Competency Model for Pathologists

CAP Learning

Proprietary Information

March 2016
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ABOUT THE COMPETENCY MODEL FOR PATHOLOGISTS
The College of American Pathologists (CAP) is expanding its Competency Model for Pathologists. The CAP worked with the ABMS definitions of the MOC competency categories to make them pathology specific; the College identified specific competencies for each MOC category. The CAP intends this model to serve as a guide for pathologists in planning CME, career planning, meeting MOC requirements, preparing for board recertification, practice re-tooling, and/or targeting performance improvement.

COMPETENCY ORGANIZATIONAL STRUCTURE

The Model is organized by MOC Content Category

Each competency is organized into a hierarchical structure. The page begins with the ABMS MOC competency category name and definition. That is followed by the CAP competency name, competency definition, sub-competencies (if applicable), competency areas and knowledge and skill statements. An illustration of this structure is provided below.

ABMS MOC Competency Category: category name inserted here
ABMS MOC Competency Category Definition: category definition, modified specifically for pathology, inserted here

CAP Competency: competency name inserted here
CAP Competency Definition: competency definition inserted here

← CAP Medical Knowledge/Patient Care (MK/PC) Sub-Competencies – optional level: used only for very large practice areas; not used at all in the remaining four ABMS MOC competency categories

CAP MK/PC Sub-competency Definition: sub-competency definition inserted here

← Competency Areas

MK/PC, Practice-Based Learning & Improvement, and Systems-Based Practice Competency Areas are stated as topics (ie, nouns).

Interpersonal & Communication Skills and Professionalism Competency Areas are stated as behaviors (ie, verbs + nouns).

← Knowledge and Skill Statements – generally, 5-7 statements per Competency Area
## RELATED LEARNING ACTIVITIES
Click on a link below to access a listing of learning activities associated with each competency.

### Medical Knowledge / Patient Care

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### Systems Based Practice

| Informatics                      | Practice Finance                               | Practice and System Integration                                                                   |

### Interpersonal Communication Skills

| Building and Maintaining         | Communication                                 | Teamwork                                                                                          |

### Professionalism

| Ethics                           | Leadership                                    | Respect for Diversity                                                                             |

### Practice-Based Learning and Improvement

| Assimilation of External Evidence | Practice Analysis                            | Process and Outcome Improvement                                                                   |
COMPETENCIES
Click an MOC category name to access competencies for that category.

Interpersonal and Communication Skills

Demonstrate interpersonal and communication skills that result in effective information exchange and teaming with patients, the patients' families, and professional associates.

Medical Knowledge/Patient Care

Medical Knowledge
Demonstrate knowledge about established and evolving biomedical, clinical, and cognate sciences and the application of this knowledge to pathology.

Patient Care
Demonstrate a satisfactory level of diagnostic competence and provide appropriate and effective consultation in the context of pathology services.

Practice Based Learning and Improvement

Demonstrate ability to investigate and evaluate diagnostic and laboratory practices in your own lab, appraise and assimilate scientific evidence, and improve laboratory practices and patient care.

Professionalism

Demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to diverse patient population.

Systems-Based Practice

Demonstrate understanding of and contribution to local, regional, and national health care systems, and support health care in system-based practice definition.
MOC Category: Interpersonal and Communication Skills

Demonstrate interpersonal and communication skills that result in effective information exchange and teaming with patients, the patients’ families, and professional associates.

Competencies
Click a competency name to access the competency page.

Building and Maintaining Relationships
Communication
Teamwork
Competency: Building and Maintaining Relationships

Competency Definition:
Developing strong and enduring relationships through professional networking, consideration of others, and the effective management of conflict situations.

Competency Areas:
A. Network with Others
B. Recognize Others
C. Manage Conflict Effectively

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Network with Others
- Participate actively in local or national professional organizations
- Attend medical staff meetings on a regular basis and solicit input on laboratory operations
- Take initiative to stay connected with professional contacts
- Take initiative to share relevant technical and professional information with others (e.g., new advances in laboratory medicine, research etc.)

Competency Area: Recognize Others
- Treat everyone with courtesy, regardless of position
- Reciprocate communication, assistance, and feedback, recognizing that relationships are not one-sided
- Recognize and praise the contributions of others
- Understand the work style and communication preferences (e.g., Meyers Briggs type indicator) of colleagues and adapt accordingly

Competency Area: Manage Conflict Effectively
- Encourage healthy conflict and stifle unhealthy conflict
- Develop an understanding of the others’ viewpoint during conflict situations
- Be willing to negotiate a solution that meets the needs of both sides
- Do not personalize conflict, focus on the problem not the person
- Remain composed during conflict situations

RELATED LEARNING OPTIONS
Click: Building and Maintaining Relationships

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Supporting Committee(s) N/A
Competency: Communication

Competency Definition:
Initiating and maintaining dialogue with clinicians, patients, peers, hospital administration, and staff in order to positively impact patient outcomes; presenting ideas in a clear, concise and meaningful way while actively listening to and inviting input from others.

Competency Areas:
A. Listen Actively
B. Adapt to Audience
C. Present Ideas Effectively
D. Facilitate Dialogue
E. Communicate Effectively in a Multidisciplinary Setting

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Listen Actively
- Wait to hear the speaker’s entire message before responding
- Set aside distractions (e.g., cell phones, computer) and remain actively engaged in all forms of communication
- Strike a balance between talking and listening during a conversation or meeting
- Paraphrase the speaker’s main points in order to check for understanding
- Ask questions at appropriate times to clarify the speaker’s points

Competency Area: Adapt to Audience
- Shape and clarify content to fit the informational needs of the listener
- Use language familiar to the audience
- Adapt the tone the message to fit the listener and situation
- Respect the time constraints of the situation and/or listener(s)
- Choose the most appropriate communication medium for the situation (face to face, PowerPoint, email, phone, etc.)

Competency Area: Present Ideas Effectively
- State a point of view clearly, directly, and tactfully
- Articulate and support opinions and ideas through the use of data, evidence-based resources, visuals and/or concrete examples
- Synthesize and summarize information in a clear, concise and compelling manner
- Demonstrate effective non-verbal skills such as eye contact, vocal tone, volume, gesturing and physical stance

Competency Area: Facilitate Dialogue
- Encourage others to respond to ideas and acknowledge their point of view
- Keep conversations on-track and re-direct the discussion when necessary
- Use safe and respectful language in dialogue with others
- Participate in meetings while listening to all viewpoints
- Lead an effective meeting and exercise appropriate authority when needed

Competency Area: Communicate Effectively in a Multidisciplinary Setting
- Initiate conversations with caregivers (e.g., clinicians, nurses) when needed to ensure appropriate tests have been ordered
- Review patient specific information and/or test results with clinicians and other caregivers and provide a clear explanation of diagnosis and treatment implications where appropriate
- Initiate a dialogue with the clinician when test results are un-interpretable or do not fit with the morphological or clinical profile of the patient
- Explain the significance of findings in appropriate venues (reports, face-to-face, conferences)
- Participate actively and contribute knowledge in multidisciplinary conversations and meetings regarding patient care (e.g., tumor boards, medical executive committee, quality, infection control)

**RELATED LEARNING OPTIONS**
Click: Communication

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**Supporting Committee(s)** N/A
Competency: Teamwork

Competency Definition:
Supporting and actively contributing to team/departmental goals through effective collaboration, personal responsibility, respect for others, and knowledge sharing.

