissection, description and histologic sampling of various specimen types readily available in the laboratory? Are gross room techniques controlled to reduce cross-contamination, errors and inconsistencies including the following: • cleaning of and well-maintaining instruments and work surfaces? • multiple specimens on the same case clearly differentiated in dictation? • the availability of multiple-colored inks or dyes for marking tissue margins? • the inking of specimens prior to cutting into the specimen? • cassettes not packed too tightly with tissue? • preferred thickness of tissue in cassettes? Does the laboratory have a process for trained histology personnel responsible for tissue processing to provide feedback on the quality of the tissue sections received for processing (e.g., to pathologist or responsible individual)?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.2 **PS**	Specimen identity and integrity is maintained at all times during the processing and examination steps.	ADASP[2] AHS[1] CAP[5] – COM.06200	Are there systems in place throughout the path of workflow to reduce specimen identification errors including cassette (blocks) and slides? Is each block of tissue identified by the case accession number and by any descriptor assigned during grossing? If additional blocks are prepared later, do all lists and logs reflect these additions? Is identification affixed to blocks in a manner that remains legible? Is each slide identified by the case accession number and by a descriptor unique to the block from which it is cut? Is cassette and slide identification information indelible, legible, and able to withstand all stages of processing and conditions of storage? Is the system of transport of specimens from one site to another designed to prevent loss of specimens? Is there evidence of all of the following prevention processes: • contamination and carry-over of extraneous tissue? • flotation errors (i.e., wrong tissue on the slide)? • specimen mix-ups? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.3	The laboratory ensures the technical quality of tissue processing.	AHS[1] Canadian Association of Pathologists[2] CAP[1] - ANP.23120, .23130 CAP[3] - 7:81-85	Are specimens fixed for an appropriate length of time prior to testing? Are there defined processing programs for various types and sizing of specimens and/or tissues? Are new tissue processing schedules validated against the standard laboratory processing schedule? Are tissue processors alarmed in case of malfunction? Are tissue processor solutions changed at regular intervals? Is there evidence of daily review of the quality of the tissue processing by a supervisor or designate? Does the laboratory: • monitor and document time before fixation? • monitor and document exposure to surface drying or excessive heat if present? AND • ensure specimens are fixed in accordance with current best practice recommendations?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.4	The laboratory ensures the technical quality of tissue embedding.	AHS[1] CAP[1] - ANP.21397 CAP[3] - 7:82	Do embedding work lists include sufficient information including all of the following where applicable: • the case or surgical number? • the cassette identifier? • the number of tissue pieces per cassette? • any special embedding instructions? • the number of slides to be cut? Is only one cassette opened at a time while embedding? Are forceps cleaned or wiped between cases to prevent cross-contamination? Are there processes in place to document and resolve any discrepancies identified during embedding? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.5	The laboratory ensures the technical quality of tissue microtomy.	AHS[1] CAP[1] – ANP.11716, .11734, .21397 Guidance: Scope of practice involving high volumes of like or similar specimen types may preclude the exclusion of consecutive cutting of like or similar specimen types.	Is there a policy to ensure that like or similar specimens are not cut consecutively, where feasible? Are there criteria defining the sectioning thickness of paraffin embedded tissues for various tissue types and procedures? Do tissue sections meet all of the following criteria: • cut from sufficient depth in the block to include the entire tissue plane? • of appropriate thickness? • free from interfering tissue folds and tears? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.7.6	The laboratory ensures the technical quality of tissue staining.	AHS[1] CAP[3] - 7:78-80	Is there evidence that hematoxylin, eosin and other routine stains are monitored using control slides on each day of staining? Is there evidence that control slides are processed with every special stain or batch of stains? Are control slides made available to pathologists? Is the pH of buffers and reagents monitored? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.8	The laboratory has policies and processes for obtaining and documenting intradepartmental and external consultations and/or reviews.	ADASP[2] AHS[1] CAP[1] - ANP.10150 CAP[3] - 6;50-60	Are there clear definitions of true consultations versus quality assurance reviews? Are consultations identified for all of the following: • pathologist-perceived diagnostic difficulty? • lack of consensus? • a second opinion was requested? Are intradepartmental and external consultations and/or reviews documented in a systematic manner? Is there internal documentation of concordance between the original findings and any consult and/or review findings regardless of the origin of the request or where the review was performed? Does documentation include diagnostic concordance and error classification and/or patient impact when disagreement is noted? Is there evidence of a prospective review system of a defined percentage of all surgical pathology cases (percentage based on size of practice and available resources)? Are prospective reviews integrated into the normal workflow? Are all of the following additional review processes implemented where applicable: • mandatory second pathologist review when indicated by current standard of care? • prospective documented review of challenging cases? • a retrospective review of a percentage of all cases (random or by organ system)?

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			• mandatory review of any outside pathology materials upon which a definitive therapy is planned in referral institution? • external consultation by sub-specialty pathologists in an appropriate proportion of cases? • review of outside diagnoses of in-house case? • clinical impact assessments and the determination of the percentage of specimens in each clinical impact category?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.9	External cases submitted to the laboratory for consultation are accessioned, handled and reported according to the standard practices of the laboratory.	CAP[1] - ANP.10250 CAP[3] – 3:14	Are external cases that are submitted to the laboratory accessioned, handled, and reported according to the laboratory's standard practices? Is a copy of the final pathology report sent to the originating laboratory? Does the laboratory ensure that the original material, including slides and blocks, are promptly returned to the originating facility? In situations where the original material is not returned, is a request sent to the originating laboratory requesting permission to retain the slides and accepting transfer of stewardship of patient materials? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.7.10	The laboratory has a process for the retrieval and review of pertinent previous cytologic and/or histologic material from the patient where appropriate.	ADASP[2] CAP[1] – ANP.10050	Is there evidence of retrieval and review of pertinent previous cytologic and/or histologic material from the patient where appropriate? Is documentation of retrospective reviews included in the current patient report? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.7 Surgical Pathology - Examination Policies, Processes and Procedures continued			
AP.2.7.11	The results of specialized ancillary studies are correlated with the morphologic diagnosis.	AHS[1] CAP[1] – ANP.12400 Guidance: Ancillary studies include (for example): immunohistochemistry, nucleic acid probes, cytogenetics, flow cytometry, electron microscopy.	Is there evidence that the results of specialized ancillary studies are correlated with the morphologic diagnosis? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.8 Surgical Pathology - Quality Assurance of Examination Procedures			
AP.2.8.1	The technical quality of histologic preparations is routinely monitored.	AHS[1] CAP[1] – ANP.10042, .11734 CAP[3] - 7:77-89	Is there a review of slide quality to ensure all of the following: • proper and/or complete fixation? • proper orientation? • tissue sections are cut from sufficient depth in the block to include the entire tissue plane? • appropriate tissue thickness? • slides are free from interfering tissue folds and tears? • quality of staining? • quality of cover slipping? Is there evidence of regular review by a supervisor or designate? Are there mechanisms to provide feedback to the histology laboratory regarding the quality of histological preparations including: • embedding to ensure correct orientation, alignment, etc.? • microtomy? • staining? When histologic preparations are inadequate or cross-contamination between specimens or cases is identified, are feedback and corrective action recorded?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.8 Surgical Pathology - Quality Assurance of Examination Procedures continued			
AP.2.8.2	Pathologists participate in conference board and/or Tumor groups.	ADASP[2] AHS[1] OMA[1]	Do conference board and/or tumor group meetings meet the following criteria: • review of specific reports and/or slides and materials to identify errors? • assessment of all new surgical pathology diagnoses of malignancy in an organ system? • discussion of treatment planning and case management? Is the tumor group interdisciplinary including pathologists, oncologists and other clinicians? Are the tumor board review outcomes monitored?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.8 Surgical Pathology - Quality Assurance of Examination Procedures continued			
AP.2.8.3	The laboratory monitors defined examination quality indicators and adherence to established targets	AHS[1] ADASP[2] CAP[3] - 6:45-72	Are the following quality indicators monitored where applicable: • percentage of identification and integrity errors during the production of histologic specimens? • percentage of specimens with poor technical quality? • percentage of documented ancillary test requests and the rate of those tests that were technically satisfactory? • percentage of intra-operative consultations in each correlation category? • rate of diagnostic deferral at the time of frozen section and/or intra-operative consultation? • the turnaround time for single block intra-operative consultations? • percentage of specimens with intra-departmental review? • percentage of specimens in each correlation category following intra-departmental review? • percentage of specimens sent for external review? • percentage of specimens receiving tumor board review? • rate of cytology and/or surgical pathology correlation? • peer review error rate in final diagnosis? Is there evidence that quality indicator benchmarks are being achieved? Where quality indicator targets are not achieved, is there evidence of investigation and corrective action? Has the laboratory established additional examination quality indicators relevant to the outcome of patient care and scope of laboratory services? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.9 Surgical Pathology - Post-examination Policies, Processes and Procedures			
AP.2.9.1	There is a comprehensive surgical pathology report that includes all relevant information essential to the diagnosis and patient care, including intra- and extra-departmental consultations.	CAP[1] – ANP.10150, .12155, .12170, .12425 CAP[3] - 3:15-16; 6:61-65	Do surgical pathology reports include all of the following, where applicable: • patient identification? • gender? • date of birth? • patient location? • physician? • date of procedure? • clear identification of separate tissues submitted? • gross descriptions and microscopic findings, where performed, that support the pathologic diagnosis? • ancillary studies? • any required disclaimers if patient testing is performed using Class I analyte-specific reagents (ASRs) obtained or purchased from an outside vendor? • intra-operative consultation findings? • intradepartmental consultations, where appropriate? • external consultations? • diagnoses that comply with recognized pathological entities, standard terminology and use clear unambiguous language? • reporting pathologist? Do the surgical pathology report gross descriptions include all of the following: • type, number, dimensions and/or weight of specimens? • measurements and extent of gross lesions, as applicable? • other information essential to the diagnosis and patient care? • processing information including: ○ a key or summary noting block and slide designations?

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			○ type of specimen fixation and processing? ○ ischemic time? ○ length of time in fixative, as applicable? Where multiple diagnoses are made, are they clearly separated?
