



COLLEGE OF AMERICAN PATHOLOGISTS (CAP) - REGULATORY COMPLIANCE

Delegation of Authority

January 3, 2018

In accordance with standards established by the Clinical Laboratory Improvement Amendments (CLIA) and adopted by the College of American Pathologists (CAP) TLC.11425 (Delegation of Functions), the Medical Director for the Laboratory of Pathology, NCI, CCR has delegated responsibilities and authority to Section Directors / Technical Supervisors (Section Heads) and General Supervisors, meeting the CLIA qualifications for the specialties supervised. All section heads for LP's clinical services meet the CLIA requirements for supervising high-complexity testing, and are identified on the sections' Laboratory Personnel Evaluation Roster. Authorized roles and responsibilities include:

- Ensuring availability to the laboratory section as needed for on-site, telephonic or electronic consultation.
- All technical and regulatory compliance for the assigned discipline or service.
- Implement and maintain CAP standards, selection of equipment and methodologies, validation and implementation of new methods and instruments, communication of laboratory data, and resolution of technical problems and ensuring remedial actions are taken when necessary.
- Ensuring policies and standard operating procedures (SOPs) are relevant and appropriate, and SOPs are reviewed biennially.
- Ensuring enrollment in Proficiency Testing programs for all analytes, and ensuring compliance with Quality Assurance, Quality Control, and Performance Improvement programs.
- Personnel Management: ensuring staff qualifications, training, competency, and continuing education requirements are met.
- All Technical Directors/Supervisors identify training needs, and have authority to train and competency assess technical and administrative staff that support patient-care responsibilities in their clinical sections.
- General Supervisors have delegated authority to: perform training and competency assessment in their disciplines, but must meet the general supervisor qualifications for high complexity testing if assessing staff performing high-complexity testing; monitor test performance; and ensure remedial actions at taken when test systems deviate from established performance specifications.

The following staff have been delegated as Technical Directors, designees by the Medical Director, tasked with authority of roles and responsibilities listed above:

Elaine S. Jaffe, MD	Head of Hematopathology
Maryalice Stetler-Stevenson, MD, PhD	Head of Flow Cytometry Unit
Stefania Pittaluga, MD, PhD	Hematopathology Fellowship Program, and In-Situ Hybridization Lab
Mark Raffeld, MD	Head of Molecular Diagnostics
Armando Filie, MD	Head of Cytopathology and Quality Management Committee Chair
Markku Miettinen, MD	Head of General Surgical Pathology and Immunohistochemistry
Martha Quezado, MD	Program Director AP Residency, Deputy Head Surgical Pathology
David Kleiner, MD, PhD	Head of Post-Mortem, Laboratory Information System, and Tissue Procurement and Processing Facility (TPPF)
Svetlana Pack, PhD	Head of Chromosome Pathology Unit
Joseph Chinquee, DHSc, MT(ASCP)DLM	Clinical Manager, Head Histopathology and Clinical Operations Regulatory Compliance and LP Safety Officer

Frederic G. Barr, MD, PhD
Medical Director, Deputy Chief
Laboratory of Pathology

Frederic Barr

1/3/2018