Competency Areas:
A. Contribute to Team Goals
B. Respect Team Roles and Interdependencies
C. Collaborate with Others

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Contribute to Team Goals
- Champion the goals and desired outcomes of the team/department
- Place team accomplishment ahead of personal success
- Provide assistance as needed and accept requests to assist others
- Take initiative and full responsibility for assigned tasks
- Educate team members and colleagues about your area of expertise

Competency Area: Respect Team Roles and Interdependencies
- Understand own role and the roles of team members
- Expect and facilitate sharing of information within the team
- Respond to requests and communication from others in a timely manner
- Respect role boundaries (avoid assuming others’ work) and hold team members accountable
- Support the team leader

Competency Area: Collaborate with Others
- Avoid exerting undue influence
- Encourage the healthy debate of ideas
- Strive for consensus on key decisions when possible
- Ensure adequate input from others when consensus cannot be reached
- Examine own errors directly and openly

RELATED LEARNING OPTIONS
Click: Teamwork

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Supporting Committee(s) N/A
MOC Category: Medical Knowledge/Patient Care

Medical Knowledge
Demonstrate knowledge about established and evolving biomedical, clinical, and cognate sciences and the application of this knowledge to pathology.

Patient Care
Demonstrate a satisfactory level of diagnostic competence and provide appropriate and effective consultation in the context of pathology services.

Competencies
Click a competency name to access the competency page.

- Autopsy
- Breast Pathology
- Cardiovascular Pathology
- Chemistry
- Cytogenetics
- Cytopathology
- Dermatopathology
- Endocrine Pathology
- Forensic Pathology
- Gastrointestinal Pathology
- Genitourinary Pathology
- Genomics
- Gynecologic/Obstetric Pathology
- Head and Neck Pathology
- Hematology
- Hematopathology
- Hemostasis Pathology
- Hepatopathology
- Heritable Disease Pathology
- Histocompatibility
- Identity and Relationship Testing
- Immunohistochemistry
- Immunology
- Infectious Disease Pathology
- Laboratory Medical Direction
- Microbiology
- Molecular Genetics
- Molecular Oncology
- Neuropathology
- Ophthalmic Pathology
- Orthopedic Pathology
- Pediatric Pathology
- Pharmacogenomics
- Pulmonary Pathology
- Renal Pathology
- Soft Tissue Pathology
- Toxicology/TDM
- Transfusion Medicine/Blood Banking
- Transplant Pathology (Solid Organ)
Competency: Autopsy

Competency Definition:
Employs best practices in performance of the autopsy; these best practices include: obtaining permission for the autopsy and correct referral of Medical Examiner cases, participation where appropriate in death certification/defining cause of death, competent and safe performance of external and internal autopsy dissection, interpretation of patient clinical history, gross and microscopic findings as well as utilization of special techniques, and accurate reporting and communication to maximize educational value and contribution to quality assurance and future patient care.

Competency Areas:
A. Death Certification/Cause of Death  
B. Autopsy Permission  
C. Medical Examiner/External Authority Referrals  
D. Autopsy Safety  
E. Autopsy Procedures – External  
F. Autopsy Procedures – Internal  
G. Procedures Post-dissection  
H. Special Techniques  
I. Frequent Findings  
J. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Death Certification/Cause of Death
- Determine if a death is an expected or unexpected occurrence
- Distinguish between pronouncement of death and certification of death
- Distinguish immediate, intermediate and underlying (proximate) causes of death as they appear on the death certificate
- Differentiate mechanisms of death from non-specific processes and etiologically specific causes of death (eg, mechanisms - cardiac or respiratory arrest, non-specific processes - congestive heart failure or gastrointestinal hemorrhage, etiologically specific - atherosclerotic heart disease or bleeding gastric peptic ulcer)
- Given the potential additive effects of multiple medical conditions, select (when appropriate) a principal cause of death to serve as the underlying (ie, proximate) cause of death
- Identify circumstances when it may be appropriate to qualify a cause of death as probable or presumed
- Distinguish between appropriately and inappropriately completed cause of death statements
- Differentiate conditions included on the death certificate in Part I (cause of death) from those included in Part II (other significant conditions)

Competency Area: Autopsy Permission
- Demonstrate knowledge of hospital/ local policies regarding death processing and procurement of autopsy consent
- Demonstrate knowledge of hospital/ local/ state policies regarding autopsy permission requirements for stillborns/ fetuses
- Determine the validity of the autopsy consent by assessing appropriate authorization by next-of-kin as designated by state laws and hospital policy
- Ensure review of and adherence to restrictions to the autopsy imposed by next-of-kin
- Ensure proper identification of the body to be autopsied (eg, inspect toe tag and/or hospital identification band)
- Preserve patient confidentiality and privacy (eg, do not discuss case specifics in public places)
- Promote the practice of obtaining autopsy permission to other health care professionals and educate on the value of the autopsy in Medicine
Competency Area: Medical Examiner/External Authority Referrals

- Demonstrate knowledge of local laws regarding notification of deaths to external authorities (e.g., Medical Examiner/Coroner/Justice of the Peace if applicable)
- Define manner of death and classify deaths accordingly
- Identify circumstances of death that require notification to external authorities and ensure appropriate referral of such deaths
- Document all communications to external authorities in the patient’s medical record

Competency Area: Autopsy Safety

- Ensure appropriate instrumentation availability and facilities to carry out autopsies in accordance with universal safety procedures
- Determine if a death is clinically considered to be due to a recognized high-risk pathogen (e.g., Creutzfeldt-Jacob disease, HIV, tuberculosis) or associated with potential environmental risk (e.g., implanted/injected radioactive substances)
- Utilize a special autopsy facility for high-risk pathogen autopsy if one is available or determine if the case should be referred to another institution
- Employ special autopsy procedures appropriate for high-risk pathogen (e.g., control of fluids/tissues for Creutzfeldt-Jacob, decontamination for Creutzfeldt-Jacob, prevention of drying/aerosolization for tuberculosis)
- Prepare specimens from high-risk pathogen cases for confirmatory documentation (e.g., microbial culture, electron microscopy, immunohistochemistry, molecular studies)
- Ensure post-autopsy cleanup procedures are appropriate for high-risk pathogen or environmental risk (e.g., wash contaminated surfaces with commercial bleach and rinse surgical instruments in 2N NaOH)
- Report infectious disease case(s), as appropriate, to institution infectious disease control department and/or local and state agencies according to guidelines

Competency Area: Autopsy Procedures - External

- Confirm patient identity, utilizing both permission form and body identification tags/bands
- Communicate with members of the clinical team/caregivers prior to starting the autopsy
- Determine autopsy permission restrictions as recorded on permission form and adhere to those restrictions
- Describe and report external features (e.g., apparent age, sex, habitus, rigor and livor mortis and key measurements in fetal/neonatal cases such as body length, head and abdominal circumference)
- Document all relevant external findings including in “hidden” areas (e.g., lesions, scars, tattoos, pigmentary changes, pharynx, nose, ear canal, lymph nodes, anus, and between fingers/toes)
- Photograph relevant findings
- Request or conduct imaging studies such as x-ray as appropriate and as available (e.g., trauma cases)

Competency Area: Autopsy Procedures - Internal

- Perform autopsy utilizing standard dissection techniques (e.g., Letulle/Rokitansky or Virchow method)
- Record relevant weights and measurements as well as findings including, as appropriate, photography
- Examine skull and brain including meningeal membranes and pituitary, identifying normal and abnormal features
- Obtain blood and other fluids for potential chemical/other studies (e.g., cerebrospinal fluid, urine, vitreous)
- Prepare preparations for cytopathologic examination as needed (e.g., “touch prints” of tumors)
- Select appropriately sized tissue (approximately 1 cm thick) for retention to allow optimal fixation for possible histologic preparations and subsequent microscopic evaluation
- Select relevant tissues for special studies (e.g., immunohistochemistry, lymphoma studies, electron microscopy, cytogenetics, molecular studies)
- Review case, in teaching programs, with the attending pathologist
- Prepare and communicate clinically relevant and timely provisional anatomic diagnoses (PAD)
Competency Area: Procedures Post-dissection
- Review and correct clinical summary and macroscopic description
- Trim saved tissues for microscopy utilizing macroscopic descriptions and the PAD as a guide
- Review slides and document histopathology as appropriate to institution practice
- Select appropriate histologic sections for special studies (eg, histochemistry, immunohistochemistry) and document findings
- Obtain results of ancillary studies (eg, microbiology, chemistry) and incorporate them into the final report
- Obtain results of previous anatomic studies (eg, biopsy, resection, cytopathology), including studies from other institutions, and incorporate them, where appropriate, into the final report
- Review entire case, in teaching programs, with attending pathologist
- Ascertain, when appropriate and wherever possible, the cause of death based on the collective findings of the case