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			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.9 Surgical Pathology - Post-examination Policies, Processes and Procedures continued			
AP.2.9.2	All data elements in the surgical pathology report conform to provincial cancer protocols, where available.	CAP[1] – ANP.12350 CAP[3] – 6:61	Do all data elements in the surgical pathology report conform to provincial cancer protocols, where available? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.9.3	All surgical pathology data elements are reported using standardized, structured synoptic reporting templates and/or protocols, where available.	AHS[1] CAP[1] – ANP.12350	Are all surgical pathology data elements reported using standardized, structured synoptic reporting templates and/or protocols? Is all information relevant to staging and grading included on the reports to facilitate interpretation by the physician, where applicable? Is each diagnostic parameter pair listed on a separate line? Are all data elements and responses listed together in one location in the pathology report? Are narrative style comments permitted in addition to, but not as a substitute, for synoptic reporting? Are the standardized synoptic reporting templates updated to reflect changes to reference protocols? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.9 Surgical Pathology - Post-examination Policies, Processes and Procedures continued			
AP.2.9.4 **PS**	The laboratory ensures that all reports containing interpretations by the pathologist indicate that a responsible pathologist has reviewed and approved the completed report prior to its release.	CAP[1] – ANP.11660, .12170 ISO[1] – 7.4.1.6	Is there evidence that the responsible pathologist has reviewed and approved the completed report prior to its release? When the diagnosing pathologist is not available for timely review and approval of the completed report, does the laboratory have a policy and procedure for review and approval of that report by another pathologist? Do the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performed final verification appear on the report?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.9 Surgical Pathology - Post-examination Policies, Processes and Procedures continued			
AP.2.9.5 **PS**	The laboratory has a policy and processes for the communication and documentation of significant and unexpected surgical pathology findings.	ADASP[2] ADASP[3] ADASP[4] AHS[1] ASCP[1] CAP[1] – ANP.12175 CLSI[4] – QMS01 – 4.2.4, 4.3.1, 4.3.2 ISO[1] – 7.4.1.3, 7.4.1.4	Does the laboratory have a policy for the communication and documentation of significant and unexpected surgical pathology findings? Is there evidence that the laboratory has consulted clinical medical staff to define diagnoses classified as "significant and unexpected"? Is there a list of significant and/or unexpected surgical findings that must be reported as soon as possible including all of the following: • cases that have immediate clinical consequences (e.g., vasculitis, transplant rejection, acute leukemia, etc.)? • malignancy in an uncommon location or specimen type (e.g., hernia sac, intervertebral disk material, tonsil, etc.)? • unrecognized perforation of an organ (e.g., fat in an endometrial curettage)? • unintended surgical consequences or misidentification of a specimen? • suspicion of wrong site surgery? • discovery of clinically significant infections? Is there a list of discrepant surgical pathology findings that must be reported as soon as possible including significant disagreement between all of the following: • frozen section and permanent diagnosis? • immediate interpretation and final FNA diagnosis? • primary pathologist and outside pathologist consultation? Does the process ensure that such diagnoses are received by the clinician?

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			Is there documentation of notification of all of the following including: • date and time? • responsible individual communicating the results? • person notified using identifiers traceable to that person? • examination results? • any difficulty encountered in meeting this requirement?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.9 Surgical Pathology - Post-examination Policies, Processes and Procedures continued			
AP.2.9.6 **PS**	The laboratory has policies and procedures for the issuing and management of provisional, amended and/or corrected and addendum reports.	AHS[1] CAP[1] – ANP.12175, .12185 CLSI[4] – QMS01 - 4.3.2.2 ISO[1] – 7.4.1.8, 8.4.2 Guidance: **Amended and/or corrected –** diagnostic alterations: changes in the final diagnosis or the diagnosis comment filed that represent diagnostic alterations (e.g. change in diagnosis, margin status or vascular invasion). **Addendum –** additional information only: does not alter the intent of the original report (e.g. addition of information that was not available at time of sign out such as diagnostic studies such as special stains, clarification of clinicopathological data or report elements).	Does the laboratory issue a provisional report when the pathologist anticipates a delay in producing the final report? Are there clear directions that indicate when an amended and/or corrected or addendum report is required and the steps to be taken when issuing the report? Are amended and/or corrected and addendum reports clearly identified on all forms of patient reports (paper, video displays, etc.)? Are amendments to reports that would affect current patient care reported promptly to the responsible physician? Do alterations to records or results indicate the date, time, person who made the changes, and person notified? Are alterations made in such a way that the original entry is visible? In the case of a computer record, is the original entry identified and retained? Is the original result part of the permanent patient record? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.9 Surgical Pathology - Post-examination Policies, Processes and Procedures continued			
AP.2.9.7	Post-examination quality issues are documented and followed up using occurrence management processes.	ADASP[2] AHS[1] CAP[3] - 5:44	Is there evidence of occurrence management of all the following errors: • transcription? • verification? • report delivery? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.9.8	The laboratory ensures the appropriate retention of surgical pathology records and materials.	CAP[1] – ANP.11550, .12500 CAP[3] – 3:16-17 Guidance: Retention times to be defined by the nature of the examination or specifically for each record type.	Is there a policy for protecting and preserving the integrity and retrieval of surgical pathology materials and records? Do retention periods meet all of the following criteria: • based on established and/or recognized best practice guidelines? • appropriate to provide documentation for adequate quality control and medical care? Is there evidence that materials and records are retained in accordance with the established retention policy? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.10 Surgical Pathology - Quality Assurance of Post-examination Procedures			
AP.2.10.1	The laboratory monitors defined post-examination quality indicators and adherence to established targets.	ADASP[2] AHS[1] CAP[3] - 6:61-65	Are the following quality indicators monitored: • percentage of transcription, verification, and report delivery errors? • percentage of amended and/or corrected pathology reports? • percentage of pathology reports with addendums (additional information; no changes to original report)? • percentage of reports containing all required elements from the provincial cancer reporting protocols? • total identified non-conforming events? Is there evidence that quality indicator benchmarks are being achieved? Where quality indicator targets are not achieved, is there evidence of investigation and corrective action? Has the laboratory established additional post-examination quality indicators relevant to the outcome of patient care and scope of laboratory services? For extra-departmental cases, are the following indicators monitored: • consultation report delivery errors? AND • incomplete consultation reports? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.10 Surgical Pathology - Quality Assurance of Post-examination Procedures continued			
AP.2.10.2	There is comprehensive prospective quality assurance audit of reports for completeness and incorporation and/or correlation of ancillary study findings and consultations as defined in the quality management system.	ADASP[2] AHS[1] Pathology Case Reviews[1]	Is there evidence of prospective audits of reports for the inclusion and correlation of ancillary study findings? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.10.3	The laboratory establishes turnaround time for surgical pathology reports in consultation with the users of laboratory services.	ADASP[2] AHS[1] CAP[3]- 6:65-70 CAP[4] – GEN.41345	Is the turnaround time monitored for the following: • from time of specimen receipt to the time the first report is issued? • from dictation to transcription of report? • on simple and/or small cases (histology level IV)? • on complex and/or large cases (histology levels V & VI)? Is there a mechanism to identify difficult or special cases? Is the assigned level adjusted following review, if required, to accurately reflect the complexity of case? Are identified problems with turnaround times adequately monitored and addressed? Are turnaround time targets evaluated at defined intervals? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.10 Surgical Pathology - Quality Assurance of Post-examination Procedures continued			
AP.2.10.4	The laboratory monitors stakeholder satisfaction in various areas of pathology services.	ADASP[2] AHS[1] CAP[3]- 6:70-72	Is there evidence that the clinician satisfaction rate is monitored in the following areas of pathology services: • diagnostic accuracy? • communication of relevant information? • notification of significant abnormal results? • timeliness of reporting? • quality of professional interactions? • pathologist responsiveness to problems? • tumor board presentations? • courtesy of laboratory staff? • teaching conferences and courses? • pathologist accessibility for frozen sections? Are the frequency and number of stakeholder complaints tracked? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.11 Surgical Pathology - Safety			
AP.2.11.1 **SS**	The laboratory has specific policies and procedures for the safe handling of tissues that may contain radioactive material.	CAP[1] - ANP.11275 CLSI[9] - GP17-A3 – 9.3 Guidance: Tissue that may contain radioactive material include, for example, sentinel lymph nodes, breast biopsies, prostate "seeds", etc.).	Does the laboratory have specific policies and procedures for the safe handling of tissues that may contain radioactive material? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.11.2 **SS**	Open automated tissue processors are operated at least five feet away from the paraffin dispenser and combustible material storage.	CAP[1] - ANP.24050 Guidance: Tissue processors that operate as a closed system and confine ignitable vapor hazards within the processor do not require the five feet of separation.	Are automated tissue processors at least five feet away from: • paraffin dispensers? • combustible material storage? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.12 Surgical Pathology - Intra-operative Consultations			
