College of Physicians and Surgeons of Saskatchewan
Laboratory Quality Assurance Program

Policy Manual

2016 Edition

LABORATORY QUALITY ASSURANCE POLICY MANUAL

SUMMARY OF POLICY MANUAL CHANGES

The following policies have been revised, added, or deleted:

REVISED:

2016 Transfusion Medicine Policy #1
Transfusion Medicine Policy #7
General Policy #7

2015 Transfusion Medicine Policy #2 – Maintenance of Competence
Hematology Policy #1 – D-dimer

2014 Hematology Policy #1

2013 Anatomic Pathology Policy #4

2012 Point-of-Care Testing Policy #2

ADDED:

2016 Microbiology Policy #3
Microbiology Policy #4 (still in progress)

2014 General Policy #7

2013 Point-of-Care Testing Policy #3 (formerly Microbiology Policy #3)
Point-of-Care Testing Policy #4
Hematology Policy #1

2012 Anatomic Pathology Policy #4

DELETED:

2016 General Policy #2
General Policy #3
General Policy #5 (now a guideline)
General Policy #6
Anatomic Pathology Policy #1
Anatomic Pathology Policy #3
Hematology Policy #1

2013 General Policy #4
Microbiology Policy #1
Microbiology Policy #2

2012 General Policy #1

LABORATORY QUALITY ASSURANCE POLICY MANUAL

Table of Contents

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 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.

GENERAL

General Policy #7

ISSUE:

Proficiency Testing (PT)/ External Quality Assessment (EQA)

BACKGROUND:

PT/EQA is one measure of a laboratory's analytical performance in comparison to peers, reference standards and/or reference laboratories. It serves as external validation of the quality of laboratory results and also as a valuable self-monitoring tool. This benefits the laboratory, patients, testing personnel and oversight bodies.

POLICY:

Each facility shall enroll in formal external PT/EQA for each test listed on the Medical Laboratory License. Where no external PT/EQA is commercially available, the laboratory shall design PT/EQA (ie. split testing) in order to ensure quality.

All PT/EQA results must be shared with the Laboratory Quality Assurance Program.

All Educational challenges are graded by the LQAP based on expected answers in the Participant Summaries.

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

Point-of-Care Testing 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.

Point-of-Care Testing Policy #4

ISSUE:

Group A Streptococcus by POCT

BACKGROUND:

POCT is available for Group A streptococcus antigen detection.

As Group A Streptococcus is not common in adults, confirmation is not necessary except when in contact with school-age children.

Confirmation is necessary in patients ≤25 years of age.

POLICY:

If the Group A Streptococcus POCT result is negative in patients ≤25 years, a second swab must be sent for culture (for Group A, C and G Streptococcus and *Arcanobacterium haemolyticum*).

The "Gold Standard" remains a culture performed in the medical laboratory.

Any laboratory implementing a POCT kit for Group A Streptococcus detection must validate the sensitivity for the population being screened.

All other elements of POCT Policy #1 must also be followed.

ANATOMIC PATHOLOGY

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 #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 retrospective and prospective review of selected cases by a second pathologist.**

MICROBIOLOGY

Microbiology Policy # 3

ISSUE:

Throat Swabs

BACKGROUND:

Throat swab specimens are most commonly collected to diagnose infections caused by *S. pyogenes* (Group A streptococcus) and occasionally to investigate possible post-infectious sequelae, like glomerulonephritis or acute rheumatic fever. *S. Pyogenes* should always be reported.

Throat cultures can also yield large (not pinpoint) colony-forming beta-hemolytic streptococci harboring the Lancefield Group C or Group G antigen belonging to *Streptococcus dysgalactiae* subsp. *equisimilis*. They are associated with upper respiratory tract infections similar to *S. pyogenes*, infections. Cases of post-streptococcal glomerulonephritis have also been described. Group C and G streptococci should always be reported. In the 15-25 year-old age group, *Arcanobacterium hemolyticum* can also cause acute pharyngitis, but is not associated with any post-infectious sequelae. It should be reported routinely in this age group.

Culture of any other suspected agents of disease such as: *N. gonorrhoeae, C. diphtheriae* should be performed only at the request of the ordering physician.

Anti-streptolysin O titres (ASOT) are commonly used in diagnosis of acute rheumatic fever. In-patients with symptoms of acute rheumatic fever, ASOT ≥ 200 Todd units are considered significant. ASOT are not appropriate for investigation of streptococcal pharyngitis. Throat culture remains the gold standard for confirming pharyngitis caused by Group A Streptococcus.

POLICY:

Susceptibility Testing:
Antimicrobial susceptibility testing of these isolates is not required unless the patient is known to be allergic to penicillin. Perform antimicrobial susceptibility tests according to the most current Clinical and Laboratory Standards Institute (CLSI) document M100 - Performance Standards for Antimicrobial Susceptibility Testing.

Reporting Results:

i. **If culture is negative, report out as 'No Group A, C or G Streptococcus Isolated'.**
ii. **If culture is positive for Group A Streptococcus, report 'Group A Streptococcus Isolated'.**
iii. **If either Group C or Group G Streptococcus is positive report out as 'Group C Streptococcus' or 'Group G Streptococcus Isolated'.**
iv. **If Arcanobacterium hemolyticum is cultured, report out 'Arcanobacterium hemolyticum can be a cause of pharyngitis, and it is usually sensitive to antibiotics used to treat streptococcal tonsillitis'.**

References:

1. Isenberg et al, eds. Clinical Microbiology Procedures Handbook, ASM Press
2. Versalovic J et al, Manual of Clinical Microbiology, 10th ed., 2011 ASM Press: Washington DC.

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 Health Canada Blood Regulations, 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 annually, per technologist, to include a minimum of 8 patient 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

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

POLICY:

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.**
   - **Temperature charts documenting proper storage of the components must be available if requested by the receiving facility. The charts must indicate facility name, date range and a record of daily review.**

4. **Blood components shall be shipped in validated damage resistant containers that are designed to include a tamper evident seal. Transport time shall not exceed the limit of the validated container.**

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 for Transfusion" for available product, or "Not for Transfusion" if the products are quarantined;
   (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 evident seal intact
   (ii) Visual inspection acceptable
   (iii) Documentation is reviewed prior to accepting units for transfusion
   (iv) Storage records acceptable if provided.

8. **When blood products are shipped for inventory purposes it is the responsibility of the receiving facility to document disposition. When blood products are shipped with a patient there shall be an established process to ensure traceability of all blood products and plasma protein products.**

Appendix A

SAMPLE INTERFACILITY TRANSFER OF BLOOD AND BLOOD PRODUCTS FORM

Packing Slip #_____

Shipping Facility - Complete the following and enclose with the shipment.

Shipping Facility Name: _____

Receiving Facility Name: _____

Component Name	Donation # / Lot #	ABO/Rh	Visual Inspection	Product Status (Available / Quarantined)	Date Received into Shipper's Inventory	Quantity
					Total Shipped	

Have all products been stored according to manufacturer's directions?

☐ Yes ☐ No Signature: _____ Date: _____

Copies of storage temperature records: ☐ included
☐ Available Upon Request

☐ **Packed by Hospital Staff**: Signature_____ Date: _____ Time: _____

NOTE: All shipments must be secured with a Tamper Evident Seal prior to shipping.

RECEIVING FACILITY: Complete the following

Tamper Evident Seal Intact	☐ Yes	☐ No	
Visual Inspection Acceptable for all products	☐ Yes	☐ No	
Storage Temps Acceptable	☐ Yes	☐ No	☐ Not Required

Signature: _____ Date: _____ Time: _____