Competency Area: Special Techniques
- Determine when to collect vitreous, blood, urine, bile, or stomach contents for toxicology or culture and collect specimens with correct technique
- Utilize imaging techniques such as x-ray as appropriate and available and recognize strengths and limitations of each method
- Employ special techniques to identify pneumothorax or air embolism
- For suspected ischemic heart disease, consider epicardial dissection with in toto removal of coronary arteries, decalcification, and sectioning at 5 mm intervals
- If available, identify when to use cytogenetics, flow cytometry or molecular testing for fresh or frozen tissue and use the correct technique for retrieval and storage
- Recognize when to acquire tissue for research and collect expeditiously using the best technique
- Employ special stains, immunohistochemistry, and electron microscopy where available and applicable to reach a diagnosis

Competency Area: Frequent Findings
- Document findings of trauma including musculoskeletal injuries
- Identify congenital abnormalities in fetal/stillborn autopsies
- Recognize hemorrhage (ie, retroperitoneal, pericardial with tamponade) and assess for etiology/potential sources
- Assess the decedent for signs of systemic infection, in particular opportunistic infections in immunocompromised patients
- Evaluate organs and tissues for the presence of malignancy and perform studies to identify the primary tumor
- Identify gross and microscopic evidence of pulmonary embolus
- Diagnose gross and microscopic findings of myocardial infarction
- Determine if findings of abdominal compartment syndrome are present, including ischemic bowel

Competency Area: Reporting and Communication
- Communicate with members of the clinical team/caregivers prior to starting the autopsy
- Prepare a well-organized, thorough preliminary/provisional autopsy diagnosis report (PAD) including at least principal gross findings
- Perform appropriate literature searches to support pathologic findings with citation of references in the autopsy report as needed
- Generate and disseminate a clear, concise final autopsy report which integrates clinical history, gross and microscopic findings, and ancillary testing to document the pathologic basis for disease/explain relevant pathophysiologic events
- Communicate results to clinician(s), quality assurance committee(s) and, when appropriate, families
- Document and communicate discrepancies between premortem diagnoses and autopsy findings to relevant clinicians in a professional manner
• Prepare and present autopsy cases in intradepartmental autopsy conferences, interdepartmental Mortality and Morbidity conferences and other meetings
• Collaborate with other members of the health care team to learn from autopsy results and develop evidence-based health care delivery strategies that improve patient care

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Supporting Committee(s) N/A
Competency: Breast Pathology

Competency Definition:
Employs best practices in evaluating and reporting breast specimens; integrates clinical, pathologic, and radiologic information in support of optimum patient care; keeps up to date and participates in multidisciplinary breast cancer management.

Competency Areas:
A. Breast Lesion Identification
B. Core Biopsy
C. Radiologic/Pathologic Correlation
D. Breast Conservation
E. Sentinel Lymph Node Assessment
F. Ancillary Studies
G. Treatment Implications
H. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Breast Lesion Identification
- Diagnose and understand the clinical significance of commonly recognized breast lesions, eg, epithelial proliferative lesions, columnar cell lesions (including flat epithelial atypia), papillary and fibroepithelial lesions, lobular neoplasia, special and no special type carcinomas, mimics of carcinoma and spindle cell proliferations
- Distinguish usual ductal hyperplasia from atypical ductal hyperplasia and low-grade ductal carcinoma in situ (DCIS)
- Recognize and distinguish morphologic mimics of carcinoma in breast pathology
- Describe the morphologic and clinical features typically associated with BRCA1 mutation
- Describe the relationship between morphologic features of carcinomas and expected predictive factor results

Competency Area: Core Biopsy
- Recognize the limitations of core biopsy in diagnosing some breast lesions and understand when lack of correlation between histologic and radiographic findings requires additional tissue for study
- Determine when to recommend excision based on core biopsy findings
- Recognize in resection specimens the changes/artifacts associated with previous core biopsy, eg, squamous metaplasia, lesion disruption and epithelial displacement
- Ensure that tissue used for predictive factor testing is appropriate and that issues such as specimen adequacy, fixation and artifacts do not render testing unreliable

Competency Area: Radiologic/Pathologic Correlation
- Understand the importance of communication between pathologists and radiologists in evaluating specimens obtained with image guidance
- Recognize the importance of radiographic information (including reviewing specimen radiographs) in ensuring optimal pathologic evaluation
- Suggest additional steps when initial pathologic examination does not identify the targeted lesion (eg, mammographic evaluation of blocks)
- Correlate the histopathologic findings with imaging and clinical findings, in regards to calcifications, masses, densities, architectural distortions and enhancing lesions
- Recommend a course of action when the pathologic findings do not correlate with imaging studies
Competency Area: Breast Conservation
- Determine when re-excision is recommended following breast conservation surgery
- Determine appropriate tissue submission for histologic examination based on imaging and gross features
- Understand the significance of invasive or in situ carcinoma at or near margins within the context of a specific case

Competency Area: Sentinel Lymph Node Assessment
- Explain the role of sentinel lymph node biopsy in breast cancer
- Ensure that sentinel lymph nodes are appropriately evaluated
- Explain the utility of ancillary assessment of sentinel lymph nodes (eg, cytokeratin staining) and discuss potential pitfalls in interpretation
- Classify sentinel lymph node findings following AJCC criteria
- Understand the significance of macrometastases as compared with isolated tumor cells

Competency Area: Ancillary Studies
- Describe the requirements for specimen handling, appropriate fixation intervals and assay validation as recommended in the current ASCO/CAP HER2 and ER/PR testing guidelines
- Describe the scoring criteria for HER2 and hormone receptors as recommended in the current ASCO/CAP HER2 and ER/PgR testing guidelines
- Understand how decalcifying agents and fixatives other than buffered formalin can alter the results of IHC and ISH tests
- Address discrepancies between expected biomarker test results and morphologic findings
- Describe a course of action to address discrepancies in results between multiplex gene assays and predictive factor tests
- Understand the role of internal and external controls in ensuring accurate predictive factor test results
- Understand the relationship between the molecular classification of breast cancer, morphologic features, tumor grade and predictive factor test results
- Understand the use and limitations of biomarker testing
- Describe how molecular profiling can be used to help refine the classification of breast cancer, assess prognosis, and predict response to therapy
- Understand how multiplex gene assay results can be impacted by specimen selection/histologic features (eg, DCIS, inflammation)

Competency Area: Treatment Implications
- Recognize the importance of HER2 targeted therapy and appropriately select patients for its use
- Understand the effect of neoadjuvant therapy on specimen evaluation
- Understand appropriate patient selection criteria for using a multiplex gene assay for the purpose of informing treatment decisions
- Understand basic breast cancer treatment options as predicted by test results
- Explain the pathologic factors that influence post-surgical radiation therapy
- Understand how to integrate traditional pathologic data and predictive factors with molecular data and resolve discordant results prior to treatment planning decisions
- Explain which patients are most likely to benefit from the addition of chemotherapy based on the tumor’s histopathologic features, predictive factors, and molecular profile
- Describe how proliferation has been correlated with prognosis and response to chemotherapy for patients with invasive breast cancer
- Explain how multi-parameter gene/protein expression assays are used to determine prognosis and treatment of patients with breast cancer
Competency Area: Reporting and Communication

