UNIVERSITY OF CALIFORNIA, DAVIS
HEALTH SYSTEM, SACRAMENTO
Department of Pathology and Laboratory Medicine

Quality Management Program and Performance Improvement Plan **Administrative Procedure 710.A**

MISSION STATEMENT

The Department of Pathology and Laboratory Medicine supports the University of California, Davis Health System's (UCDHS) mission to fulfill four interwoven commitments simultaneously: education, research, patient-centered care, and public service. The department is committed to leading through innovation and to meet the health system's mission of improving lives and transforming health care.

The Department of Pathology and Laboratory Medicine is dedicated to providing a full range of accessible, consistent, high quality and cost effective laboratory tests and services that support education and research and are responsive to the needs of UCDHS patients, staff and faculty. The Department of Pathology and Laboratory Medicine is an active participant in the planned, systematic, Health Systems wide approach to process design, performance measurement, assessment and improvement.

SCOPE OF SERVICES

The Department of Pathology and Laboratory Medicine provides comprehensive, accredited pathology and laboratory services to the University of California, Davis Medical Center and Health System, a university-affiliated, tertiary care, > 600 bed, trauma, teaching hospital with Level 1 Trauma / Emergency Service, Hospital Based outpatient clinics, a Primary Care Clinic network of outpatient clinics and a regional outreach program. UCDHS admits more than 33,000 patients per year and handles more than 900,000 clinic and office visits. The medical center's emergency room treats more than 180 patients per day on average.

The scope of services includes:

A. Clinical Pathology – Transfusion Services, Chemistry, Microbiology, Immunology, Hematology, Coagulation, Urinalysis, Molecular Pathology, Flow Cytometry, Point of Care Testing (POCT), Toxicology, Hematopoietic Progenitor Cell Laboratory (HPCL), Biorepository, Laboratory Information Services, Client Services, Partners in Education, and Laboratory Management
B. Anatomic Pathology – Surgical Pathology, Neuropathology, Histology, Cytology, Cytopathology, Renal Pathology, Hematopathology and Autopsy
C. Outreach Laboratory Services
D. Consultation Services in each of the previously specified areas

The Department's customers include UC Davis Medical Center patients, out-patient primary care patients, faculty and staff and the general health care community of the greater Sacramento and Davis metropolitan areas and inland Northern California.
The important value characteristics relevant to services provided include the Institute of Medicine's Six Quality Domains:

-Accurate and timely pathology and laboratory testing and services (Timeliness)
-Customer satisfaction by meeting customer expectations
-Sustainable attainment of quality objectives
-Ability to reduce or eliminate medical errors and Patient Safety (Safety)
-Personnel follow ethical practices to ensure no conflicts could influence the quality of work (Equity)
-Patient confidentiality is maintained and patients are treated with respect at all times (Patient Centeredness, Respect and Caring)
-Operational and productivity improvements (Effectiveness)
-Cost reduction and avoidance (Efficiency)
-Test and blood utilization review (Efficiency)

CUSTOMER SERVICE

The department participates in hospital wide customer service programs such as patient satisfaction monitors and laboratory specific monitors. The department maintains a Client Services team who field questions, concerns and complaints from clients and patients. Client Services team documents calls (call log). Customer complaints are documented and tracked through hospital wide incident reporting system, with additional department tracking done by the Quality Manager. Staff received customer service training by hospital training modules (e.g. UC Learning, AIDET) and by vendor training (e.g. ARUP).

LICENSURE, CERTIFICATION AND ACCREDITATION

Licensure, certification and accreditation provide a framework for program structure and management, creating a culture of excellence across the organization. UC Davis Health System and Medical Center maintain Joint Commission certification; the standards and emphasis on clinical practice guidelines help organization establish a consistent approach to patient care, reducing the risk of error.

The Department of Pathology Laboratories are CLIA certified and follow CLIA personnel qualifications for Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, Cytology General Supervisor and Testing Personnel. CLIA requirements can be found on the CLIA website (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/apcsubm.pdf) and in lab administrative policies and procedures.

Laboratories maintain required State of California Department of Health Services (CDPH) annual licensure. State licenses and FDA registrations are maintained for breast milk, tissue bank, blood and biologics, and cellular components. Voluntary accreditations are maintained to help provide framework for the highest standards of testing and services: College of American

Pathologists (CAP), AABB (formerly American Association of Blood Banks), Foundation for the Accreditation of Cellular Therapy (FACT).

In addition to laboratory licenses, all staff maintain the required state licenses and certifications to perform their job functions: Clinical Laboratory Scientists (CLS), Certified Phlebotomy Technicians (CPT), Histology Technicians (HT) and Cytotechnologists (CT).

PERSONNEL
Staff are hired in accordance with posted job descriptions following federal, state and local laws and regulations, as well as UCDHS policies. The UCDHS Human Resources Department maintains hiring documents. Personnel records such as licensure and certification are maintained by the department's Administrative Services staff. New employees participate in hospital provided orientation. Staff participate in required annual hospital and laboratory safety training, department training, continuing education, competency assessment, and performance evaluations related to their job functions. Access to hospital Human Resources records are controlled by the HR department. Other laboratory records such as annual performance evaluations and competency records are maintained by Section Supervisors and laboratory managers.

FACILITIES
The Department of Pathology and Laboratory Medicine consists of hospital campus-based labs at 2315 Stockton Blvd.: Pavilion Main Lab, Cancer Center Hematology Lab, Cancer Center Progenitor Lab, Point of Care Testing Lab, and the Pathology Lab. Off campus labs include the Specialty Testing Center (STC) at 5340 Business Dr. (Special Chemistry, Toxicology, Microbiology, Immunology, Flow Cytometry, and Molecular Pathology) and Progenitor Lab off-site storage facility at 3671 Business Drive, Suite 120.

Hospital campus Hospital Based Clinics (HBC) have phlebotomy draw stations/labs which perform minimal specimen processing and are responsible for specimen transport to the Pavilion Main Lab. HBC locations are: ACC Ellison Building, Cypress Building, Glassrock Building and Cancer Center.

RESPONSIBILITIES
Quality and performance improvement is the concern of every member of the Department of Pathology and Laboratory Medicine, and as such, all faculty and staff are members of the quality team. The Laboratory Director and Chair is responsible for the design, implementation, documentation, assessment and improvement of the Quality Management Program (QMP). The quality program undergoes periodic review of current values, customer needs, service capabilities, goals and objectives to prioritize new objectives, consistently moving toward continual improvement. The QMP is coordinated with other plans within the Health System

(Quality and Safety Committee, Medical and Surgical Staff, Nursing Services, etc.). The Laboratory Director is responsible for annually reporting the department's performance data, operational changes, and improvement initiatives to the Hospital Quality and Safety Operations Committee (QSOC).

The implementation of the QMP and Performance Improvement Plan (PIP) is overseen by the committees of Clinical Pathology Continuous Quality Improvement (CPCQI) and Anatomic Pathology Continuous Quality Improvement (APCQI). The quality teams establish process improvement goals and objectives, and assign action tasks and target dates. Improvements are assessed and measured for effectiveness.

All Department of Pathology and Laboratory faculty and staff are responsible for various components and/or functions of the plan, from review and development of the plan to identifying problems and solutions. The Quality Manager serves as the Quality Team Manager. Each lab section supervisor serves as the Quality Team Leader, with all staff serving as quality team members. Each quality team member is expected to provide input on quality issues, safety concerns, and process/performance improvement. Team Leaders are expected to report quality issues and improvement recommendations to the Quality Manager, who reports to the department APCQI and CPCQI committees.

Individual faculty and staff members;

1. Perform tasks and services according to written policies and procedures and quality standards
2. Establish policies and procedures following appropriate guidelines
3. Identify and report problems (or potential problems)
4. Participate in quality and performance measurement through monitoring evaluation
5. Participate in defining quality and performance standards
6. Participate in quality and performance improvement processes
7. Maintain safe work practices and environment

Medical Directors, Managers and Supervisors:

1. Ensure department tasks and services are performed according to written procedures and quality and performance standards
2. Review policies and procedures and quality assurance records, as applicable
3. Coordinate performance of quality measures through quality and performance improvement monitoring and evaluation.
4. Identify problems (or potential problems) that do not meet quality and performance standards

5. Initiate and coordinate quality and performance improvement processes through an error management system that detects errors, investigates root cause(s), documents corrective action, and prevents future errors
6. Participate in defining quality and performance standards
7. Provide quality and performance improvement monitoring and evaluation guidance and advice
8. Teach and facilitate quality and performance improvement processes
9. Identify tests in the section that use an IQCP: provide risk assessments to evaluate potential sources of error, write a quality control plan approved by the laboratory director prior to implementation, define all aspects monitored based on the potential errors identified during the risk assessment, monitor ongoing quality assessment performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP.

QUALITY COMMITTEES

The department has two Quality Committees (P&P 780.A *Pathology Quality Committees*):

Clinical Pathology Continuous Quality Improvement (CPCQI)
Anatomic Pathology Continuous Quality Improvement (APCQI)

In addition, the Blood Bank section has a formal quality committee;

Blood Bank Continuous Quality Improvement (BBCQI)

The technical section quality teams consist of operational laboratory section supervisors, staff and section medical directors. Sections are encouraged to report to one of the department's CQI committees. Other quality sub-committees and/or quality workgroups are established on an ad hoc basis at the discretion of the CQI committee chairs, Managers, Supervisors, Quality Manager, CAO or the Department Chair.

The department is represented on hospital quality oversight committees, including the Regulatory and Accreditation Committee (RAC), Stem Cell Continuous Quality Improvement Committee (Stem Cell CQI), Transfusion Committee, Test Utilization Committee and Hospital Safety Committee.

POLICIES AND PROCEDURES

The department follows hospital policies and procedures when applicable. Establishing laboratory specific policies and procedures is the responsibility of the section medical directors and staff. All new and significantly revised policies and procedures are approved by the Laboratory Director. Section specific policies and procedures are reviewed and approved

biennially by the Section Medical Directors. The Lab Administrative policies and procedures are reviewed and approved biennially by the Laboratory Director. All staff are expected to follow established policies and procedures.

Document Control

Documents (policies and procedures and department HR records) are maintained electronically on the department's shared drive (S drive) and in the hospital's approved document control system (OnBase).

Master paper copies of Lab Administrative policies and procedures (with the Director's "wet" signature) are maintained in the Pavilion Lab (CAO's office); file copies of Lab Administrative policies and procedures are maintained in the STC library. Backup paper copies of technical section policies and procedures are maintained in the technical sections. Only the current versions of department policies are to be used.

EQUIPMENT

Equipment needs are reviewed by technical sections and purchased or leased as needed. Equipment installation is overseen and tracked by the hospital Clinical Engineering Department. Equipment qualification, maintenance, service, and daily functions such as calibration are managed by Section Supervisors in collaboration with the hospital Clinical Engineering Department. Records of service maintenance and repairs are maintained by Clinical Engineering Department and the sections.

SAFETY

Supervisors are responsible for the safety of their staff. Employees receive employee orientation and annual safety training through hospital and department training modules. Staff are notified of safety issues via safety postings on bulletin boards, fliers, hospital wide announcements and emails. Lab staff participate in hospital provided safety programs including health (hepatitis, TB, and influenza vaccines), safety (needle stick, fire drills, chemical safety, ergonomic safety, emergency preparedness drills and evacuation plans).

Product and equipment recall and safety notice notifications are received from vendors/suppliers to the section contacts, and to the Quality Manager through the hospital Clinical Engineering Department's safety notice program managed. ECRI weekly notifications are sent to the department's Quality Management section and are forwarded to each lab section for review and investigation. Resolution is documented by the QM section in the ECRI database.

ERRORS, OCCURENCES AND EVENTS MANAGEMENT

The department follows hospital and department required error reporting and notification to regulatory agencies such as CDPH, FDA, and CMS. Lab errors, events and occurrences are identified, investigated, root cause(s) determined, corrective actions implemented, tracked and

identified for preventive actions and process improvement opportunities. The lab sections monitor section specific errors, and report significant errors in the hospital's incident reporting (IR) system, managed by the department's Quality Manager. The Quality Manager tracks significant errors and error trends, and reports to the appropriate CQI committees.

ASSESSMENTS

External Assessments:

The department participates in external quality assessments such as inspections by College of American Pathologists (CAP), AABB (formerly American Association of Blood Banks), Foundation for Accreditation of Cellular Therapy (FACT), The Joint Commission and the FDA. The department enrolls in and reports to approved Proficiency Testing programs (CAP, NASCOLA).

Internal Assessments:

The department quality teams perform and monitor key quality indicators, perform and report internal audits, and review blood utilization and blood wastage. Documentation of current key quality indicators is maintained by the Quality Manager. Data are analyzed to determine if opportunities for improvement exist, and comparative or bench marking data are utilized when available. Quality indicators are periodically reviewed to ensure the desired processes are being assessed, and to determine if frequency of monitoring is appropriate to achieve desired improvement.

Quality indicators are documented, reviewed and submitted to the Quality Manager who will submit to appropriate CQI committees. Key indicators may consist of, but are not limited to:

a. Workload, Cost and Productivity Trends (CAO)
b. LIS monitors
c. Turnaround times (TAT) and trends for Anatomic Pathology tests and processes
d. TAT and trends for Clinical Pathology tests and processes
e. Stem cell monitors
f. ASCUS:SIL Ratio (Cytology Supervisor)
g. Clinical effects of discrepant frozen sections (Gross Room Director or Supervisor)
h. TAT for intra-operative frozen section
i. Blood utilization and wastage (Blood Bank Quality Specialist)
j. Customer/Patient Satisfaction (Client Services Manager)
k. FNA/Biopsy Correlation (Cytology Supervisor)
l. GYN adequacy (Cytology Supervisor)
m. GYN Cytology/Surgical Biopsy Correlation (Cytology Supervisor)
n. Adverse events (Blood Bank Quality Specialist and Quality Manager)
o. Hospital Incident Reports: errors, complaints and adverse events (Quality Manager)
p. Rejected specimens (Quality Manager)
q. Specimen handling/processing errors

r. Amended/edited reports (Section Supervisor)
s. Critical Value reporting TAT (Quality Manager)
t. Quality assurance codes and immunohistochemical staining (IHS) adequacy

QUALITY AND PERFORMANCE IMPROVEMENT

Data analysis of the key quality indicators may lead to opportunities for process, performance and quality improvement projects. The quality team will devise strategies for improvement and implement the improvement plan. The outcomes of improvements will be documented and reviewed to ensure the changes achieved desired outcomes and improvements.

Departmental improvement projects are reported to the department faculty and staff when applicable. Projects may also be presented at department Faculty/Staff meetings. The team will devise appropriate indicator(s) to substantiate positive process change has been effectively implemented. The hospital encourages improvement projects that reach across multiple hospital departments/divisions in order to reduce duplicative efforts and to encourage interdepartmental collaboration.

REFERENCES:

CLSI. *Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*. CLSI document QMS01. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

CLSI. *Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*. CLSI document GP26-A4. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2012

CLSI. *QualityManagement System: Continual Improvement; Approved Guideline—Third Edition*. CLSI document GP22-A3. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2011

CLSI. *Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline—First Edition*. CLSI document GP35-A. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010

CMS. *IQCP Individualized Quality Control Plan; Developing and IQCP A Step-by-Step Guide.* CDC, CMS, U.S. Department of Health and Human Services.

PROCEDURE HISTORY

Date	Written/Revised By	Revision	Approval Date	Approved By
4/92	D. O'Sullivan	New	4/92	H. Jensen, MD
5/93	D. O'Sullivan	Revised	5/93	H. Jensen, MD
5/94	D. O'Sullivan	Revised	5/94	K. Sazama, MD, JD
5/95	D. O'Sullivan	Revised	5/95	R. Cardiff, MD, PhD
6/96	D. O'Sullivan	Revised	6/96	R. Cardiff, MD PhD
3/97	Delores Brown	Revised	4/97	E. Larkin, MD
11/97	D. O'Sullivan	Annual Review	11/97	E. Larkin, MD
11/98	D. O'Sullivan	Annual Review	11/98	E. Larkin, MD
8/00	D. O'Sullivan	Annual Review	8/00	E. Larkin, MD
6/01	D. O'Sullivan	Annual Review	6/01	E. Larkin, MD
7/02	D. O'Sullivan	Annual Review	8/02	R. Green, MD
5/03	D. O'Sullivan	Annual Review	5/03	R. Green, MD
2/04	D. O'Sullivan	Revised	2/04	R. Green, MD
10/04	D. O'Sullivan	Annual Review	10/04	R. Green, MD
8/05	B. Harris	Annual Review	10/05	R. Green, MD
10/06	B. Harris	Revised	10/06	R. Green, MD
5/07	B. Harris	Annual Review	5/07	R. Green, MD
4/08	D. Wright	Revised	4/08	R. Green, MD
4/09	D. Wright	Revised	4/09	L. Howell, MD

Date	Written/Revised By	Revision	Approval Date	Approved By
4/10	D. Wright	Revised	4/10	L. Howell, MD
4/11	D. Wright	Revised	4/11	L. Howell, MD
5/13	T. Cox	Revised: CQI committees; deleted Appendix A	5/13	L. Howell
11/14	T. Cox	Revised: renamed; added QM Program essentials	11/14	L. Howell
08/16	S. Okimura	Revised: Added IQCP to Responsibilities of Medical Directors, Managers and Supervisors; added CMS reference; removed PCCPI	08/16	L. Howell
8/17	S. Okimura	Annual Review	10/17	L. Howell via OnBase