AP.2.12.2	The quality of intra-operative consultation preparations is adequate for intra-operative diagnosis.	CAP[1] – ANP.11810 OMA[1] – 4:2.6	Is the quality of histological sectioning and staining adequate for intra-operative diagnoses? Are appropriate measurements and descriptions of tissue recorded prior to performing frozen sections?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.2.12.3	The pathologist performing an intra-operative consultation has access to the patient's history including radiographic and previous pathologic diagnosis, where appropriate.	ADASP[2] CAP[3]- 6:47-48	Is there evidence that the pathologist performing an intra-operative consultation has access to the patient's history including radiographic and previous pathologic diagnosis, where applicable? Is there a process for the handling of intra-operative consultations with inadequate patient history? Does the laboratory provide regular feedback to submitting physicians on the provision of inadequate history?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.12 Surgical Pathology - Intra-operative Consultations continued			
AP.2.12.4	Tissues and slides from intra-operative consultations are appropriately processed for further examination, correlation and retention.	ADASP[2] AHS[1] CAP[1] – ANP.12050, .12075 CAP[3]- 3:15 CAP[5]- COM.06100	Are all intra-operative consultation slides permanently labelled, stained, and mounted? Are these slides retained with the rest of the slides from the case? Following frozen section examination, is the residual frozen tissue: • labelled with two identifiers? • routinely processed into paraffin and a histologic section prepared and examined for comparison with the frozen section interpretation? Is a correlation of frozen section findings with a permanent section prepared from routinely fixed and processed residual frozen tissue performed? Does the laboratory have a policy that justifies any exemptions to this requirement? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.12.5	A second pathologist reviews cases where there is an intra-operative consult, for correlation using defined concordance categories.	ADASP[2] AHS[1] CAP[3]- 6:50-51 OMA[1]	Are permanent sections read by a pathologist who did not provide the intra-operative consult or are concordances between intra-operative consults and permanent sections confirmed by a second pathologist? Is the review performed prior to case sign-out? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.12 Surgical Pathology - Intra-operative Consultations continued			
AP.2.12.6	The laboratory maintains contemporaneous reports of intra-operative consultations.	CAP[1] – ANP.11850 CAP[3] – 6:50	Are the results documented and signed by the pathologist who made the diagnosis at the time of the intra-operative consultation? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.12.7	Processes are in place to ensure the accurate reporting of intra-operative consultations.	CAP[1] – ANP.11900, .11950, .12000 ISO[1] 15189 – 7.4.1	Does the laboratory have a policy requiring all of the following: • the pathologist speaks directly with intra-operative medical and/or surgical personnel if verbal reports are given? • the patient's identification is checked and confirmed before delivery of any verbal report? Is there a process in place to handle reports when the requesting physician cannot be contacted? Are all intra-operative consultation reports integrated into the final surgical pathology report? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.12 Surgical Pathology - Intra-operative Consultations continued			
AP.2.12.8 **PS**	When significant disparity exists between initial intra-operative consultation and final pathology diagnosis, the laboratory reconciles and documents the disparities in the surgical pathology report.	AHS[1] CAP[1] - ANP.10100 CAP[3] - 60-51 Guidance: Intra-operative consultations include frozen section, intra-operative cytology, and gross evaluations.	Are intra-operative consultation discordances classified in accordance with established guidelines? Are significant intra-operative consultation discordances treated as sentinel events requiring investigation and action? Are discrepancies reconciled on the final pathology report? Are the medical consequences of each significant discordance (outcome review) determined and assigned an appropriate quality assurance category according to clinical impact? Is the percentage of intra-operative specimens in each concordance category monitored? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.2.12.9	The laboratory establishes turnaround time for intra-operative frozen sections.	AHS[1] CAP[4] – GEN.41345	Is the turnaround time monitored for intra-operative consultations? Are there established pathologist response times for intra-operative frozen sections? Are identified problems with turnaround times adequately monitored and addressed? Are turnaround time targets evaluated at defined intervals? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.2.12 Surgical Pathology - Intra-operative Consultations continued			
AP.2.12.10 **SS**	Routine decontamination of the cryostat is performed at defined intervals.	CAP[1] - ANP.23410 CLSI[6] – M29-A4 – 13.7.6 CLSI[9] - GP17-A3 – 9.1 CSMLS[1] – 16.8 ISO[2] 15190-20 – 13.8	Is there evidence of decontamination of the cryostat at defined intervals? Where disposable microtome blades are not used, is decontamination of the microtome in the cryostat performed: • at defined intervals? AND • when an infective case is sectioned?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.2.12.11 **SS**	All personnel performing frozen sectioning wear appropriate personal protective equipment.	CLSI[9] – GP17-A3 – 9.1.1 ISO[2] 15190-20 – 13.8	Are all personnel performing frozen sectioning required to wear: • puncture and penetration resistant gloves? • N-95 particulate respirator? • gowns? • eye protection?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.0 ANCILLARY STUDIES			
AP.3.1 Ancillary Studies - Histochemistry			
AP.3.1.1	Histochemical stains are of high quality, and satisfactorily demonstrate the tissue components or organisms for which they were designed.	CAP[1] – ANP.11734, .21395 CAP[3] – 7:77 CAP[5] – COM.50500	Is the quality of histochemical stains verified on each day of use? Does the laboratory perform special stains appropriate to their scope of services and demonstrated need? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.2 Ancillary Studies - Immunofluorescence Microscopy			
AP.3.2.1	Appropriate positive and negative controls are performed for immunofluorescence microscopy.	CAP[1] – ANP.21850 CAP[3] – 7:77	Are internal antigens used as positive controls? When internal positive controls are absent, are daily external positive controls performed? Is a negative reagent control in which the patient tissue is processed in an identical manner to the test specimen but with the primary antibody omitted performed for each patient test specimen? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.3 Ancillary Studies - Immunohistochemistry (IHC)			
AP.3.3.1	There is a system to record the date and time of delivery of immunohistochemistry slides to the pathologist.	ADASP[1]	Is there evidence that the laboratory documents the date and time of delivery of immunohistochemistry slides to the pathologist? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.3.2	The procedure manual includes appropriate modifications for the performance of IHC staining on specimens other than formalin-fixed, paraffin-embedded.	AHS[1] CAP[1] – ANP.22300	Does the procedure manual include appropriate modifications for the performance of IHC staining on specimens other than formalin-fixed, paraffin-embedded such as: • frozen sections? • air-dried imprints? • cytocentrifuge or other liquid-based preparations? • decalcified tissue? • tissues fixed in alcohol blends or other fixatives? If decalcified tissues are tested, are all of the following reported: • fixation time prior to decalcification? • type of decalcifying reagent? • time of decalcification? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.3.3	The laboratory routinely monitors the pH of IHC buffers.	CAP[1] – ANP.22500 CAP[2] – CYP.04320 CAP[3] – 8:96	Is there evidence of routine monitoring of the pH of IHC buffers when a new batch is prepared or received? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.3 Ancillary Studies - Immunohistochemistry (IHC) continued			
AP.3.3.4	The laboratory performs appropriate antibody controls for IHC.	AHS[1] CAP[1] – ANP.22550, .22570, .22660 CAP[3]- 8:97-100	Is there evidence that positive tissue controls meet all of the following criteria: • are used for each antibody? • are performed on sections of tissue known to contain the target antigen? • use the same epitope retrieval and immunostaining protocols as the patient tissue? • are included on the same slide as the patient tissue or is one separate positive control included per staining run for each antibody in the run (batch control)? When batch controls are run, are all control slides reviewed by the laboratory director or designee on each day of patient testing? Does the laboratory maintain separate positive control specimens for all possible combinations of fixation, processing, and specimen types? Where this is not possible, does the laboratory: • maintain a bank of formalin-fixed tissue specimens as its positive controls? AND • demonstrate that these patient specimens exhibit equivalent immunoreactivity? Does the laboratory have a process for the prevention of false-negative results due to the exclusive use of normal tissues that have high levels of antigen expression as positive controls? Is there evidence that negative tissue controls meet all of the following criteria: • assess the presence of nonspecific staining in patient tissue as well as the specificity of each antibody?

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			• assess the specificity of each antibody by exhibiting no staining of tissues known to lack the antigen? • are processed using the same fixation, epitope retrieval and immunostaining protocols as the patient tissue? • are processed for each antibody in a given run? Is the type of negative tissue control specified in the procedure (i.e., separate sections, internal controls or multi-tissue blocks)? Is there evidence that negative reagent controls meet all of the following criteria: • assess nonspecific or aberrant staining in patient tissue related to the antigen retrieval conditions and/or detection system used? • are run for each block of patient tissue being immunostained? • for cases in which there is simultaneous staining of multiple blocks from the same specimen with the same antibody, is a single negative control performed on one of the blocks, provided that all such blocks are fixed and processed identically? • for stains on different types of tissues or those using different antigen retrieval protocols or antibody detection systems, does the procedure specify which cases only require one negative reagent control? • control for each reagent protocol and antibody retrieval condition? • for large antibody panels employing multiple antigen retrieval procedures, use the most aggressive retrieval procedure in the particular antibody panel? Are separate sections of patient tissue processed using the same reagent and epitope retrieval protocol as the patient test slide, except that the primary antibody is omitted, and replaced by any of the following: • an unrelated antibody of the same isotype as the primary antibody (for monoclonal primary antibodies)?

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			• an unrelated antibody from the same animal species as the primary antibody (for polyclonal primary antibodies)? • the negative control reagent included in the staining kit? • the diluents/buffer solution in which the primary antibody is diluted? For laboratories using biotin-based detection systems, are appropriate negative controls used? Are results of positive and negative controls documented, either in internal laboratory records, or in the patient report?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.3 Ancillary Studies - Immunohistochemistry (IHC) continued			
AP.3.3.5	The laboratory has a process to address nonspecific false-positive staining from endogenous biotin where appropriate.	CAP[1] – ANP.22615 CAP[3] – 8:98	If the laboratory uses an avidin-biotin complex detection system or a related system such as streptavidin-biotin or neutravidin-biotin, does the procedure address nonspecific false-positive staining from endogenous biotin? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.3.6	The laboratory validates new antibodies and detection system reagents, prior to use in patient diagnosis.	CAP[1] – ANP.22750, .22760 CAP[3]- 8:95-96	Is the performance of new lots of antibody and detection system reagents tested in parallel with old lots? Is each new antibody or antibody clone validated for specific fixation and processing procedures to ensure that all of the following are optimal: • titration? • antigen retrieval? • detection system? • fixation? Once optimized, are panels of tissues tested to determine the assay's sensitivity and specify? Is there evidence of validation and/or verification of new antibodies? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.3 Ancillary Studies - Immunohistochemistry (IHC) continued			
AP.3.3.7	The laboratory ensures the quality of IHC examinations and interpretative results.	AHS[1] CAP[1] - ANP.22900 Canadian Association of Pathologists[1] Canadian Association of Pathologists[2]	Does the laboratory ensure surgical specimens are received with proper fixation including all of the following: • appropriate specimen container? • appropriate fixative or preservative? • appropriate amount of fixative or preservative? • appropriate fixation times? • adherence to requirements to exceptions for routine fixation? Are antigen retrieval or enhancement techniques used for IHC when necessary? Is there a process to ensure the quality and consistency of staining? Is the interpretation of individual biomarkers standardized? Does the interpretation include indications for gene analysis?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.3 Ancillary Studies - Immunohistochemistry (IHC) continued			
AP.3.3.8	The laboratory monitors defined IHC quality indicators and adherence to established targets.	ADASP[2] CAP[3]-8:101-102 CAP[5]- COM.01520	Are the following quality indicators monitored for IHC: • frequency and causes of repeat stains? • turnaround time? • report audit for integration of stains with morphologic diagnosis? • annual review of antibody inventory and frequency of use? • enrollment and/or performance in external proficiency tests directly impacting patient therapy (e.g., HER2, ER)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.5 Ancillary Studies - Predictive Markers			
AP.3.5.2	Patient reports for immunohistochemical tests that provide independent predictive information include essential report elements.	CAP[1] – ANP.22969 CAP[3] – 8:101	For immunohistochemical studies used to provide diagnostic predictive information independent of other histopathologic findings, does the laboratory include all of the following information in the patient report: • the type of specimen fixation and processing? • the antibody clone or probe and general form of detection system used? • result scoring for IHC tests? • the criteria used to determine a positive vs. negative result, and/or scoring system? • limitations related to suboptimal pre-examination factors that may affect results (e.g., prolonged ischemic time, unknown ischemia time, over or under fixation)? • any indication of a differential diagnosis based on IHC? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.5.3	The laboratory compares its patient results with published benchmarks and evaluates inter-observer variability among the pathologists in the laboratory for immunohistochemical tests.	CAP[1] – ANP.22970 CAP[2] – CYP.04520 CAP[3] – 6:45, 8:102	Are there established limits of acceptable variation among pathologists? Is there evidence of investigation when the established variation limits are exceeded? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.5 Ancillary Studies - Predictive Markers continued			
AP.3.5.4	The laboratory appropriately validates and/or revalidates IHC testing to ensure optimal performance.	CAP[1] – ANP.22780 CAP[2] – CYP.04530, .04550 CAP[3] – 8:94-96	Is there evidence that IHC testing is: • validated to ensure optimal performance? • revalidated when conditions change that may affect performance? • validated and/or revalidated by testing a sufficient number of cases to ensure that expected results are achieved? For each estrogen receptor (ER) and/or progesterone receptor (PgR), is there evidence of the following: • initial test validation? • revalidation if significant changes are made in testing methods (e.g., antibody clones, antigen retrieval or detection system, pre-treatment protocol)? For each HER2 assay method, is there evidence of all of the following: • initial test validation? • validation study for specimens fixed in a medium other than 10% neutral buffered formalin to ensure concordance with results from formalin-fixed tissues? • revalidation if significant changes are made in testing methods (e.g., antibody clones, antigen retrieval protocol or detection system, pre-treatment protocol)? Are patient specimens fixed in the same manner as the specimens used for the validation studies? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.5 Ancillary Studies - Predictive Markers continued			
AP.3.5.5	The laboratory ensures appropriate specimen fixation for HER2 and ER and/or PgR assays.	AHS[1] Canadian Association of Pathologists[2] CAP[1] – ANP.22983 CAP[2] - CYP.04550	In the laboratory guide to services, are all of the following indicated: • timeline requirements for the immersion of specimens in fixative after the biopsy or resection procedure (e.g., within 1 hour)? • process to follow if delivery of a resection specimen to the pathology department is delayed? • requirement for the documentation of the time of removal of the tissue and the time of immersion of the tissue in fixative for submission to the laboratory? Is there evidence that the laboratory adheres to all of the following criteria: • monitors time before fixation (ischemic time)? • monitors exposure to surface drying or excessive heat (e.g., cautery damage) if present? • slices larger specimens at 5 – 10 mm intervals after appropriate gross inspection and margin designation? • fixes specimens in an appropriate fixative that has been tested and validated for each antibody? • places specimens into appropriate volume of fixative within 1 hour and time of immersion into fixative is documented? • has defined and validated fixation times based on specimen size and type? • revalidates fixation times longer than 72 hours and makes any necessary adjustment to the antigen retrieval steps during IHC staining? • uses controls that reflect the total fixation time range of 8 hours – 10 days during optimization and validation of new antibodies? • validates any other fixatives used in parallel with the recommended fixative? • has a policy that addresses time of fixation for specimens obtained from another institution? • qualifies any negative result for specimens not meeting fixation guidelines?

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			C □ P □ E □ N □ N/A □
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.5 Ancillary Studies - Predictive Markers continued			
AP.3.5.6	The laboratory ensures appropriate decalcification procedures for HER2 and ER and/or PgR assays.	Canadian Association of Pathologists[2]	Is there evidence that the laboratory adheres to all of the following criteria: • performs decalcification only after adequate fixation? • uses separate controls on decalcified specimens which are fixed and decalcified in the same manner as the test? • employs separate validation of procedures for each antibody performed on decalcified specimens? • monitors the type of decalcifier, temperatures (not to exceed 37°C) and length of time in the fluid? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.5.7	The laboratory uses appropriate and recognized scoring criteria for the interpretation of Class II and/or prognostic markers.	ASCO[1] Canadian Association of Pathologists[1] CAP[1] – ANP.22969	Does the laboratory use appropriate and recognized scoring criteria for the reporting of all of the following: • HER2 and/or neu by IHC? • ER and/or PgR tests by IHC? Are the scoring criteria included in the pathology report, along with the clone of antibody and details of the method used? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.6 Ancillary Studies - Digital Image Analysis			
For the purposes of this standard, Digital Image Analysis refers to the computer-assisted detection or quantification of specific features in an image following enhancement and processing of that image, including but not limited to IHC, DNA analysis, morphometric analysis, and FISH and/or ISH.			CAP[1]
AP.3.6.1	There is a system to record the date and time of delivery of digital images and prints to the pathologist.	ADASP[1]	Is there evidence that the laboratory documents the date and time of delivery of digital images and prints to the pathologist? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.6.2	The pre-examination phase of the test system has been validated for each assay for digital image analysis.	CAP[1] – ANP.23004	Is there validation of the pre-examination phase for each assay including all of the following: • acceptable specimen preservation? • fixation parameters (time and type of fixative)? • processing? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.6	**Ancillary Studies - Digital Image Analysis continued**		
AP.3.6.4	The laboratory has processes for the appropriate use and handling of control specimens.	CAP[1] – ANP.22570, .23018, .23020	Are control materials: • run at more than one expression (level) concurrently with patient and/or client specimens? AND • tested in the same manner and by the same personnel as patient and/or client specimens? Is a negative control used to ensure that non-staining areas are scored as negative? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.3.6.5	The laboratory has guidelines for identification of appropriate areas and cells for analysis.	CAP[1] – ANP.23027, .23028	Is there evidence that: • appropriately trained and qualified personnel select or confirm the appropriate areas for analysis? AND • use of specific guidelines and procedures for the evaluation of heterogeneous cell populations particularly if there is background or nonspecific staining or if there is cell debris, endogenous pigment, and/or artifacts of aging, sectioning, or preparation? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.3.6 Ancillary Studies - Digital Image Analysis continued			
AP.3.6.9	Final patient reports include essential elements.	CAP[1] – ANP.23036, .23038	Does the final image analysis report include all of the following where applicable: • interpretation by the responsible pathologist? • specimen source? • name of the vendor and imaging system used? • the antibody clone and source? • the antigen retrieval method? • any limitations of the test result? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.0 AUTOPSY PATHOLOGY			
AP.4.1 Autopsy Pathology - Personnel			
AP.4.1.1	All autopsies are performed by trained and certified personnel, as defined in the QMS.	CAP[1] – ANP.33050 ISO[1] 15189 – 6.2.1	Are all autopsies performed by trained and certified personnel, as defined in the QMS? Are pathology attendants and/or assistants supervised directly or indirectly by a pathologist? Is the performance of non-pathologist(s) who perform autopsy services evaluated by a pathologist on a regular basis? Where autopsy services are performed by pathology assistants or other non-pathologist laboratory staff, does the laboratory have defined criteria for the following: • the procedures that may be performed by these individuals? • specific indications where a pathologist is to be consulted? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.4.2 Autopsy Pathology - Quality Management System			
AP.4.2.1	The findings of the post-mortem examination are available for clinicopathological correlations and quality improvement initiatives.	CAP[1] – ANP.30100 CAP[3]- 10	Is there evidence that the findings of the post-mortem examination are available for clinicopathological correlations and quality improvement initiatives? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.2 Autopsy Pathology - Quality Management System continued			
AP.4.2.2	Autopsy findings are incorporated into the institutional quality management program and communicated inter-departmentally, where appropriate.	CAP[1] – ANP.30100, .30150 CAP[3]- 10	Are autopsy findings incorporated into the institutional quality management program and communicated inter-departmentally, where appropriate, including all of the following: • reporting newly diagnosed infectious diseases to the hospital infection prevention committee? • presentation and/or review by institutional quality assurance committees? • reporting issues related to quality of care to risk management or sentinel event review committees? Are autopsy findings that were clinically unapparent but important specifically documented and communicated inter-departmentally? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.4.3 Autopsy Pathology - Physical Facilities			
AP.4.3.2 **SS**	Ventilation in the morgue is in accordance with local, provincial and other applicable guidelines.	CSA[2] – 6.13.3.1, Table 1 GOA[3]	Is the ventilation in the morgue in accordance with local, provincial and other applicable guidelines? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.4 Autopsy Pathology - Equipment, Reagents & Supplies			
AP.4.4.1	Provisions are available for satisfactory storage of bodies.	CAP[1] – ANP.32400 CAP[3] – 10:156,168	Is there evidence of satisfactory storage of bodies (refrigeration or embalming)? Are the temperatures of refrigeration units monitored? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.4.4.2 **SS**	The laboratory appropriately maintains autopsy equipment.	CAP[1] - ANP .32450, .33650 CAP[3] – 10:156,168	Are scales and balances accurately calibrated? Are morgue instruments clean, sharp and well-maintained? Are knives safely stored? Does the autopsy room have equipment and appropriate disinfectants for the decontamination of instruments and surfaces? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.4.4.3	Appropriate equipment and reagents are available and maintained for performance of special studies.	CAP[1] – ANP.33650 CAP[3] – 10:156,168	Is there appropriate equipment and reagents available and maintained for performance of toxicologic and microbiologic special studies? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.5 Autopsy Pathology - Pre-examination Policies, Processes and Procedures			
AP.4.5.1	There are policies, processes and procedures relating to the receipt and storage of bodies.	CAP[1] – ANP.32400 CAP[3] – 10:156,166,167	Are there policies, processes and procedures relating to the receipt and storage of bodies? Is there a 'chain of evidence' process in place where required? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.4.5.2	There is a procedure for obtaining autopsy consent, including who may give consent.	CAP[1] – ANP.31070 CAP[3] – 10:156,165	Is there a procedure for obtaining autopsy consent, including who may give consent? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.4.5.3	The laboratory has a policy to assess the appropriateness of performing a hospital autopsy, that complies with applicable statutes and regulations.	CAP[1] – ANP.31100 GOA[2] - 20	Does the laboratory have a policy to assess the appropriateness of performing a hospital autopsy that is in compliance with applicable statutes and regulations? Does the policy identify hospital deaths that are subject to possible medical examiner or coroner jurisdiction? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.5 Autopsy Pathology - Pre-examination Policies, Processes and Procedures continued			
AP.4.5.4	Requests for autopsy include required information.	CAP[1] – ANP.31070 CAP[3] – 10:156,165,178 CAP[4] – GEN.40750 ISO[1] – 7.2.3.1	Does the requisition and/or order entry include all of the following where applicable: • patient's first and last name? • a second patient identifier? • date of birth? • gender? • date and approximate time of death? • place of death (ward and/or service)? • name of requesting physician and/or health care provider? • test requested (limited or full autopsy)? • clinical data and/or indication for autopsy? • legal consent to autopsy (including indication of medical examiner's authorization)? • determination of disposition or disposal of the body?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.4.5.5	Available clinical records are reviewed and/or clinical information discussed with the attending physician before conducting the autopsy.	CAP[1] – ANP.33000 CAP[3] – 10:156,165,178	Is there evidence that pertinent available clinical records are reviewed and/or clinical information discussed with the attending physician or designate prior to conducting autopsies?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.4.5.6	The identity of deceased patients is confirmed prior to autopsy.	CAP[1] – ANP.33025	Is there a procedure requiring the verification of patient identity during preparation for an autopsy?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.6 Autopsy Pathology - Post-examination Policies, Processes and Procedures			
AP.4.6.1	The laboratory issues a provisional autopsy report where necessary.	CAP[1] - ANP.33350 CAP[3] – 10:158,179	Does the provisional autopsy report include all of the following where applicable: • all pertinent findings? • date & time of autopsy? • date of report? • name of pathologist performing autopsy? • name of autopsy assistant? • preliminary cause of death?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.6 Autopsy Pathology - Post-examination Policies, Processes and Procedures continued			
AP.4.6.2	There is a comprehensive final autopsy pathology report that includes all relevant information essential to the diagnosis, including intra- and extra-departmental consultations.	CAP[1] – ANP.33200, .33350 CAP[3] – 10:158	Does the final autopsy report include all of the following where applicable: • patient identification information? • date and approximate time of death? • name of requesting physician and/or healthcare provider? • details of death or clinical history? • test requested (limited or full autopsy)? • date and time autopsy? • date of report? • name of pathologist performing the autopsy? • name of prosector assisting the pathologist? • formal intra- and extra-departmental consultations? • clear and concise gross and microscopic descriptions? • any ancillary procedures used? • all pertinent findings? • a key or summary noting block and slide designations to allow identification of the source of specific microscopic sections? • information on laterality and on specific lesions sampled? • cause of death, if determined? Do all findings and the descriptions support the diagnosis? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.6 Autopsy Pathology - Post-examination Policies, Processes and Procedures continued			
AP.4.6.3 **PS/SS**	The laboratory has a policy for the handling and communication of unexpected autopsy pathology findings.	ADASP[2] ASCP[1] CAP[1] - ANP.30160	Does the laboratory have a policy for the handling and communication of unexpected autopsy pathology findings including all of the following: • findings that require notification of the medical examiner's office? • findings that may influence the attending physician's completion of the death certificate? • discovery of a reportable infectious disease?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.4.6.4	The laboratory ensures the appropriate retention of autopsy pathology records and materials.	CAP[1] – ANP.33400, .33500, 33380 CAP[3] – 3:17	Is there a policy for protecting and preserving the integrity and retrieval of autopsy pathology materials, records, photographs and/or digital images? Are the retention periods: • based on established and/or recognized best practice guidelines? AND • appropriate to provide documentation for adequate quality control and medical care? Is there evidence that materials and records are retained in accordance with the established retention policy?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.7 Autopsy Pathology - Quality Assurance of Post-examination Procedures			
AP.4.7.1	The laboratory has established turn-around-times for the issuing of provisional or preliminary and final reports.	CAP[1] – ANP.33100, .33120 CAP[3] – 10:154	Does the laboratory have established turnaround times and thresholds based on established best practice and service needs? Does the laboratory monitor turnaround times for the issuing of: • provisional reports? AND • final autopsy reports? If cases exceed the established turnaround time, is there documentation of the reason for the delay? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.4.8 Autopsy Pathology - Safety			
AP.4.8.1 **SS**	Autopsy services are provided in a safe manner.	CAP[1] - ANP.24200, .33650, .34000, .34050, .34150, .32180 CLSI[9] - GP17-A3 – 9.2	Does the lab have appropriate safety policies, processes and procedures that include all of the following: • contaminated cases and/or specimens, hazardous chemicals, etc. are posted in the autopsy suite? • waste disposal? • disposition or cleaning of items for re-use upon completion of the autopsy? • cleaning after an autopsy, cleaning after possible contamination or cleaning at scheduled intervals? • proper handling of highly infectious cases, and disposal of tissues? • reduction or elimination of hazards, both chemical and infectious? • special handling of cases in which Transmissible Spongiform Encephalopathies (TSE) (e.g. Creutzfeldt-Jakob disease) is suspected? • minimization of aerosols when an electric or mechanical bone saw is used? Does the lab have the appropriate facilities, equipment and instruments that include all of the following: • appropriate signage at entrances to the autopsy laboratory warning of potential hazards and the need for appropriate protective measures? • limited and controlled access to the morgue or body receiving and handling areas and autopsy suite? • containers for contaminated waste and hazardous chemicals? • equipment and apparel to provide protection to eyes, hands, and skin surfaces from direct and aerosolized exposures during autopsy performance? • appropriate ventilation? • ergonomic systems for lifting bodies?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.5.0 ELECTRON MICROSCOPY			
AP.5.2 Electron Microscopy - Equipment, Reagent and Supplies			
AP.5.2.1	The laboratory appropriately maintains equipment for electron microscopy services.	CAP[1] – ANP.23400, .53000, .53100, .53150 CLSI[9] - GP17-A3 – 9.1 CSMLS[1] – 16.8	Do ultramicrotomes meet all of the following criteria: • clean? • well-maintained? • properly lubricated? • without excessive play in the advance mechanism? Are ultramicrotome knives sharp and free of nicks? Does the electron microscope meet the following criteria: • maintained and repaired at regular intervals? • calibrated after major maintenance? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.5.3 Electron Microscopy - Pre-examination Policies, Processes and Procedures			
AP.5.3.1	Examination request forms include appropriate and pertinent information.	CAP[3] – 3:12 CAP[4] – GEN.40750	Does the examination request form include: • sources of tissue? AND • appropriate clinical data? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.5.3 Electron Microscopy - Pre-examination Policies, Processes and Procedures continued			
AP.5.3.2	There is a system to record the date and time of delivery of electron microscopy slides to the pathologist.	ADASP[1]	Is there evidence that the laboratory documents the date and time of delivery of electron microscopy slides to the pathologist? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.5.4 Electron Microscopy - Examination Policies, Processes and Procedures			
AP.5.4.1 **PS**	Specimen and image identity is maintained at all times during the processing and examination steps.	CAP[3] – 3:13 CAP[5] – COM.06100, .06200	Is the identity of every specimen and image, including blocks, slides and electron micrographs, maintained through each step in processing? Are blocks identified adequately? Are slides of face sections (semi-thin) and one-micron sections labelled with all of the following: • case or accession number? patient name? • block designator? • slide designator? Are electron micrographs identified with all of the following: • case or accession number? • patient name? • block designator? • original magnification? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.5.5 Electron Microscopy - Quality Assurance of Examination Procedures			
AP.5.5.1	A pathologist reviews appropriate sections of embedded tissue to ensure that appropriate areas are selected for electron microscopic examination.	AHS[1] CAP[1] – ANP.52100, .52150	Are the following sections reviewed by the pathologist: • sections of embedded tissue? AND • where appropriate, one-micron sections prepared after trimming or ultra-thin sectioning?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.5.5.2	Several slides and electron photomicrographs are examined to ensure sufficient quality for proper interpretation of ultrastructural changes.	AHS[1] CAP[1] – ANP.52300	Are several slides and electron photomicrographs examined to ensure sufficient quality for proper interpretation of ultrastructural changes?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.5.6 Electron Microscopy - Post-examination Policies, Processes and Procedures			
AP.5.6.1	Reports include, where appropriate, correlation of electron microscopy findings with routine light microscope and other ancillary studies.	CAP[1] - ANP.54000 CAP[3] – 3:14	Does the report include correlation of electron microscopy findings with routine light microscope and other ancillary studies?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.5.6 Electron Microscopy - Post-examination Policies, Processes and Procedures continued			
AP.5.6.2	The laboratory ensures the appropriate retention of electron microscopy records and materials.	CAP[1] – ANP .55100 CAP[3] – 3:16,17 Guidance: EM Materials and Records include: • accession log records • wet tissue • resin blocks and grids pictures and reports	Is there a policy for protecting and preserving the integrity and retrieval of electron microscopy materials and records? Are the retention periods: • based on established and/or recognized best practice guidelines? AND • appropriate to provide documentation for adequate quality control and medical care? Is there evidence that materials and records are retained in accordance with the established retention policy? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.5.7 Electron Microscopy - Safety			
AP.5.7.1 **SS**	Electron microscopy services adhere to appropriate safety policies, processes, and procedures.	CAP[1] – ANP.57000, .57070, .57100 GOA[1] – part 4 ISO[2] 15190-20 – 13.6	Are there procedures for the safe handling and disposal of osmium tetroxide, epoxy resins and other hazardous chemicals? Is there evidence of personnel training in the handling of these materials? Does the laboratory adhere to established permissible limits of osmium tetroxide exposure? Is a spill kit available for osmium tetroxide? Are there measures to avoid direct contact with epoxy resins? Is the electron microscope checked for radiation leakage at the time of installation and after major repair? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.0 CYTOPATHOLOGY			
AP.6.1 Cytopathology - Personnel			
AP.6.1.1	All cytopathology screening is performed by appropriately qualified and trained personnel or automated screening technology.	CAP[2] - CYP.07900 CAP[3] – 9:116,128	Is all cytopathology screening performed by: • pathologists with appropriate qualifications and/or experience in cytology OR • technologists with appropriate qualifications OR • automated screening technology? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.1.2	The laboratory ensures appropriate technical and interpretive training for automated instrument procedures.	CAP[4] – GEN.55450 CAP[3] – 9:128	Is there evidence of staff training before the implementation of any automated instrument procedure including liquid-based preparation techniques and high-resolution image analysis techniques? Does the training program include both technical and interpretive training by formal external training programs or internal laboratory programs provided by personnel with documented competence? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.1 Cytopathology - Personnel continued			
AP.6.1.3	The laboratory has established workload limits for gynecologic cytology screening.	CAP[2] – CYP.08450, .08550, .08575 CAP[3]- 9:115-116 CSC[1] – 8.0	Does the laboratory have established workload limits for gynecologic cytology screening based on established and/or recognized best practice guidelines? Are additional responsibilities considered when evaluating workload? Is there a separate documented workload policy for the automated screening of cytology slides, if applicable? Is there evidence of the monitoring of the workload of individual cytotechnologists? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.2 Cytopathology - Quality Management System			
AP.6.2.1	The laboratory has a defined and documented quality management system for cytopathology.	CAP[3]- 9 CAP[5] – COM.04000 ISO[1] – 5.4.2, 8.9	Is there evidence of a defined and documented quality management system for cytopathology? Does AP laboratory management have the responsibility for the design, implementation, maintenance and improvement of the QMS? Does the cytopathology QMS meet the needs of patients and all personnel responsible for patient care? Does the cytopathology QMS clearly define the responsibilities, authority and interrelationships of all personnel? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.4 Cytopathology - Equipment, Reagents & Supplies			
AP.6.4.1	The laboratory ensures that all cytologic stains and working solutions are appropriately labelled and maintained.	CAP[2] – CYP.04100 CAP[5] – COM.30300, .30400	Are all cytologic working solutions and stains properly labelled with the contents, and, if applicable, expiration date and/or date prepared, changed and/or filtered, storage requirements? Are stains assessed at defined intervals by technical assessment on actual case material, and as part of the evaluation of cytopathology cases to ensure their proper storage and acceptable quality? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.5 Cytopathology - Pre-examination Policies, Processes and Procedures			
AP.6.5.1	For gynecologic and non-gynecologic cytopathology specimens, the examination request form includes appropriate specific clinical information.	AHS[1] CAP[4] – GEN.40750 CLSI[1] – GP15-A3 – 6.2	Does the examination request form for gynecologic and non-gynecologic cytopathology specimens include appropriate specific clinical information where applicable? Does the examination request form for gynecologic specimens also include all of the following clinical information where appropriate: • date of last menstrual period? • hormone and other therapies? • previous Pap test and biopsy results? • HPV testing results and vaccine status? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.5 Cytopathology - Pre-examination Policies, Processes and Procedures continued			
AP.6.5.2	The laboratory has policies and processes for the appropriate collection, receipt, and processing of gynecologic specimens to ensure specimens are acceptable for examination and viability is maintained.	CAP[2] – CYP.07452 CAP[3]- 9:117-118 CLSI[8] MM13-A – 3.4.5, 4.2.6, 5.4.1.7	Does the laboratory have defined criteria for the adequacy of gynecologic specimens that categorizes specimens as either satisfactory or unsatisfactory for interpretation? Do the criteria specify that any specimens with atypical cells are always categorized as "satisfactory", although the report may include comments on the quality of the preparation? Do laboratory reports clearly distinguish specimens that are unsatisfactory for diagnostic interpretation? For specimens that are satisfactory for evaluation, does the laboratory describe the presence or absence of endocervical and/or transformation zone components and any other quality indicators? For specimens that are unsatisfactory for evaluation, do reports indicate reason and whether the specimen was rejected or fully evaluated? For amplified molecular examinations using liquid-based cervical cytology (LBC) specimens, is there a procedure in place to ensure absence of cross contamination of specimens during the LBC processing steps? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.5 Cytopathology - Pre-examination Policies, Processes and Procedures continued			
AP.6.5.3	The laboratory has policies and processes for the appropriate collection, receipt, and processing of non-gynecologic specimens to ensure specimen s are acceptable for examination and viability is maintained.	CAP[2] – CYP.07666 CAP[3]- 9:113 CLSI[3]- GP23-A2	Does the laboratory have defined criteria for the adequacy of non-gynecologic specimens that categorizes specimens as either satisfactory or unsatisfactory for interpretation? For specimens that are unsatisfactory for evaluation, do reports indicate reason? Is heparin used when required (e.g., body cavity fluids)? Are urine and CSF specimens refrigerated if processing cannot be performed within one hour? Are other cytology specimens refrigerated if processing cannot be performed within four hours? Are there procedures to handle cytology specimens in off-hours? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.5 Cytopathology - Pre-examination Policies, Processes and Procedures continued			
AP.6.5.4	The laboratory provides instructions for the appropriate collection of fine needle aspirate specimens for cytologic examination.	CAP[1] – ANP.12094 CAP[2] – CYP.03366 CAP[3]- 9:132 CAP[4] – GEN.40100, .40115, .40491 CAP[5]- COM.06100, .06200 NCCLS[2] – GP20-A2 - 4,5	Do collection instructions and/or procedures describe all of the following where applicable: • verification of patient identification using two patient identifiers? • the preferred method for preparation of slides (proper fixation of slides and labelling of slides)? • the proper labelling and identification of all slides and containers of fluid with two patient identifiers? • amount of specimen? • fixatives, or special media? • special handling or transport? • patient preparation? • patient consent? • positioning the patient and palpating the lesion and/or mass? • site specific considerations? • antiseptic preparation? • anaesthesia? • equipment? • non-aspiration technique? • aspiration technique? • post-aspiration patient care? • complications? • progress and/or procedure notes?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.5 Cytopathology - Pre-examination Policies, Processes and Procedures continued			
AP.6.5.5	FNA slides are of sufficient quality for diagnosis.	AHS[1] CAP[1] - ANP.11734, .12096 CAP[3]- 9:114	Is there a process to ensure that FNA slides are of sufficient quality for diagnosis? Does the procedure for staining FNA specimens include measures to prevent cross contamination? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.5.7	The preparation of all cytology specimens for microscopic analysis facilitates the maintenance of a high level of technical competence and quality.	AHS[1] CAP[3]- 9:114 CSC[1] – 5.0	Are cytology specimens prepared for microscopic analysis using accepted preparation techniques? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.5 Cytopathology - Pre-examination Policies, Processes and Procedures continued			
AP.6.5.9	The laboratory monitors defined cytopathology pre-examination quality indicators and adherence to established targets.	AHS[1] CAP[2] – CYP.03800 CAP[3] – 9:113	Are all of the following cytopathology pre-examination quality indicators monitored: • specimen acceptance and adequacy? • percentage of specimen identification errors? • percentage of specimens with inadequate history? Has the laboratory established additional pre-examination quality indicators relevant to the outcome of patient care and scope of laboratory services? Is there evidence that quality indicator benchmarks are being achieved? Where quality indicator targets are not achieved, is there evidence of investigation and corrective action? Does the laboratory provide regular feedback to submitting physicians on inadequate pre-examination elements? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.6 Cytopathology - Examination Policies, Processes and Procedures			
AP.6.6.1	The laboratory has procedures to prevent cross-contamination between gynecologic and non-gynecologic specimens.	AHS[1] CAP[2] – CYP.04150 CAP[3]- 9:114 CSC[1] – 5.5	Does the laboratory have procedures to prevent the following: • cross-contamination of gynecologic and non-gynecologic specimens during processing and staining? AND • non-gynecologic specimens that have high potential for cross-contamination from other non-gynecologic specimens? For highly cellular cases: • are direct smears prepared after the other cases? AND • are the staining fluids changed or filtered between each of the highly cellular cases? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.6.2	The Papanicolaou Stain (or modified stain) or other appropriate permanent nuclear stain is used for gynecologic or non-gynecologic specimens.	CAP[2] – CYP.07439, .07685 CAP[3]- 9:114 CLSI[1] – GP15-A3 - 11.1.3 CSC[1] – 5.3	Are gynecologic or non-gynecologic specimens stained using the Papanicolaou Stain (or modified stain) or other appropriate permanent nuclear stain? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.6 Cytopathology - Examination Policies, Processes and Procedures continued			
AP.6.6.3	There are defined criteria specifying findings in gynecologic slides that must be referred for review and/or interpretation by a pathologist.	AHS[1] CAP[2] – CYP.07465 CAP[3]- 9:119 CSC[1] -8.11.1	Does the laboratory have defined criteria specifying findings in gynecologic slides that must be referred for interpretation by a pathologist including slides in all of the following categories: • malignant or suspicious for malignancy? • low and high grade squamous intraepithelial lesions? • atypical squamous cells? • atypical glandular cells? • reactive or repair? Where significant discrepancies in interpretation exist between the cytotechnologist and pathologist, are case reviews with a colleague performed prior to reporting? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.6.4	The laboratory has defined processes for the correlation of gynecologic cytopathology findings with available clinical information.	AHS[1] CAP[2] – CYP.07569 CAP[3]- 9:120 CSC[1] – 13.2.1.1.1	Is there evidence of correlation of gynecologic cytopathology findings with available clinical information including targeted rescreening of high-risk cases such as: • recent history of vaginal bleeding? • history of cervical and/or vaginal and/or vulvar carcinoma? • previous abnormality? • abnormal cervix upon speculum examination? • DES exposure? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.6 Cytopathology - Examination Policies, Processes and Procedures continued			
AP.6.6.5	The laboratory has a process to identify and rescreen slides not successfully processed by automated screening methods.	CAP[2] – CYP.05292 CAP[3]- 9:128	Is there evidence that slides that fail screening by an automated instrument meet the following criteria: • clearly identified? • completely rescreened by another method? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.6.6 **PS**	The laboratory has a defined process for the resolution of disparities between histological and cytological findings.	AHS[1] CAP[2] – CYP.01900 CAP[3]- 9:120-121	Is there evidence of the resolution of disparities between histological and cytological findings? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.6.7	For non-gynecologic cases, the laboratory correlates the cytologic results with the clinical information, histological findings and ancillary studies.	AHS[1] CAP[2] – CYP.07675, .06850 CAP[3]- 9:131 CSC[1] – 14.3.4	Is there evidence of correlation of all, or a subset of, non-gynecologic cytology specimens with all of the following: • histological findings? • clinical information? • ancillary studies (e.g., molecular studies, immunocytochemistry)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.7 Cytopathology - Quality Assurance of Examination Procedures			
AP.6.7.1	The technical quality of cytologic preparations is reviewed on each day of use and with change of stains.	AHS[1] CAP[2] – CYP.04300. 04900 CAP[3]- 9:114	Is the technical quality of preparations (cytospins, cell blocks, and liquid based automated preparations) checked on each day of use and with change of stains? Is there evidence that cellular and nuclear detail is sufficient for proper interpretation? If preparation and staining is performed by a different laboratory: • is there evidence available to the laboratory performing the interpretations that the acceptability of the staining and controls has been verified? • is there a mechanism for the interpreting laboratory to provide feedback to the laboratory that prepared the slides?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.7 Cytopathology - Quality Assurance of Examination Procedures continued			
AP.6.7.2	The laboratory has a comprehensive protocol for the prospective rescreening of gynecologic slides.	AHS[1] CAP[2] – CYP.07478, .07480, .07491, .07504, .07655, .07660 CAP[3]- 9:120	Does the laboratory have rescreening criteria defining the percentage and case selection based on relevant patient population and practice environment? Do rescreening activities include the following prospective reviews, such as: • targeted? • random? • rapid? Is there evidence of comparison of rescreening results with original screening results? Are the results of gynecologic cases selected for rescreening not reported until the rescreen is complete? Does the laboratory have a system to evaluate and document the ongoing performance of individuals performing cervicovaginal cytology screening against the overall statistics for the laboratory as a whole? Is there evidence of each individual's diagnostic discrepancies, and corrective action taken? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.7 Cytopathology - Quality Assurance of Examination Procedures continued			
AP.6.7.3	The laboratory maintains statistical data on the number of cases of sentinel pathology results and/or diagnostic categories and evaluates data against established benchmarks.	CAP[2] – CYP.04520, 07600, .07650, .07692 CAP[3]- 9:130 CSC[1]	Does the laboratory maintain statistical data on all of the following: • total number of cases examined? • number of cases reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)? • number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison? • number of cases where cytology and histology are discrepant? • number of cases where any rescreen of a normal or negative specimen result in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms? • number of negative cases rescreened before sign-out? In evaluating its statistics, is the patient population considered? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.7 Cytopathology - Quality Assurance of Examination Procedures continued			
AP.6.7.4	The laboratory monitors defined cytopathology examination quality indicators and adherence to established targets.	AHS[1] CAP[2] – CYP.01900, .07600 CAP[3] – 9:117-134	Are the following cytopathology examination quality indicators monitored where applicable: • percentage of identification and integrity errors during the production of cytopathology slides and/or specimens? • percentage of specimens with adequate technical quality? • percentage of documented diagnostic ancillary test results? • percentage of gynecological cytopathology specimens with review and/or consultation? • percentage of non-gynecological cytopathology specimen s with review and/or consultation? • percentage of specimen s in each category following retrospective review? • percentage of specimen s in each clinical impact category following clinical impact assessment? • percentage of patient cases with slide review, specimen s in each concordance category and clinical impact category? • degree of gynecological and/or histological correlation? • degree of non-gynecological and/or histological correlation? Is there evidence that quality indicator benchmarks are being achieved? Where quality indicator targets are not achieved, is there evidence of investigation and corrective action?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.8 Cytopathology - Post-examination Policies, Processes and Procedures			
AP.6.8.1	There is a comprehensive cytopathology report that includes all relevant patient and laboratory data.	AHS[1] CAP[2] – CYP.05300, .05316, .05350, .06475 CAP[3]- 9:116 CSC[1] – 10.0	Do cytopathology reports include all of the following, where applicable: • patient's first and last name? • a second patient identifier (e.g., personal health number)? • date of birth? • gender? • requesting physician? • accession number? • examination performed? • the identification of testing laboratory and referral labs? • name of the responsible reviewing pathologist? • identifier of the screening cytotechnologist for reports on negative gynecologic cytology (not including repair)? • unique identifier of the requester and the requester's location? • specimen collection date and time? • indication if the quality of the primary specimen received was unsuitable for examination or could have compromised the result? • date and time of receipt by the laboratory? • anatomic source and/or type of specimen? • description of fixative and pre-analytic variables that may affect ancillary testing (e.g., type of fixative, time in fixative)? • interpretation of results and/or diagnosis? • indication and/or flagging of abnormal results? • other comments on factors which may have affected the examination results? • reference to consultations obtained? • indication of amended results? • date and time of release of report? • designation of automated screening device?

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			Do reports clearly state the interpretation representing the highest degree of abnormality present? When a pathologist has performed a diagnostic review of the slides, does the report indicate his and/or her name, initials or signature (in written or electronic form)? Is the reviewing pathologist's name distinct from any other pathologist names (e.g., the laboratory director) on the report? Are electronic signatures authorized for each case by the pathologist who performed the review? If a report contains the signature and/or initials of a pathologist or cytotechnologist attesting to an activity other than review of the slides (e.g., verification of results of automated screening instruments), does the report clearly indicate that the signature and/or initials attest to the other activity, not review of the slides? For FNA procedures where a preliminary, intra-operative assessment of adequacy is made, is the assessment documented in the cytopathology report? Are amendments to reports that would affect current patient care reported promptly to the responsible physician?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.8 Cytopathology - Post-examination Policies, Processes and Procedures continued			
AP.6.8.2	The laboratory has defined criteria for the reporting of cytopathology findings.	AHS[1] CAP[2] – CYP.06100 CSC[1] – 10.5.1, 10.6	Do cytopathology reports clearly state whether disease is present, absent, or uncertain? When a definite diagnosis cannot be rendered (i.e., terms such as "inconclusive," "indeterminate" or "non-diagnostic" are used), do reports specify the reason? Is the most current version of the Bethesda System or other standard descriptive terminology that includes a general categorization and descriptive diagnosis used for reporting gynecologic cytopathology reports? Are interpretive terminologies and published classification systems used for the reporting of non-gynecologic cytopathology report? When appropriate (e.g., fine needle aspiration specimens of mass lesions), is a statement regarding the adequacy of the specimen included, with a description of the limitations of the specimen when a specific diagnosis cannot be made?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.6.8.3	Laboratory records identify the cytotechnologists who have reviewed the cytology slides.	CAP[2] – CYP.05316 CSC[1] – 10.2, 10.3	Do laboratory records identify the cytotechnologist reviewing the cytology slides by name, initials, or other identifier in laboratory records?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.8 Cytopathology - Post-examination Policies, Processes and Procedures continued			
AP.6.8.4	For gynecologic cases reviewed by a pathologist, and for all non-gynecologic cases, the laboratory ensures and documents that the reviewing pathologist has reviewed and approved the completed report before release.	AHS[1] CAP[2] – CYP.05332, .07670 CSC[1] – 10.2, 10.3	For gynecologic cases reviewed by a pathologist, and for all non-gynecologic cases, is there evidence that the reviewing pathologist has reviewed and approved the completed report before release? If the diagnosing pathologist is not available for timely review and approval of the completed report, does the laboratory have a policy and procedure for review and approval of that report by another pathologist? In that circumstance, do the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification appear on the report? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.8 Cytopathology - Post-examination Policies, Processes and Procedures continued			
AP.6.8.5	The laboratory has a policy and processes for the communication and documentation of significant and unexpected cytopathology findings.	CAP[2] – CYP.06450 CLSI[4]– QMS01 – 4.2.4, 4.3.1, 4.3.2 ISO[1] - 7.4.1.3, 7.4.1.4	Does the laboratory have a policy for the communication and documentation of significant and unexpected cytopathology findings? Is there evidence that the laboratory has consulted clinical medical staff to define diagnoses classified as "significant and unexpected"? Is there a list of significant and/or unexpected cytopathology findings that must be reported as soon as possible? Does the process ensure that such diagnoses are received by the clinician? Is there documentation of notification including all of the following: • date and time? • responsible individual communicating the result? • person notified using identifiers traceable to that person? • examination results? • any difficulty encountered in meeting this requirement? Does the procedure include results received on specimens sent to referral laboratories for examination? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.8 Cytopathology - Post-examination Policies, Processes and Procedures continued			
AP.6.8.6	The laboratory maintains a cross-reference of cytological and histological material.	CAP[3]- 9:120,131,134	Is there evidence of a cross-reference of cytological and histological material? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.8.7	The laboratory maintains records of intra- and extra-departmental consultations.	CAP[2] – CYP.02100 CAP[3]- 9:119,124,130,133	Is there evidence of documentation of intra- and extra-departmental consultations? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.8.8 **PS**	The laboratory performs a comprehensive retrospective review and result correlation where appropriate whenever a new high grade squamous intraepithelial lesion (HSIL) - moderate or severe dysplasia, carcinoma in situ, CIN II or III or malignant cervical and/or vaginal cytology is reported.	AHS[1] CAP[2] – CYP.07517, .07530, .07543, .07556 CAP[3] - 9:119,120,121,130, 131,134	For new diagnoses of HSIL or malignant cervical and/or vaginal cytology, does the laboratory meet all of the following criteria: • rescreen all available previously negative slides from the patient? • issue a corrected report if a significant discrepancy is found which would affect current patient care? • obtain and review follow-up histological reports or material if available within the laboratory? • correlate the histologic diagnosis to the cytologic findings when the histologic diagnosis is available? • document the number of cases that have histologic correlation? • document attempts to obtain follow-up histological information for correlative review when a follow-up histological report or material is not available within the laboratory? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.8 Cytopathology - Post-examination Policies, Processes and Procedures continued			
AP.6.8.9	Cytopathology slides are stored in an appropriate manner.	CAP[2] – CYP.07100 CAP[3] – 3:16,9:129	Are cytopathology slides stored: • in a manner to permit timely retrieval? • in an organized manner? • accessible for retrieval? • in a pest free area? • in a manner to prevent contamination from blood or other fluids or tissues? AND • at room temperature for optimal preservation of their integrity?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
AP.6.8.10	The laboratory ensures availability of cytopathology materials.	CAP[2] – CYP.07200, .07300 CAP[3] – 3:16	Is there evidence of a tracking mechanism that monitors the use, circulation, referral, transfer and receipt of original slides and/or blocks sent for consultation and legal proceedings? Is there a record of return of slides and/or blocks? Is there evidence of follow-up for slides and/or blocks that have not been returned?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.9 Cytopathology - Quality Assurance of Post-examination Procedures			
AP.6.9.1	The laboratory monitors defined cytopathology post-examination quality indicators and adherence to established targets.	AHS[1] CAP[2] – CYP.07480 CAP[3]- 9:117-134 CSC[1] – 13.0	Are the following cytopathology post-examination quality indicators monitored: • percentage of revised cytopathology reports (addendum, amended and corrected)? • clinical satisfaction rate in various areas of cytopathology services? • total activity volumes for cytopathology? • total non-conforming events identified by all cytopathology metrics whining each phase of the path of workflow? Has the laboratory established additional quality indicators relevant to the outcome of patient care and scope of laboratory services? Is there evidence that quality indicator benchmarks are being achieved? Where quality indicator targets are not achieved, is there evidence of investigation and corrective action? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.6.9 Cytopathology - Quality Assurance of Post-examination Procedures continued			
AP.6.9.2	The laboratory establishes turnaround time for cytopathology reports in consultation with the users of laboratory services.	AHS[1] CAP[3] - 9:125, 129, 132 CAP[4] – GEN.41345 CSC[1] – 14.2.7, 14.3.6	Are turnaround times identified and/or monitored for the following: • for the majority of routine specimens? • from the time of receipt of the specimen in the laboratory to the time of issue of the report? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.6.9.3	Where appropriate, the laboratory maintains statistical data on high-risk human papillomavirus (HR-HPV) tests performed on ASC-US cases.	CAP[2] – CYP.07653 CAP[3] - 9:127,128	Are records maintained for high-risk human papillomavirus (HR-HPV) tests performed on ASC-US including the following: • total number of HR-HPV tests performed on ASC-US cases? • total number of positive HR-HPV ASC-US cases? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY			
For the purposes of this standard, telepathology applies to the practice of pathology, in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record and includes the following modes: ■ Static telepathology – interpretation based on pre-selected still image(s) ■ Dynamic telepathology - viewing real-time images ■ Virtual slides and/or whole slide imaging			ATA[1] CAP[4]
AP.7.0.2	There are established programs for the initial and on-going training and competency assessment for telepathology users.	ATA[1] Canadian Association of Pathologists[3] CAP[4] – GEN.51728, .52900	Does the laboratory assess the training requirements for all users of the telepathology system as appropriate to their role? Are telepathology services supported by personnel who meet the following criteria: • has equipment specific training as provided by the manufacturers? • are responsible for the monitoring of quality and confidentiality of transmitted images? • are trained in maintaining a viable system? Is there evidence of all of the following: • initial training on each telepathology system (modality and application) prior to use? • training updates when software or hardware changes are implemented? • assessment of initial competency following training? • on-going competency assessment? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY CONTINUED			
AP.7.0.3	Materials and equipment used for telepathology meet established telepathology clinical, quality and interoperability requirements.	ATA[1] Canadian Association of Pathologists[3]	Does the laboratory have defined criteria for the clinical use and application of telepathology methods and systems? Does the laboratory adhere to specification and selection criteria for telepathology materials and equipment? Does telepathology software support and/or comply with the required patient identifiers? Are there established criteria ensuring that there is sufficient storage space for telepathology software and patient data? Does telepathology software meet all provincial and national privacy and encryption standards? Does the telepathology system meet minimum acceptable industry standards for telepathology images? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.7.0.4 **PS**	Identification of telepathology images meets the requirements for laboratory specimen identification.	ATA[1] Canadian Association of Pathologists[3] – 10 CAP[4] – GEN.50057	Are telepathology images uniquely identified and traceable to the source material and/or case? Is the identity of images maintained by the established unique identifiers at all times during processing (diagnostic interpretation, image capture, reporting, storage and retrieval)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY CONTINUED			
AP.7.0.5	Relevant clinical information is available to the individual reviewing the case at the time of slide and/or image(s) review.	ATA[1] Canadian Association of Pathologists[3] – 10,13 CAP[4] – GEN.50614	Is relevant clinical information available to the individual reviewing cases at the time of slide and/or image(s) review, including at a minimum, the information on the surgical pathology requisition form? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.7.0.6	Telepathology and remote data assessment sites ensure the confidentiality, privacy and security of patient information and data is maintained in accordance with provincial and national regulations.	ATA[1] Canadian Association of Pathologists[3] – 15 CAP[4] – GEN.52842 ISO[1] – 4.2	Does the laboratory have policies to ensure the confidentiality of patient information is maintained in accordance with provincial and national regulations? Is telepathology and/or remote data assessment hardware and/or software compliant with established provincial and national guidelines and requirements for privacy and security as they relate to capture, storage, transmission, access to and disposal of patient data? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.7.0.7	There are established business and service continuity plans for each telepathology modality and application.	ATA[1]	Is there evidence of all of the following: • downtime procedures for network, interface and/or telepathology equipment failures? • disaster recovery plans for all applications, modalities and components within each system? • adequate back-up and archive mechanisms? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY CONTINUED			
AP.7.0.8	Telepathology hardware and software is installed, maintained and upgraded in accordance with vendors' specifications.	ATA[1] Canadian Association of Pathologists[3] – 12	Is there evidence of maintenance and service in accordance with vendor recommendations? Is there evidence of daily operation including all specialized settings used to obtain best image quality? Is a test environment maintained to ensure that all software upgrades, maintenance, and repairs made to the telepathology infrastructure do not interfere with the production module? Do user workstations conform to minimum requirements based on current industry standards and user application? Is there evidence of reporting and troubleshooting identifying variations in acceptable image quality as it relates to capture, transmission, storage and/or retrieval? Is there evidence of follow-up of image problems and/or variations? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.7.0.9	When significant disparity exists between telepathology interpretation and the microscopic glass slide, the laboratory reconciles and documents the disparities.	CAP[3] – 6	Does the laboratory follow established departmental processes for consultation discrepancies? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY CONTINUED			
AP.7.0.10	There is a comprehensive telepathology report that includes all relevant information essential to the diagnosis and patient care.	ATA[1] Canadian Association of Pathologists[3] – 15 CAP[4] – GEN.52850	Does the laboratory's LIS track telepathology consultations used for diagnostic purposes? Is the LIS considered the single source of truth for all telepathology reports and images? Is terminology used for telepathology reports compliant with recognized pathological entities and current best practices (e.g., SNOMED CT)? Is there a mechanism for documenting the intra-procedural results for real-time evaluations? Do telepathology records include diagnoses made and statements of adequacy assessment, preliminary diagnosis, or recommendations for additional studies provided at the time of evaluation? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY CONTINUED			
AP.7.0.12	Telepathology images used for diagnostic interpretation are readily accessible and retained in accordance with the facility retention requirements for glass slides.	ATA[1] Canadian Association of Pathologists[3] – 15	Are telepathology images: • readily accessible? AND • retained in accordance with facility retention requirements? Are all annotations associated with an image used for diagnostic interpretation maintained and retrievable with the original image? Is user access to stored digitized images and metadata monitored and documented for the designated life of the image? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.7.0 TELEPATHOLOGY CONTINUED			
AP.7.0.13	The laboratory monitors defined telepathology quality indicators and adherence to established targets.	ATA[1] Canadian Association of Pathologists[3] – 14 CAP[4] – GEN.52860	Is there evidence that the laboratory meets the following criteria: • has defined quality indicators for telepathology? • monitors adherence to the established targets? • investigates and initiates corrective action when targets are not achieved? Does the laboratory quality assurance program include the review of consultations and primary diagnoses performed via telepathology? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
AP.7.0.14	The laboratory has policies, processes and procedures for the validation and/or verification of whole slide imaging systems.	ATA[1] CAP[4] – GEN.52920 Canadian Association of Pathologists[3] – 12	Does the validation and/or verification process include: • close emulation of the real-world clinical environment? • specimen preparation types and clinical settings relevant to the intended use(s)? • performance by personnel adequately trained to use the system? • assessment of intraobserver concordance between digital and glass slides? • evaluation of the entire whole slide imaging system, with reevaluation if a significant change is made to a previously validated system? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
AP.8.0 MOLECULAR PATHOLOGY			
For Molecular Pathology standards – please refer to the Molecular Diagnostics & Genetics Standards document.			

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