- Follow published recommendations for breast cancer reporting and appropriate staging
- Comply with current ASCO/CAP ER/PgR and HER2 reporting guidelines
- Generate clear, accurate and complete reports that effectively communicate results and treatment implications to the patient’s health care team
- Demonstrate willingness and ability to discuss current issues relating to breast carcinoma with clinicians and multidisciplinary health care teams, (eg, predictive factor testing, hereditary breast cancer and techniques to improve patient safety)
- Explain the impact of preanalytic variables on predictive factor testing to clinicians and multidisciplinary health care teams

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Supporting Committee(s) N/A
Competency: Cardiovascular Pathology

Competency Definition:
Employs best practices performing gross examination and microscopic interpretation in the diagnosis of cardiovascular diseases; these best practices include: specimen collection, gross evaluation, and appropriate sampling and handling for routine and ancillary testing; integrating laboratory results and imaging findings with morphologic, immunophenotypic, and molecular findings; understanding how specific diagnoses impact treatment and outcome; and accurate reporting and communication to ensure clear and comprehensive diagnosis and optimal patient care.

Sub-competencies:
1. Atherosclerosis and Ischemic Heart Disease
2. Cardiac Neoplasms and Pseudoneoplasms
3. Cardiac Transplant Pathology
4. Cardiomyopathies and Myocarditis
5. Congenital Heart Disease
6. Non-Atherosclerotic Vascular Disease
7. Valvular Disease

Sub-competency: Atherosclerosis and Ischemic Heart Disease

Sub-competency Definition:
Applies best practices in procedures for evaluation of coronary arteries and heart, integrating the morphologic interpretation of coronary arteries with the clinical history, laboratory values and specialized ancillary testing results to diagnose atherosclerotic heart diseases and its complications.

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Reporting and Communication
D. Testing Methods
E. Clinicopathologic Correlation
F. Consequences and Complications
G. Treatment and Intervention Implications

COMPETENCY AREA /KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Recognize the epidemiology, modifiable (ie, age, gender, genetics) and non-modifiable risk factors (ie, hyperlipidemia, hypertension) associated with atherosclerosis
- Recognize the pathogenesis (ie, endothelial injury, hemodynamic disturbances) related to atherosclerosis
- Distinguish between the clinical syndromes associated with ischemic heart disease (ie, angina pectoris, chronic ischemic heart disease, myocardial infarction, sudden cardiac death)
- Recognize the pathogenesis (ie, coronary artery occlusion, myocardial response) of myocardial infarction
- Recognize the importance of typical clinical features, electrocardiographic changes and elevation of cardiac enzymes in the diagnosis of myocardial infarction
- Identify the evolution of morphological and ultrastructural changes in myocardial infarction with time

Competency Area: Specimen Handling
- Demonstrate the skill to dissect the main coronary arteries and their branches from the heart
- Recognize the importance of proper decalcification and sectioning of coronary arteries for appropriate assessment of atherosclerosis
- Demonstrate the skill to handle hearts with coronary artery bypass graft surgery (ie, measure the lengths of the grafts and carefully dissect the grafts, distal anastomotic sites and the distal runoffs)
- Use imaging studies like x-ray examination, for hearts with coronary artery stents before processing
Competency Area: Reporting and Communication

- Generate clear, concise, and accurate reports that effectively communicate the clinical and pathologic correlation and treatment implications to the patient’s health care team
- Integrate results of ancillary testing into the final diagnosis
- Generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency Area: Testing Methods

- Use imaging studies like x-ray examination for demonstrating the stents in arteries and vascular grafts
- Utilize histochemical method (triphenyltetrazolium chloride) for gross specimens for early ischemia
- Utilize immunohistochemistry methods (C4D, C9, Troponin T) for early ischemic changes
- Interpret electron microscopic characteristics of early changes of myocardial infarction

Competency Area: Clinicopathologic Correlation

- Correlate clinical history, imaging findings with morphologic features of atherosclerotic coronary arteries.
- Correlate clinical history, imaging findings with morphologic features of coronary arteries with intervention (ie, angioplasty and stenting)
- Correlate clinical history (ie, duration of bypass grafting surgery), and imaging findings with morphologic features of hearts with bypass grafts
- Generate integrated pathology report with clinical, imaging and morphology findings

Competency Area: Consequences and Complications

- Recognize the morphology of the atherosclerotic plaques and consequences of atherosclerotic coronary artery disease (ie, stenosis, acute plaque change)
- Recognize location, wall extension and size of acute myocardial infarct
- Recognize the evolution of morphological changes (gross and microscopic and ultrastructural) in myocardial infarction with time
- Distinguish the morphological features and clinical significance of scattered microscopic infarcts, subendocardial infarction, and transmural infarct
- Recognize the early complications, within two weeks of myocardial infarction (ie, rupture of cardiac wall and cardiac tamponade)
- Recognize evidence of late cardiac remodeling
- Recognize the long term complications of myocardial infarction (ie, arrhythmia, Dressler syndrome, sudden death)

Competency Area: Treatment and Intervention Implications

- Recognize the morphological changes in vessels after therapeutic intervention (ie, plaque rupture, dissection in the media and abrupt closure) post balloon valvuloplasty
- Recognize the morphological changes in vessels after therapeutic stenting (ie, early thrombosis and migration, perforation post stenting)
- Assess the morphological changes in synthetic or autologous grafts (ie, early thrombotic occlusion, fibrointimal proliferation, atherosclerotic plaques) used to replace damaged vessels or bypass diseased arteries
- Recognize the morphological changes of myocardial infarction secondary to reperfusion changes after coronary intervention
Competency: Cardiovascular Pathology
Sub-competency: Cardiac Neoplasms and Pseudoneoplasms

Sub-competency Definition:
Applies best practices in evaluation of cardiac tumor specimens, integrating the morphologic interpretation with the clinical history, laboratory values and specialized ancillary testing results to diagnose cardiac neoplasms and other mass forming lesions.

Competency Areas:
A. Disease Types
B. Differential Diagnosis
C. Ancillary Studies
D. Treatment and Intervention Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- List the relative frequencies of the most common tumors involving the heart
- Describe the most common benign primary cardiac tumors and describe their typical clinical presentations
- Identify common malignant primary cardiac tumors

Competency Area: Differential Diagnosis
- Generate a list of likely tumors based on the given cardiac chamber in which the tumor arises and whether it is intramural or growing into that chamber
- Indicate which of the primary cardiac tumors are more likely to arise during childhood
- List non-neoplastic processes that may clinically resemble cardiac neoplasms
- Diagnose the most common primary atrial masses (myxoma, papillary fibroelastoma, mural thrombus) based on their histopathologic features
- Diagnose the most common intramural cardiac masses using histopathology
- Diagnose pericardial-based neoplasms on the basis of their characteristic histopathologic features
- Recognize features indicating malignant potential in cardiac neoplasms

Competency Area: Ancillary Studies
- Utilize immunohistochemistry and molecular ancillary testing to appropriately classify primary cardiac sarcomas and lymphomas
- Employ immunohistochemistry to differentiate cardiac myxoma with hemorrhage from organizing hematoma with exuberant organization

Competency Area: Treatment and Intervention Implications
- List the genetic syndromes associated with cardiac myxomas, rhabdomyomas, and fibromas
- Distinguish cardiac neoplasms with metastatic potential from benign tumors
- Recognize potential complications (embolization, obstruction, arrhythmia, etc.) typically associated with specific cardiac neoplasms
- Determine when evaluation of margins is required for cardiac tumors
**Competency: Cardiovascular Pathology**  
**Sub-competency: Cardiac Transplant Pathology**

**Sub-competency Definition:**  
Applies best practices in procedures for evaluation of post-transplant endomyocardial biopsies, explanted native hearts and failed allografts, integrating the morphologic interpretation of such specimens with the clinical history, laboratory values and specialized ancillary testing to diagnose acute and chronic cardiac allograft rejection, infections, and neoplastic processes.

**Competency Areas:**  
A. Disease Types  
B. Specimen Handling  
C. Differential Diagnosis  
D. Reporting and Communication  
E. Testing Methods  
F. Ancillary Studies

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Disease Types**
- Identify the etiology, pathogenesis, and clinical features of acute cellular and antibody mediated rejection  
- Identify the etiology, pathogenesis, and clinical features of chronic rejection including transplant arteriopathy in explanted failed allografts at retransplantation or autopsy  
- Recognize the histologic features of recurrent disease, especially amyloidosis and giant cell myocarditis in post-transplant endomyocardial biopsy samples

**Competency Area: Specimen Handling**
- Recommend the preparation and handling necessary for a post-transplant endomyocardial biopsy sample including proper fixation and triage for special or ancillary studies when indicated  
- Establish the rationale for basic dissection approaches to explanted native hearts as well as failed cardiac allografts including short axis horizontal (bread loaf), four chamber echocardiographic plane, and parasternal long-axis plane

**Competency Area: Differential Diagnosis**
- Recognize the light microscopic features of acute (cellular) and antibody mediated rejection  
- Identify the gross and histologic features of chronic rejection including transplant arteriopathy in explanted failed allografts at retransplantation or autopsy  
- Describe the histologic features of recurrent disease, especially amyloidosis and giant cell myocarditis in post-transplant endomyocardial biopsy samples  
- Recognize the light microscopic features of acute ischemic (preservation) injury, healing and healed previous biopsy sites, endocardial lymphocytic infiltrates (Quilty effect), viral myocarditis secondary to cytomegalovirus (CMV) and adenovirus, infection with toxoplasmosis, and post transplantation lymphoproliferative disorder (PTLD)

**Competency Area: Reporting and Communication**
- Generate clear, concise and accurate reports that effectively communicate endomyocardial biopsy results and treatment implications to the patient’s health care team  
- Report the histologic findings from post-transplant endomyocardial biopsies utilizing the 2004 International Heart and Lung Transplantation (ISHLT) Grading scale for both cellular and antibody mediated rejection
Competency Area: Testing Methods
- Recognize the light microscopic features of acute (cellular) and antibody mediated rejection
- Recognize the gross and histologic features of chronic rejection including transplant arteriopathy in explanted failed allografts at retransplantation or autopsy

Competency Area: Ancillary Studies
- Recognize the pattern of positive immunohistochemical (IHC) or immunofluorescent (IF) staining for C4d or C3d in post-transplant endomyocardial biopsy specimens consistent with antibody mediated rejection
- Recognize the pattern of positive staining with T cells (CD3), B cells (CD 20), Kappa and Lambda light chains and in situ hybridization for EBV (EBER) in post transplantation lymphoproliferative disorder (PTLD)
- Recognize the pattern of positive IHC staining for cytomegalovirus (CMV), and adenovirus

Competency: Cardiovascular Pathology
Sub-competency: Cardiomyopathies and Myocarditis

Sub-competency Definition:
Applies best practices in procedures and clinical indications for evaluation of cardiac specimens (endomyocardial biopsy, myectomy, and resection'autopsy specimens), integrating the morphologic interpretation with the clinical history, laboratory values and specialized ancillary testing results to diagnose myocarditis and cardiomyopathies (primary and secondary).

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Differential Diagnosis
D. Ancillary Studies
E. Treatment and Intervention Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS
Competency Area: Disease Types
- Recognize myocarditis and list possible causes
- Distinguish primary from secondary forms of cardiomyopathy
- Identify the etiologies and physiologic consequences of dilated cardiomyopathy
- Define arrhythmogenic cardiomyopathy and discuss possible mechanisms
- Define hypertrophic cardiomyopathy and discuss its physiologic consequences
- Define restrictive cardiomyopathy and discuss causes of restrictive ventricular physiology
- Determine what features in a cardiac biopsy specimen suggest a chronic and irreversible process
- Recognize the cardiac myocyte nuclear changes that occur in myocyte hypertrophy

Competency Area: Specimen Handling
- Establish instructions for obtaining biopsy samples in the cardiac catheterization lab and processing in the histology laboratory
- Determine an appropriate strategy for sampling of tissue sections from autopsy and explant specimens to maximize diagnostic yield most efficiently
- Differentiate between media and fixatives alternatives to determine which is appropriate for handling specimens destined for immunofluorescence, electron microscopy, molecular testing, and other ancillary tests
Competency Area: Differential Diagnosis
- Identify clinical and pathologic criteria for secondary causes of dilated cardiomyopathy
- List the Dallas Criteria for myocarditis
- Classify likely causes of myocarditis based on the pattern and type of inflammation seen microscopically
- Utilize appropriate histochemical stains when evaluating specimens to help determine the etiology of cardiomyopathy
- Recognize the distinguishing features of morphologic mimics of hypertrophic cardiomyopathy
- Differentiate between amyloidosis, eosinophilic endomyocardial disease, and primary restrictive cardiomyopathy on the basis of gross and microscopic features
- Recognize the specific histopathologic and molecular features of arrhythmogenic cardiomyopathy
- Compare the specific histopathologic and molecular features of arrhythmogenic cardiomyopathy with its mimics

Competency Area: Ancillary Studies
- Compare the benefits versus limitations and cost of viral nucleic acid testing of cardiac samples in the diagnosis and treatment of myocarditis
- Review the likelihood of detecting a causative genetic mutation in patients with congenital dilated cardiomyopathy, hypertrophic cardiomyopathy, and arrhythmogenic cardiomyopathy
- Determine when genetic testing for "channelopathies" should be recommended in the investigation of sudden death with a structurally normal heart
- Identify the role of immunofluorescence staining for cell junction proteins in possible cases of arrhythmogenic cardiomyopathy
- Determine when amyloid subtyping by mass spectrometry should be performed

Competency Area: Treatment and Intervention Implications
- Recognize the significance of giant cell myocarditis versus other types of myocarditis in terms of clinical management
- Determine when genetic testing may be indicated for hypertrophic cardiomyopathy and how this might impact its clinical diagnosis, management and family screening
- List the common causes of death in patients with dilated cardiomyopathy

Competency: Cardiovascular Pathology
Sub-competency: Congenital Heart Disease

Sub-competency Definition:
Applies best practices in procedures for evaluation of congenital heart disease in autopsy and explanted native hearts, integrating gross morphology with clinical and surgical history, imaging studies.

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Reporting and Communication
D. Clinicopathologic Correlation
E. Consequences and Complications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Discuss the etiology (embryologic basis), pathogenesis, and clinical features of cardiovascular shunts (e.g., atrial septal defect (ASD), ventricular septal defect (VSD), atrioventricular septal defect, aortopulmonary septal defect and patient ductus arteriosus (PDA))
• Recognize the etiology, pathogenesis and clinical features of conotruncal anomalies (eg, tetralogy of Fallot (TOF), pulmonary atresia with ventricular septal defect, double outlet right ventricle, persistent truncus arteriosus, complete transposition of the great arteries, congenitally corrected transposition of the great arteries)
• Recognize the etiology, pathogenesis and clinical features of single functional ventricles (eg, tricuspid atresia, double inlet left ventricle, aortic atresia (hypoplastic left heart syndrome), pulmonary atresia with intact ventricular septum)
• Recognize the etiology, pathogenesis and clinical features of cardiovascular obstructions (eg, aortic stenosis, pulmonary stenosis, coarctation of the aorta)
• Recognize the etiology, pathogenesis and clinical features of additional anomalies (eg, anomalous pulmonary venous connection, Ebstein’s anomaly, coronary and conduction anomalies)
• Distinguish morphologic features of diseases that cause cyanosis
• Distinguish morphologic features of diseases that cause acyanotic congenital heart disease

Competency Area: Specimen Handling
• Describe the importance of initial evaluation of pulmonary artery and vein connections, number of spleens and malrotations of the bowel as well as location of the liver
• Confirm relative position of vena cavae, azygos, and hemiazygos veins, as well isomerism changes of atria and bronchi if anomalies in these areas exist
• Describe the procedure for formalin fixation of the combined heart and lung block (ie, inflating lungs by transtracheal gravity or syringe injection perfusion; the heart by syringe or continuous perfusion system)
• Describe the utility of four chamber and short axis echocardiographic planes of dissection along with parasternal long axis, selected windows and inflow /outflow approaches based on clinical imaging and operative and/or catheter-based interventions

Competency Area: Reporting and Communication
• Generate concise reports utilizing the segmental approach for evaluation and description of anomalies and overall relationships
• Document interventions including catheter-based as well as open operative procedures
• Describe status of interventions as well as secondary effects of original disease, secondary effects of intervention and methods of failure if present

Competency Area: Clinicopathologic Correlation
• Describe the gross morphologic features of cardiovascular shunts, conotruncal anomalies, single functional ventricles, and additional anomalies
• Correlate the gross morphologic features of cardiovascular shunts, conotruncal anomalies, single functional ventricles, and additional anomalies with pretreatment and post-treatment imaging findings when appropriate

Competency Area: Consequences and Complications
• Describe the secondary cardiopulmonary effects of left to right shunts, right to left shunts, and obstructive lesions including but not limited to atrial and/or dilatation; ventricular hypertrophy, fibrosis, focal, or regional myocardial injury; native or shunt vascular thrombosis
• Describe the histologic changes using the modified Heath-Edwards grading scale of the pulmonary vasculature primarily in patients with left to right shunts who develop pulmonary hypertension
• Recommend genetic counseling to families with potential syndromic findings when appropriate
• Evaluate the autopsy or explant specimen for gross and/or microscopic changes secondary to operative treatment or interventional (catheter-based) procedures (ie, residual shunts (ASD, VSD, PDA), residual subpulmonary stenosis (TOF), residual or recurrent coarctation, residual or regression of atrial or ventricular hypertrophy or dilatation, aortic aneurysm, dissection and rupture following coarctation repair, conduit stenosis and/or calcification of bioprosthetic valve, thrombosis and or neointimal hyperplasia within conduit tube graft, or synthetic Blalock-Taussig shunt graft, partial dehiscence, mural thrombus formation or calcification of atrial or ventricular septal or interventricular closure patch or "clamshell" type device, infective endocarditis, pulmonary arteriovenous fistula, pulmonary vein stenosis, damage to sinus node or its artery, epicardial coronary arteries, ventricle, atroventricular conduction tissue, status of pulmonary hypertensive vascular disease, evidence of extracardiac infection)
Competency: Cardiovascular Pathology
Sub-competency: Non-Atherosclerotic Vascular Disease

Sub-competency Definition:
Applies best practices in evaluation of vascular specimens, integrating the morphologic interpretation with the clinical history, laboratory values and specialized ancillary testing results to diagnose diseases of the vascular system.

Competency Areas:
A. Disease Types
B. Differential Diagnosis
C. Testing Methods
D. Treatment and Intervention Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Distinguish between true, false, and dissecting types of aneurysm
- Define aortic dissection, its two major types and risk factors
- Classify vasculitis, based on vessel size
- Recognize IgG4 related inflammatory disorders versus inflammatory aortic aneurysms
- Define fibromuscular dysplasia, common sites and consequences
- Define varicose veins, predisposing factors and potential complications
- Define lymphedema and common causes
- Recognize the gross and microscopic features of giant cell arteritis
- Recognize the gross and microscopic features of polyarteritis nodosa, Kawasaki’s disease, and Buerger’s disease (thromboangiitis obliterans)

Competency Area: Differential Diagnosis
- Identify common causes of true aortic aneurysms
- Specify the different etiologies of medial degeneration in ascending aortic aneurysms
- Differentiate the various entities presenting as chronic granulomatous vasculitis
- Differentiate the various entities presenting as acute necrotizing vasculitis
- Differentiate the various vasculitis entities associated with immune complex deposition
- Define the clinical features and associations for Wegener’s granulomatosis, Churg-Strauss syndrome, and microscopic polyangiitis
- Classify the three types of fibromuscular dysplasia according to their histopathologic features
- Recognize features of vulnerable or unstable atherosclerotic plaque

Competency Area: Testing Methods
- Utilize histochemical stains (e.g., elastic, trichrome, Movat, etc) to elucidate diagnostic features of vascular diseases
- Interpret results of serologic testing for auto-immune disease that are pertinent in the classification of vasculitis syndromes
- Recommend genetic testing for familial aneurysm syndrome in appropriate cases and relate how results of this may impact early intervention

Competency Area: Treatment and Intervention Implications
- Classify aortic dissections according to either the Stanford or DeBakey classification systems
- Indicate which types of aortic dissections require emergent intervention
- Address factors that predispose to the development of venous thrombosis
- Generate a list of potential complications of venous thrombosis
Competency: Cardiovascular Pathology
Sub-competency: Valvular Disease

Sub-competency Definition:
Applies best practices in procedures for evaluation of valvular disease, integrating the morphologic interpretation of gross and microscopic features with the clinical history and laboratory results to diagnose valvular abnormalities.

Competency AREA:
A. Disease Types
B. Specimen Handling
C. Differential Diagnosis
D. Reporting and Communication
E. Testing Methods
F. Clinicopathologic Correlation

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Recognize the etiology, pathogenesis and clinical features of conditions causing calcific aortic stenosis, infective endocarditis and mitral valve prolapse
- Recognize the etiology, pathogenesis, morphology and clinical features of rheumatic heart disease
- Recognize the etiology and clinical features of mitral annular calcification and pulmonary stenosis (ie, acquired, congenital valvular, subvalvular or supravalvular)
- Recognize the various types of prosthetic valves and their complications
- Recognize the etiology, pathogenesis and clinical features of tricuspid stenosis (ie, congenital, carcinoid valvular disease, rheumatic)

Competency Area: Specimen Handling
- Understand the significance of receiving fresh valve specimen in possible cases of infective endocarditis
- Handle specimens appropriately when collecting for microbiology cultures
- Demonstrate the skill for gross inspection of the valves involving both the flow and non-surface and also of close range photographs
- Recognize the use of routine stains and special stains (ie, Movat Pentachrome in routine interpretation and special stains Gram and GMS /PAS for possible cases of infective endocarditis)
- Identify and photograph prosthetic valves, appropriate handling of prosthetic valves, including selected x-ray imaging of bioprosthetic valves for calcification

Competency Area: Differential Diagnosis
- Identify the differences in morphology causing aortic stenosis (ie, degenerative, congenitally deformed valve and post inflammatory scarring)
- Identify the difference in the gross and microscopic features differentiating vegetations of infective endocarditis and nonbacterial thrombotic endocarditis
- Recognize the differences in the morphology between infective endocarditis and endocarditis of systemic lupus erythematosus
- Differentiate between various types of mechanical and bioprosthetic valves and their complications

Competency Area: Reporting and Communication
- Communicate critical/significant diagnosis (ie, infective endocarditis) requiring immediate action.
- Integrate results of ancillary testing into the final diagnosis
- Generate clear, concise, and accurate ancillary testing documentation
- Integrate the clinical, morphological findings of prosthetic valves into a report
- Convey report findings to the clinicians, and if needed, to the manufacturing company
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams
**Competency Area: Testing Methods**
- Utilize imaging studies like X-ray examination for select cases of native and bioprosthetic valves for detection of amount of calcification
- Use microbiologic cultures recognizing the microorganisms in cases of infective endocarditis
- Utilize molecular techniques like PCR amplification and direct sequencing of DNA in cases of infective endocarditis

**Competency Area: Clinicopathologic Correlation**
- Correlate imaging findings with clinical and morphologic features of native valvular diseases
- Correlate the clinical findings (ie, the duration of implantation, the reason for explant) with the morphological findings in prosthetic valves
- Generate the integrated pathology report with clinical, morphologic, ancillary tests and include comment about treatment

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**Supporting Committee(s)**
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**Competency: Chemistry**

**Competency Definition:**
Employs best practices in performing and interpreting clinical chemistry testing. Prepares and enforces proper guidelines for collection, handling, transportation, and processing of samples related to chemistry testing, and is able to communicate with clinical staff about the issues that affect results when these proper steps are not followed; oversees implementation of new test methods maintenance and improvement of existing methods and is able to review validation testing results to assure tests meet analytical goals and clinical needs; interprets test results for common and uncommon tests in the clinical chemistry area, and is able to be an effective consultant to physicians in selection of initial tests and testing to follow-up on abnormal results or address clinical questions; recognizes limitations of chemistry tests and is able to direct the investigation of samples when results are suspected of being erroneous or misleading.

**Sub-competency:**
1. General Principles of Chemistry
2. Methods of Measurement
3. Tests for Diagnosis/Monitoring of Disease

**Sub-competency: General Principles of Chemistry**

**Sub-competency Definition:**
Applies knowledge of factors that affect the preanalytic portion of the testing process to provide appropriate controls to sample collection and handling to minimize variation; utilizes basic principles of quality control to assure that laboratory methods are performing well enough to meet clinical and regulatory requirements; interprets proficiency testing data to detect biases in methods and determine if changes in testing procedures are required; applies knowledge of statistical tests in evaluating laboratory data, as well as evaluating published literature.

**Competency Areas:**
A. Method Selection/Method Validation
B. Quality Control
C. Statistics
D. Reference Intervals
E. Pre-analytic Factors
F. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Method Selection/Method Validation**
- Select methods with minimal chemical interferences to minimize inaccuracy (biases)
- Select methods that meet clinical requirements or improve clinical utility
- Modify procedures where appropriate to improve precision (eg, enhance sensitivity, extend the analytical range, increase stability of the analyte, and reduce other variabilities in the method)
- Recognize differences in imprecision related to time that separates measurements (eg, within run < within day < within calibration)
- Determine the role of signal/noise ratio in the analytic strength of comparable measurement methods (eg, light scattering versus absorption; fluorescence, phosphorescence and chemiluminescence versus most other optical techniques (eg, chromatographic separation versus immunological binding, ordinary nephelometry versus particle enhanced nephelometry)
**Competency Area: Quality Control**
- Select appropriate control materials that will reliably evaluate method performance
- Establish control rules that will detect significant variation from baseline performance that may affect patient care or proficiency test success, but that minimize false signals
- Review control results to detect significant changes from baseline performance and investigate causes
- Evaluate proficiency testing results to detect issues in the testing process that must be corrected to meet regulatory requirements
- Establish appropriate limits for agreement between different instruments performing the same tests to assure that results are not clinically significantly different. If not possible because of methodologic differences, provide appropriate interpretive information to clinicians

**Competency Area: Statistics**
- Utilize statistical concepts, such as analytical sensitivity and specificity, bias, and variance, and techniques such as linear regression analysis, in evaluating performance characteristics of laboratory methods
- Apply statistical tools to new method evaluation, either through use of specialized commercial products or general-purpose spreadsheet software
- Utilize statistical concepts such as clinical sensitivity, clinical specificity, predictive value, and ROC curve analysis in evaluating the diagnostic performance of laboratory tests
- Define and be able to utilize statistical techniques such as arithmetic mean, geometric mean, standard deviation, and percentile rank for evaluation of population-derived data to establish reference intervals; select correct type of statistical tool depending on the distribution of data observed
- Describe the statistical techniques used to monitor significant changes in a patient’s lab results
- Describe appropriate statistical techniques to evaluate differences between measurement methods, such as t-test and F-test
- Evaluate the appropriateness and interpret the meaning of statistical tests used in published articles relating to the use of diagnostic testing to be able to advise clinical colleagues on the utility of new tests

**Competency Area: Reference Intervals**
- Identify and, when possible, account for analyte specific biologic variables (eg, population-wide such as cyclical, regional and geographic; inter-individual such as age, sex, race; and intra-individual such as physical activity, diet)
- Establish or validate appropriate reference interval based on patient population
- Differentiate basic methodologic and process issues impacting importing reference intervals by transference versus establishing them by patient study
- Incorporate into laboratory report formats: age, gender, and/or physiologic conditions impacting reference intervals or medical decision points, as appropriate
- Differentiate "reference interval", "medical decision point", "therapeutic range" (TDM), and "desirable range" (eg, lipid reporting), and appropriately incorporate these within laboratory reports as intervals or comments
- Implement reference intervals pertinent to specimen type (eg, capillary vs venous vs arterial) as appropriate

**Competency Area: Pre-analytic Factors**
- Ensure appropriate procedures are in place for proper labeling of specimens and aliquots
- Employ or advocate delta checking to warn of potential specimen artifacts or specimen identify issues
- Recognize common, unstable (especially susceptible to drawing/handling artifacts) analytes measured in your laboratory; ie, NH3, lactate, blood gases, potassium, and PT and PTT
- Communicate proper handling of blood gas specimens, including influences of plastic syringes and specimen icing
- Evaluate miscellaneous systematic chemical artifacts that may occur during specimen handling, aliquoting, or on-instrument analysis
- Recognize blood collection tube to tube contamination effects due to failure to comply with order of draw, or intentional (surreptitious) transfer of a specimen from incorrect anticoagulant to a correct tube (for example, usually caused by potassium EDTA contamination)
- Understand phlebotomy/tourniquet induced artifacts for common, susceptible analytes in venous specimens; eg, potassium, calcium
- Control, to the extent possible, specimen collection for analytes influenced significantly by time of day, diet, activity, etc.
- Use chemical assays to help identify or confirm specimen body fluid source, if requested
- Understand common artifacts seen with flawed-process venous draws near an IV site or indwelling line

**Competency Area: Reporting and Communication**

- Examine reports for possible non-random, post-analytic variables; eg, loss or alteration of information from truncation, round-off, units conversion, re-formatting, data loss or corruption via transmission, and determine appropriate follow-up
- Generate clear, accurate, and complete reports that effectively communicate test results and treatment implications where appropriate
- Set, monitor, and modify chemistry auto verification rules
- Work with other medical care professionals to define appropriate critical values and notifications (customizing to particular settings/patient populations, eg, dialysis unit, OB, previous diagnoses)
- Discuss current results and patient issues with clinicians and multidisciplinary health care teams
- Record, investigate, resolve (when indicated), and respond to reports of laboratory errors by the clinical staff

**Competency: Chemistry**

**Sub-competency: Methods of Measurement**

**Sub-competency Definition:**
Recognizes the strengths and weaknesses of different methods of measurement used in the chemistry laboratory including common interferences; applies knowledge of methodology in selecting test methods that provide accurate test results for patients; interprets results of tests based on this knowledge when results are inconsistent with clinical findings and recommends alternative approaches to testing that can determine if results are accurate or erroneous.

**Competency Areas:**
A. Photometry and Related Techniques
B. Chromatographic Methods
C. Electrophoresis
D. Immunoassay
E. Electrochemical Methods
F. Mass Spectrometry

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Photometry and Related Techniques**
- Describe the basic components of a simple (single beam) photometer
- Apply Beer’s Law, absorbance, and percent transmittance to concentration of a measurand
- Recognize the potential effect of wavelength calibration and photometric absorption error upon quantitative spectral assays; describe common materials used to assess wavelength calibration and absorbance accuracy
Employ serum hemolysis, icterus, and lipemia “indices” to assist in identification of specimens with significant interferences

Determine whether a given photometrically determined assay result, from a specimen with significant hemolysis, icterus, and/or lipemia should be reported, rejected, or qualified by comment

Describe the basic components of nephelometric and turbidimetric systems

Cite basic comparative analytic and technical advantages of nephelometry versus turbidimetry

Relate basic principles of multiwavelength spectrophotometric measurements to simultaneous determination of spectrally related compounds or mitigation of endogenous interference

Competency Area: Chromatographic Methods

Choose between multiple discreet assays versus chromatographic separation and quantitation of similar analytes; eg, several immunoassays versus chromatography for toxicology and therapeutic drug monitoring

Evaluate the special strengths and weaknesses of alternative chromatographic techniques in the method choice for an analysis

Apply knowledge of basic principles of chromatographic separation to selection of methods for analysis in the clinical laboratory

Develop program changes to chromatographic variables to enhance separations and reduce elution time

Select columns and the associated coatings or packings that best suit the analytical separations needed

Recognize the hazards of co-eluting compounds

Compare the pros and cons of detector alternatives with specimen size, and the needed precision and accuracy of a clinical assay

Monitor quality control of column chromatography with analyte retention times, peak shapes, and peak separations

Competency Area: Electrophoresis

Explain the basic physiochemical principles of electrophoresis

Describe the basic components of a simple electrophoretic system, including densitometry

Interpret electrophoretic assays performed in your laboratory

Recognize and explain the appropriate and inappropriate application of common dyes (eg, Amido Black, Coomassie Blue) to detection and quantitation of electrophoretic zones

Recognize the effects of various, common supporting media or materials upon component migration and resolution

Select and operate electrophoretic components such that clinical performance satisfies medical needs

Describe the basic principles of isoenzyme electrophoresis

Describe principle desirable characteristics of capillary zone and isoelectric focusing electrophoresis

Competency Area: Immunoassay

Recognize the several categories of immunoassays and how they differ regarding their measurement range, sensitivity and specificity

Utilize external quality controls and proficiency surveys to help manage the problem of drift in immunoassays

Recognize the advantages and disadvantages of different antigen and antibody labels

Develop expertise regarding the several types of interferences in immunoassays and some protocols that may be useful for detecting interferences

When possible, adopt advantages of rate and rate enhancement methods of nephelometric assays for proteins in low concentrations

Recognize the relative advantages and disadvantages of immunoassays versus compared to other methods for the same analyte
Competency Area: Electrochemical Methods
- Recognize inaccuracies that may result from onboard specimen dilutions in specimens with marked elevations of protein or lipids
- Use controls and frequent calibration to compensate for voltage or current drifts common to potentiometry and amperometry
- Recognize the utility of compound electrodes used for whole blood assays and the complications associated with their calibration

Competency Area: Mass Spectrometry
- Apply appropriate ion creation/fragmentation methods, particularly MALDI, electron impact, and electrospray to a wide range of analyte measurement
- Match the advantages of TOF-MS, single quadrupole MS, and tandem MS with analytical problems
- Become familiar with the analytical power and challenges presented by GC-MS and LC-MS-MS
- Adopt, when possible, techniques such as curve resolution, retention time adjustment, and custom built mass spectral libraries to improve quantitation and certainty of peak identifications
- Use isotope dilution for high accuracy calibration where appropriate

Competency: Chemistry
Sub-competency: Tests for Diagnosis/Monitoring of Disease

Sub-competency Definition:
Applies knowledge of biochemistry and physiology to selection and interpretation of common chemical laboratory tests to assist clinicians in diagnosing and monitoring patients with a variety of diseases; consults with clinicians in selection and interpretation of test results as to likely diagnostic possibilities, probability of disease progression, or prognosis of disease state. Applies knowledge of disease processes to interpretation of test results; consults with clinicians on interpretation of test results and recommends additional testing to answer clinical questions.

Competency Areas:
A. Test of Blood Gas, Acid-Base and Electrolyte Status
B. Renal Function/Status
C. Liver Function/Status
D. Cardiac Disease
E. Tests of Gastrointestinal Function
F. Endocrine Function Tests
G. Tumor Markers
H. Hematology-related Chemistry Tests
I. Proteins
J. Pregnancy-related Tests
K. Neonatal-related Tests
L. Pediatric-related Tests
M. Point-of-Care Testing

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Test of Blood Gas, Acid-Base and Electrolyte Status
- Utilize anion gap, total CO2 content, and blood gas results to interpret common simple and mixed acid-base disorders
- Recommend additional tests to evaluate patients with unexplained anion gap metabolic acidosis
- Recommend testing to help evaluate patients with hyponatremia and hypernatremia to determine pathogenetic or artifactual (eg, pseudohyponatremia) mechanisms
- Specify appropriate sample collection and handling procedures to minimize artifactual hyperkalemia
• Interpret calculated indices, such as fractional excretion of sodium (FENa) and trans-tubular potassium gradient (TTKG) in patients with electrolyte disorders
• Interpret osmolal measurements in plasma and urine

**Competency Area: Renal Function/Status**

• Recognize common patterns of renal dysfunction such as acute tubular necrosis, nephrotic syndrome, and nephritic syndrome
• Recommend tests to evaluate potential causes in patients with nephrotic or nephritic syndromes
• Consult with clinicians on selection of appropriate tests to recognize acute kidney injury
• Recognize common urine crystals and interpret their significance
• Assist testing for renal tubular acidosis
• Advise on the relative merits of creatinine and cystatin C measurement for recognizing and monitoring kidney disease
• Utilize appropriate calculations for eGFR for the population and analytic methods in use to evaluate kidney function
• Evaluate alternatives for expressing urine reference intervals; eg, spot, timed and creatinine normalized
• Recognize uses and limitations of various tests for urine protein excretion (microalbumin, total protein [and their ratios to creatinine], urine protein electrophoresis) to identify early renal injury.

**Competency Area: Liver Function/Status**

• Understand the issues influencing the selection of appropriate reference intervals for ALT
• Interpret common patterns of liver related laboratory test abnormalities
• Consult with clinicians on selection of appropriate tests to recognize cause of acute or chronic liver injury
• Employ non-invasive tests to evaluate liver fibrosis, when appropriate
• Recommend appropriate tests for monitoring patients with liver disease

**Competency Area: Cardiac Disease**

• Select appropriate sample collection and handling procedures, as well as testing methods to provide appropriate turnaround time, sensitivity, and precision for troponin testing
• Select appropriate, harmonized testing methods for lipid tests
• Interpret common patterns of lipid abnormalities
• Recommend appropriate tests to evaluate patients for cardiac risk based on age, gender, other risk factors, and family history
• Identify patterns in cardiac markers (eg, stable elevation) that may indicate a cause of elevation other than acute cardiac injury
• Select appropriate detection limits and reference limits for interpretation of troponin and natriuretic peptides

**Competency Area: Tests of Gastrointestinal Function**

• Recommend appropriate tests to evaluate patients with signs and symptoms suggestive of malabsorption
• Recommend test panels for evaluation of suspected celiac disease
• Select appropriate testing methods for detection of fecal occult blood
• Consult with clinicians on use of genetic tests for evaluation of risk for colorectal cancer
• