

Department of Pathology & Laboratory
Medicine

Quality Program Overview

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Children's Hospital
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Purpose of Document

The Department of Pathology and Laboratory Medicine prepared this statement of qualifications to assist our clients with the qualification of referral laboratory process to meet regulatory and accreditation compliance requirements.

Framework for Quality

Children's Hospital Colorado Department of Pathology and Laboratory Medicine (DPLM) is committed to excellent care and continuous improvement. A culture of quality is embedded in every section within our laboratory by creating an environment of development, continual improvement, safety, and regulatory compliance to ensure the highest quality of service.

DPLM Mission

To improve the health of children by providing high-quality pathology and laboratory services through the provision of patient care, educational, research, and advocacy programs, in strategic partnership with our providers and institutional leadership.

DPLM Services

Patient Population Served:

Patients include those who are treated within the Children's Hospital Colorado network as inpatients or outpatients, and those treated outside the CHCO network located locally, within the United States and internationally.

Ages of Patients Served:

- Fetal (pre-birth)
- Neonatal (<30 days)
- Infancy (>30 days to <1 year)
- Early childhood (>1 year to <5 years)
- Late childhood (>5 years to <13 years)
- Adolescent (>13 years to <17 years)



- Young Adult (>17 years to <22 years)
- Adult (>22 years)

Services Provided by Clinical Staff at Anschutz Campus Laboratory:

The DPLM provides clinical laboratory testing in the following sections:

- Biochemical Genetics
- Blood and Marrow & Cellular Therapeutics
- Chemistry
- Coagulation
- Flow Cytometry
- Hematology
- Immunology
- Microbiology
- Molecular Microbiology
- Mitochondrial
- Precision Diagnostics
- Urinalysis

The DPLM Transfusion Medicine Services provide the following services:

- Blood Bank
- Blood Donor Center
- Therapeutic Apheresis

Blood and blood products are prepared in accordance to AABB and FDA regulatory requirements.

The DPLM provides routine pathological testing and services in the following areas:

- Autopsy
- Cytology
- Electron Microscopy
- Histology
- Pathology consultations
- Surgical pathology

Additional laboratory services are provided at DPLM network laboratories providing limited services including:

- Chemistry
- Coagulation
- Hematology

- Immunology
- Microbiology
- Urinalysis

DPLM Locations & Contact Information

Anschutz Campus

13123 E. 16th Avenue

Laboratory B120

Aurora, CO 80045

(720)777-6711

Direct all testing and communications to the Anschutz Campus Laboratory.

Laboratories are also at the following Network of Care Locations:

- Colorado Springs Hospital (Cryostat Laboratory)
- Colorado Springs - Briargate
- Health Pavilion (Outpatient Laboratory)
- North Campus
- South Campus

Certifications & Licensures

All of our laboratories retain accreditation by the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) licensure.

SITE	CAP #	CLIA #
Anschutz Campus	2179701	06D0513583
Colorado Springs - Briargate	8647300	06D2042380
Colorado Springs Hospital	8516196	06D2163019
North Campus	7183662	06D0999405
South Campus	8843113	06D2069870
Health Pavilion	NA	06D2167680



The Transfusion Medicine sections also retain accreditation through the following agencies:

Agency	Identification or Registration #
AABB (Transfusion Medicine)	8181
FDA (Transfusion Medicine and Blood and Marrow Transplant)	1771443
FACT (Transfusion Medicine and Blood and Marrow Transplant)	NA

Quality Management System

The aim of the DPLM's Quality Management System (QMS) is to establish an organizational structure that fosters quality laboratory services and patient safety. The QMS incorporates principles, standards, activities and goals which comprise the quality functions.

The QMS incorporates the Clinical and Laboratory Standards Institute's (CLSI) twelve Quality System Essentials as well as elements of the College of American Pathologists (CAP). DPLM acknowledges that the path of workflow for laboratory testing often begins outside the laboratory's boundaries, with a provider's testing order and specimen collection. Likewise, the process often ends outside the boundaries of the physical laboratory, with the clinician's utilization of the results in patient care.

It is the goal of this QMS to provide the continuous monitoring and evaluation across the Total Testing Process from specimen receipt to result reporting. This plan was designed to ensure compliance with national, federal, state and local laws and regulations in addition to accreditation requirements, ethical standards and organizational policies. Delivering quality laboratory services is part of CHCO's mission and we strive for Continuous Quality Improvement. In the DPLM, quality comes first. The DPLM constantly seeks ways to improve the quality of the services performed, which in turn adds value for all customers. Respect, innovation, teamwork, communication and integrity are the keys to success in the continuous quality improvement journey.

Clinical and Laboratory Standards Institute's (CLSI) Quality Systems Essential (QSEs):

Structure

Organization and Leadership

- Structure
- Mission, Vision, Value
- Leadership Review
- Resources

Facilities and Safety

- Structure and Utilities
- Environmental Conditions
- Communications
- Safety Programs
- Emergency Management

Personnel

- Staff Qualifications
- Job Description
- Orientation and Training
- Competency
- Continuing Education

Process

Purchasing and Inventory

- Critical Materials and Services
- Supplier Qualification
- Supplier/Customer Agreements
- Inventory Management
- Market Recall

Equipment

- Selection and Acquisition
- Equipment Qualification
- Operations and Calibration
- Maintenance and Repairs

Process Management

- Process Design and Development
- Validation
- Performance
- Quality Control
- Change Control

Documents and Records

- Document Creation
- Use and Maintenance
- Annual Review
- Document Control
- Record Quality and Review
- Retention, Storage and Retrieval

Information Management

- Training and Reference Guides
- Software
- Interface Testing

Outcome

Event Management

- Detection, Documentation and Investigation
- Categorization and Analysis
- External Notification
- Product/Result Recall/ Correction

Monitoring and Assessment

- Quality Indicators
- Internal Audits
- External Assessments
- Proficiency Testing
- Quality Reporting

Service and Satisfaction

- Needs Assessments
- Customer Comments
- Consultation
- Complaint Resolution

Continual Improvement

- Data Analysis
- Identification of Opportunities for Improvement
- Quality Management Tools
- Process Improvement

Quality Metrics

DPLM establishes quality elements to be monitored and quality initiatives or action plans to be carried out when indicated. Each section tracks key quality metrics that:

- Are measured objectively
- Reflect key aspects of quality
- Affect a large percentage of laboratory's specimens/testing or have a high impact on patient safety
- Document the impact of specific actions taken to effect improvement



- Track progress towards achieving Quality Improvement goals
- Are systematically evaluated by the leadership and committees to identify opportunities for quality improvement

Quality metrics include all phases of analysis including preanalytical, analytical and postanalytical. Specific monitored items may change as needs are identified within the DPLM. Monitored metrics may include, but is not limited to:

Preanalytical

- Required collection information
- Specimen collection issues
- Redraw rates
- Policy & procedure review
- Patient wait times for specimen collection

Analytical

- Test volumes
- Turn-around times
- Proficiency testing
- Specimen and handling acceptability

Postanalytical

- Critical value notification rates
- Clerical errors

Operational Performance Indicators

- Incoming call volumes
- Incoming call handled ratio
- Preventative maintenance completion rates

Proficiency Testing

Each clinical laboratory section participates in formal proficiency testing through the College of American Pathologists' (CAP) Proficiency Testing (PT) Program or other approved testing program for all testing performed. When formal proficiency testing is not available alternative testing is performed.

Assessments

DPLM undergoes both internal and external assessments to determine the effectiveness of the laboratory's Quality Management System. The laboratory participates in internal and external assessments as required by federal and, as applicable, state law. Assessments such as these take many forms and are an integral part of the management of quality across the total testing process.

Program Elements - The DPLM maintains an established program for quality assurance that includes:

- External quality peer reviews for accreditation or licensure
- Proficiency testing
- Quality indicators for work processes
- Internal assessments/audits
- Performance comparison with peers and with best practices
- Quality reporting for management review

Hosting External Assessments - On-site inspections including surveys, investigations and external inspection by professional or regulatory agencies to assess the department's compliance with required standards or practices will be conducted per the assessment process.

Quality Indicators - The DPLM identifies quality indicators for both the laboratory's path of workflow and management activities (e.g., the QSEs) to systematically monitor department's contribution to overall patient care.

Evaluation of Results - The DPLM evaluates the results of external assessments, internal audits, and proficiency testing to identify opportunities for process improvement. All audit reports are submitted for management review and signature.

Performance Comparison - The DPLM compares the laboratory's performance to that of other laboratories to introduce novel approaches in characterization and achievement of best practices.

Oversight of Assessment Activities - Those responsible for Quality Management oversee the assessment activities to ensure that they are conducted within the appropriate scope on a defined schedule and that reporting and follow-up are designed to sustain DPLM's quality goals.



DPLM Client Services

For additional information, please contact DPLM Client Services at (720)777-6711.



