

College of Physicians and Surgeons of Saskatchewan
Laboratory Quality Assurance Program

Policy Manual



2012 Edition

LABORATORY QUALITY ASSURANCE POLICY MANUAL

SUMMARY OF POLICY MANUAL CHANGES

The following policies have been revised, added, or deleted in this edition of the checklist.

REVISED:

Point-of-Care Testing Policy #2

ADDED:

Anatomic Pathology Policy #4

DELETED:

General Policy #1

LABORATORY QUALITY ASSURANCE POLICY MANUAL

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Section I:

PURPOSE

PURPOSE:

The College of Physicians & Surgeons of Saskatchewan administers the Laboratory Quality Assurance Program under the authority of the Medical Laboratory Licensing Act and Regulations of the Ministry of Health. This Program was created to ensure high-quality, effective laboratory services.

MANDATE

The Laboratory Quality Assurance Program shall develop diagnostic laboratory standards (*Policies*) for the Province of Saskatchewan, evaluate and ensure compliance with those standards and provide recommendations in matters related to laboratory practice.

The policies set out in this manual are requirements for laboratories in the Province of Saskatchewan; they have been designated as policies according to section 1. of the LQAP Terms of Reference:

The Laboratory Quality Assurance Program shall:

1. Set specific standards of practice for testing within each laboratory discipline by:
 - identifying tests under purview
 - identifying acceptable pre-analytic and post-analytic practices for each test
 - identifying the appropriate level of education necessary for the performance of each test, and
 - identifying special precautions, if necessary.

The Program Management Committee (PMC) is the oversight body for operations and decision-making for the Program. It is made up of the chairs of the discipline-specific committees, along with stakeholder representatives from the Saskatchewan Association of Combined Lab and X-Ray Technicians (SACLXT); Saskatchewan Medical Association (SMA); Saskatchewan Society of Medical Laboratory Technologists (SSMLT); and Laboratory Licensing of the Ministry of Health.

Discipline-specific Quality Assurance Committees for Anatomic Pathology, Chemistry, Hematology, Microbiology and Transfusion Medicine are comprised of medical and technical experts and other stakeholder groups, as required. Each Quality Assurance committee generally consists of 2-5 members.

Many of the policies and guidelines are developed based on information identified through established practice or accreditation review. This process is integral to the function of the Program and is reviewed by the discipline-specific committees and approved by PMC.

As the Program evolves, the advancements in standards-setting processes and sophistication in technology are matched to the needs of the laboratory environment.

Section II:

GENERAL

General Policy #2

ISSUE:

Competence of Laboratory Personnel

BACKGROUND:

Medical laboratory competence is described as the application of knowledge, skills and behaviours in performance of diagnostic testing. Categories of competence may include:

- Safe work practice
- Data collection and specimen procurement/receipt
- Analysis of specimens and validation of results
- Analytical techniques
- Interpretation and reporting of results
- Quality management

POLICY:

All medical laboratory personnel including, but not restricted to, Medical Laboratory Technologists (MLTs), Combined Laboratory and X-Ray Technicians (CLXTs), and Medical Laboratory Assistants (MLAs) shall work within the scope of their competence. Persons performing diagnostic testing shall have sufficient training, skills, experience to interpret results and demonstrate competencies following training and at least annually thereafter.

General Policy # 3

ISSUE:

Relevance of Degree

BACKGROUND:

Quality laboratory services can only result when appropriately trained, competent and motivated staff perform analysis/related tasks, evaluation and reporting of results. Medical laboratory personnel require a wide skill set and a broad knowledge base.

POLICY:

Persons performing tests in a medical laboratory shall possess the qualifications as defined in the Medical Laboratory Licensing Act/Regulations, Section 9.

Laboratories employing persons who possess a bachelor's, master's or doctoral degree in a relevant science, shall adhere to the following process in assessing relevance of a particular degree:

- a) Application to Laboratory Licensing which shall include a full job description, educational qualification achieved (including description of classes completed), as well as a description of related clinical experience. This application shall be submitted in sufficient time to permit assessment prior to the hiring of the individual.**
- b) Laboratory Licensing shall refer the application to the Laboratory Quality Assurance Program, seeking its opinion, whether the degree is relevant to the stated position.**
- c) The Laboratory Quality Assurance Program shall review all information and provide its written opinion to Laboratory Licensing. This opinion may include requirements for additional training or courses of study, as applicable.**
- d) Laboratory Licensing shall determine relevance and communicate such decision with both the laboratory and the Lab QA Program.**

General Policy #4

ISSUE:

CLXTs Performing Biochemistry Procedures

BACKGROUND:

The revised Combined Laboratory & X-ray Technician's curriculum in chemistry includes: Glucose, Sodium, Potassium, Chloride, Carbon Dioxide, Alkaline Phosphatase, Alanine Amino Transferase, Gamma Glutamyl Transferase, Creatine Kinase, CKMB/TNI, Aspartate Amino Transferase, Creatinine, Urea, Total Bilirubin, Direct and Indirect Bilirubin, Magnesium, Amylase, Albumin, Calcium and Phosphorus. The Biochemistry Quality Assurance Committee supports the principle that CLXTs perform testing within their scope of training; with the provision that CLXTs shall have taken the upgrading courses to be approved for performing the revised CLXT curriculum.

POLICY:

- a) **Graduates from the CLXT training program will be allowed to practice to the scope of training obtained.**
- b) **Graduates, prior to 2000-2001, who successfully complete the Chem 198 and 199 (or the equivalent previous courses: ANLT 180 and Chem 197) will be allowed to perform the expanded scope of testing.**
- c) **Graduates from 2010 forward are approved for blood gases. Previous graduates shall complete a certified blood gas course recognized by the Diagnostic QA Program.**
- d) **Laboratory Results Correlation (PATH 181) and Quality Management (QC 194) are also recommended for equivalent educational standing.**
- e) **For sites that employ a combination of CLXTs and MLTS, only CLXTs who have completed the Chem 198 and Chem 199 courses (enhanced curriculum) will be approved to run the lipid profile, under the direct on-site supervision of the MLT.**
- f) **The CLXT that is trained and certified for a specific level of testing, as provided in the CLXT curriculum may be approved to perform testing that falls beyond their scope of training, only in situations where the CLXT is under the direct on-site supervision of an MLT or qualified professional who can verify acceptable performance and good laboratory practice.**
- g) **All training provided to the CLXT shall be documented.**

General Policy #5

ISSUE:

Duties of Medical Laboratory Assistant (MLA) or Lab Assistant (LA)

BACKGROUND:

The Medical Laboratory Assistant is an integral member of the health care team. The MLA is responsible and accountable for his/her professional actions and practices according to established standards of practice.

The defined activities of a laboratory assistant are the ultimate responsibility of the Laboratory Director or designated qualified professional, but follow the curriculum of a recognized MLA training course.

POLICY:

A medical laboratory assistant may, under the qualified laboratory professional, perform a list of tasks that are considered pre-analytic and post-analytic, and do not require interpretation or assessment. Specific work assignments should only be undertaken subsequent to thorough, documented training and instruction by qualified supervisory personnel. *Notwithstanding the defined tasks below, Transfusion Medicine testing is restricted to persons trained in Transfusion Medicine.*

Examples of tasks may include: (for a complete list, refer to the MLA Curriculum)

- **blood sample procurement**
Procurement may include, but is not restricted to patient identification; collection and labelling; accessioning/handling; specimen rejection; specimen referral.
- **sample preparation for analysis, to include centrifugation, separation, numbering, aliquoting**
- **reagent preparation/preparation of kits**
- **media preparation**
- **smear preparation, e.g. blood films**
- **staining of smears/slides for hematology, etc.**
- **coverslipping of slide preparations**
- **concentration of stool samples for parasitology examinations**
- **planting and streaking of microbiology specimens and controls**
- **set up of anaerobic and CO₂ jars**
- **titrations using a pH meter**
- **urinalysis (excluding microscopic) including pregnancy test**
- **loading of primary tube to automated instruments**
- **set up of erythrocyte sedimentation rates**
- **temperature monitoring of thermally controlled equipment**
- **filing of records and retrieval of files**
- **wash-up and glassware**

General Issue #6

ISSUE:

Supervision of Grandfathered Staff

BACKGROUND:

Supervision, as defined in the Medical Laboratory Licensing Regulations 1994, is the responsibility of the qualified professional. A further clarification of supervision is provided.

POLICY:

- 1) **The supervisor must be accessible to provide on-site supervision to grandfathered staff who perform tests for which they are grandfathered. Work may be performed in the absence of on-site supervision provided that the work performed during those times is checked within 72 hours. In cases of unscheduled leave, a contingency plan must be in place or lab work must be referred.**
- 2) **The supervisor is responsible for evaluating the competence of all grandfathered personnel and assuring that the staff maintain their competence to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of competence of the staff must include:**
 - a) **direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;**
 - b) **monitoring the recording and reporting of test results;**
 - c) **review of test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records;**
 - d) **direct observation of performance of instrument maintenance and function checks;**
 - e) **assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples;**
 - f) **adherence to appropriate safety standards;**
 - g) **assessment of problem solving skills;**
 - h) **maintenance of records that pertain to competence of individuals.**

Section III:

POINT-OF-CARE TESTING

Point-of-Care Testing Policy #1

ISSUE:

Point-of-Care Testing (POCT)

BACKGROUND:

Point-of-care testing refers to the analytical patient testing activities performed outside the physical facilities of a clinical laboratory and is often referred to as near-patient testing or bedside testing. POCT utilizes a wide variety of test kits and medical devices ranging from dipstick urinalysis and occult blood screening through robust hand-held kits to bench-mounted analyzers. Regardless of the complexity of the tools, a common feature of POCT is that operators are usually not laboratory-trained personnel. Operators without laboratory background may lack the knowledge and understanding of the principles of laboratory testing and good laboratory practices to ensure the reliability of the test results.

The purpose of this policy is to minimize the risk of unreliable test results. Benefit to the patient is based on the assumption that the accuracy and reproducibility of the POCT result is comparable to that of a licensed laboratory.

POLICY:

All POCT shall be held to the same standard as clinical laboratory testing with the aim that all testing must be safe, evidence-based, patient-centered, timely, efficient and equitable. To ensure quality management principles for the use of the diagnostic off-site/POCT, the following aspects shall be met:

- a. Training and certification of all personnel that perform POCT. There shall be centralized coordination of the POCT training program by designated, qualified personnel that also assess ongoing competence.**
- b. Evaluation and selection of instrumentation and procedures.**
- c. Establishment of quality control protocols shall include external proficiency testing participation, internal QC practices, and documentation as required by regulation. This includes two consecutive successful PT challenges/events prior to commencing testing using POCT.**
- d. Protocols for test requisitioning and result reporting, and active review of results by POCT director or designee. The report must be identified as a POCT result.**
- e. Clear, comprehensive record keeping and documentation for training, evaluation, quality assurance/control and health and safety.**

Laboratory testing performed in non-licensed settings is not approved and may be in contravention of the Medical Laboratory Licensing Act.

Point-of-Care Testing Policy #2

ISSUE:

HIV Point-of-Care Testing

BACKGROUND:

Point-of-care testing (POCT) refers to analytical patient testing activity performed outside the physical facilities of a clinical laboratory and is often referred to as near-patient testing or bedside testing. The INSTI HIV-1 Rapid Antibody test is the HIV POCT currently implemented in Saskatchewan and approved by Health Canada.

Sites performing HIV POCT must also follow the policies as identified in the Point-of-Care Testing Policy #1. [NOTE: This includes enrolling in an external proficiency testing program recognized by the Laboratory Quality Assurance Program.]

POLICY:

- (a) HIV POCT is not designed for screening the general population; it is to be used to screen patients at high risk for HIV. The site requires a license from the Laboratory Licensing Unit of the Ministry of Health and shall adhere to the same standards as the laboratory setting including quality control and external proficiency testing.**
- (b) Sites performing HIV POCT must send reactive, indeterminate and invalid specimens to the Saskatchewan Disease Control Laboratory (SDCL) for confirmation.**
- (c) Any site may send non-reactive HIV POCT specimens to the SDCL at the discretion of the qualified personnel performing the test.**
- (d) Pre- and post-test counselling as addressed in Public Health Agency of Canada is part of the HIV POCT process. This includes the risk of criminal charges arising from failure to disclose HIV-positivity and/or exposing another individual to HIV, even in cases where actual transmission does not occur.**

Reference:

PHAC Guidelines
www.phac-aspc.gc.ca

Section IV

ANATOMIC PATHOLOGY

Anatomic Pathology Policy # 1

ISSUE:

Competence of Personnel in Anatomic Pathology

BACKGROUND:

Specific skills and knowledge are required for performance of Anatomic Pathology departments.

POLICY:

All personnel working in Anatomic Pathology shall work to their scope of competence.

It is the responsibility of the laboratory director to ensure that the number and type of cytology slides to be screened does not, through fatigue (or other factors), adversely affect the cytotechnologist's ability to find, recognize and interpret abnormal cells that may be representative of a disease process. A maximum of 90 slides in one 24-hour period per technologist is recommended.

Pathology technicians/assistants shall work under the direct supervision of a qualified pathologist.

Anatomic Pathology Policy #2

ISSUE:

Specimen Acceptance/Rejection

BACKGROUND:

Procedures related to specimen procurement, transport and accessioning require:

- two client identifiers for proper patient identification. These are the patient's first and last name and a unique identifying number. The unique identifying number may include the Health Services Number (HSN), Medical Record Number (MRN) or Date of Birth.
- completed requisition including relevant history and body site
- appropriate fixative/handling of specimen
- prompt delivery to laboratory

POLICY:

Criteria for pathology/cytology specimen acceptance or rejection shall be developed, adopted and documented as policy. The nature of surgical pathology specimens is unique and cannot always be recollected.

Records of rejected specimens should be reviewed, at least annually, to ensure corrective action plans for the identification, labelling and accessioning of specimens.

Anatomic Pathology Policy # 3

ISSUE:

Standards for Providing Gynecological Cytology Services

- a) Staffing
- b) Volumes

BACKGROUND:

Gynecological cytology testing in Saskatchewan is performed, in two locations.

POLICY:

Cytology laboratories shall process a sufficient volume (25,000 cases or more) annually to maintain minimum staffing of qualified cytotechnologists, support staff and a supervising cytopathologist.

Anatomic Pathology Policy #4

ISSUE:

Anatomic Pathology Quality Assurance

BACKGROUND:

Quality assurance plays a vital role in the health care profession, protecting patients by promoting a high standard of practice and ensuring optimal care. In anatomic pathology, quality assurance is achieved through a program for the systematic monitoring and evaluation of the various aspects of the laboratory service.

POLICY:

Every pathologist reporting anatomic pathology specimens shall engage in a formalized system of quality assurance and document that activity, in order to integrate accepted quality assurance mechanisms into pathology practice.

Such programs shall include:

- **utilization of cancer checklists as mandated by the College of American Pathologists and as adopted by the Canadian Association of Pathologists;**
- **enrolment in external proficiency testing for each area of anatomic pathology (surgical pathology, gynecologic/non-gynecologic cytology, autopsy, special stains, immunohistochemistry, molecular methods, and electron microscopy) with documented results; and**
- **peer review, involving either retrospective or prospective review, of selected cases by a second pathologist.**

Section V:

MICROBIOLOGY

Microbiology Policy #1

ISSUE:

Qualifications of Staff - Analysis of specimens

BACKGROUND:

Analysis of specimens requires appropriately trained staff to interpret and certify results.

POLICY:

- a) CLXTs and MLAs who have completed acceptable microbiology training that is recognized by the accreditation program, may help in processing microbiology specimens, but may not release final results.**
- b) Registered Nurses performing Gram stains and limited microscopy in STI settings are approved subject to documented training and demonstration of competence specific to their roles.**

Microbiology Policy #2

ISSUE:

Use of Antistreptolysin O titre (ASOT) in diagnosis of Acute Rheumatic Fever (ARF)

BACKGROUND:

Infection with hemolytic Group A streptococcus may lead to poststreptococcal sequelae such as ARF and glomerulonephritis. ARF is associated with prior group A streptococcal pharyngitis, where as glomerulonephritis is associated with prior pharyngeal or skin infection with the organism. Streptococcal infections are treated to prevent ARF. Onset of ARF occurs from 2-5 weeks after streptococcal pharyngitis.

The diagnosis of ARF requires supporting evidence of antecedent group A Streptococcal infection, such as:

- record of positive throat culture, or
- record of positive rapid streptococcal antigen test performed on throat swab, or
- an elevated or rising streptococcal antibody titre.

ASOT is not a stat test. Laboratories that perform only a few tests should refer their specimens to a larger center for confirmation.

POLICY:

- a) Throat culture remains the gold standard for confirming pharyngitis caused by Group A Streptococcus.**
- b) Streptozyme is not appropriate for the diagnosis of acute streptococcal pharyngitis because of a lack of sensitivity and specificity.**
- c) ASOT is more appropriately used in identifying elevated or rising streptococcal antibody titre in the diagnosis of acute rheumatic fever.**

Microbiology Policy #3

ISSUE:

Investigation of Influenza Using Antigen Detection Such as Direct Fluorescent Antigen (DFA) or POC

BACKGROUND:

Influenza is a seasonal respiratory pathogen that peaks in the winter months. It is necessary to know whether there is circulating influenza in the community before antigen detection tests can be used as the indicator of infection.

POLICY:

The first two cases of positive antigen detection each season in a jurisdiction must be confirmed by a second method, such as culture or PCR.

Antigen detection systems may have a role in the pandemic influenza, but only after the National Reference Laboratory has confirmed how well the new strain can be detected.

Section VI:

TRANSFUSION MEDICINE

Transfusion Medicine Policy #1

ISSUE:

Standards of Transfusion Medicine Practice

BACKGROUND:

Standards for Transfusion Medicine include the safety, quality, and efficacy of blood collection, processing and transfusion.

POLICY:

All Transfusion Medicine laboratories shall adhere to the most current CSTM and Z902 standards and the following province-specific policies.

Transfusion Medicine Policy #2

ISSUE:

Maintenance of Competence

BACKGROUND:

A low threshold for crossmatches has been set in an effort to continue to provide essential services.

The Transfusion Medicine laboratory service must be current and comply with national, provincial or territorial governing bodies regarding policies, processes and procedures defining staffing requirements and staff qualifications.

POLICY:

Transfusion medicine technologists must demonstrate validation of skills to ensure minimum qualifications, responsibilities, level of authority and accountability for the services provided.

Validation of skills will be considered acceptable by performing no fewer than 12 crossmatches per year/technologist, to include a minimum of 8 patient samples and 4 proficiency testing samples.

Transfusion Medicine Policy #3

ISSUE:

Clinically Significant Antibody Notification

BACKGROUND:

Clinically significant antibodies can pose a risk to patients/persons who receive antigen positive blood and blood products. Persons who have knowledge of clinically significant antibodies may be better able to inform medical personnel and will minimize that risk.

POLICY:

All laboratories that identify clinically significant antibodies shall notify the patient in a timely manner.

Transfusion Medicine Policy #4

ISSUE:

Inter-facility Transfer of Blood and Blood Products
Requirements for Establishment of a Provincial Blood and Blood Product Shipping
Guideline between Saskatchewan Hospitals

BACKGROUND:

A standardized process for the transfer of all blood and blood products will facilitate inventory management and ensure patient safety.

POLICY:

Requirements

- 1. It is the responsibility of the employer to provide documented training in all aspects of inter-facility transfer of blood and blood products.**
- 2. The facility of origin must have a monitored blood bank refrigerator and the capability to maintain ice pack/gel pack. Proper temperatures must be maintained and documented during storage.**
- 3. The facility of origin must supply the following records to the receiving facility:**
 - The date of receipt of the product from the Canadian Blood Services.**
 - The product type, identification number and expiration date.**
 - Documentation that the product was visually inspected and acceptable when the product was placed in storage at the facility of origin.**
 - Temperature charts from the storage device to document that the product has been continuously stored at proper temperature. The charts must indicate facility name, date range and a record of daily review. The technologist's initials and date must accompany all records.**
- 4. The use of Canadian Blood Services shipping containers is acceptable provided the appropriate packing configuration is utilized and the container is in good condition. The ice packs and gel packs must be maintained at the proper shipping temperature and that shall be documented.**
- 5. Shipping Label**

The information on the transport container's outer label shall include:

 - (a) the site of origin;**
 - (b) the destination;**
 - (c) a notice that it contains human blood components;**
 - (d) any cautions or descriptions required under provincial or federal transport regulations**

- 6. The receiving facility must be notified.**

- 7. On receipt of the product, the receiving facility shall ensure:**
 - (i) Tamper proof seal intact**
 - (ii) Visual inspection acceptable**
 - (iii) Documentation is reviewed prior to implementation**
 - (iv) Storage temperature records enclosed**
 - (v) Storage temperature records acceptable**

Appendix A

Packing Slip # _____

INTERFACILITY TRANSFER OF BLOOD AND BLOOD PRODUCTS

Complete the following accurately, attach copies of storage temperature records and enclose with your components.

Section 1: SHIPPING FACILITY OF ORIGIN:

Component Name	Donation # / Lot #	Date of Receipt	Expiry Date	Quantity
			TOTALS=	

All in-date products have been stored as follows:

Fractionation Products 2° - 8°C Yes No Tech: _____ Date: _____
 Room Temp. Yes No Tech: _____ Date: _____
 (20° - 22°C)

RBC 1° - 6°C Yes No Tech: _____ Date: _____
 Frozen Plasma < -30°C Yes No Tech: _____ Date: _____
 Platelets 20° - 24°C Yes No Tech: _____ Date: _____
 With constant agitation

Copies of storage temperature records included: Yes No Tech: _____ Date: _____

Packed by Hospital Staff signature _____ Date: _____ Time: _____

NOTE: Attach Tamper Proof Seal after packing is complete.

Components Transported by: _____

Section 2: RECEIVING FACILITY

Tamper Proof Seal Intact Yes No
 Visual Inspection Acceptable Yes No
 Storage Temps Acceptable Yes No

Initials: _____ Date: _____ Time: _____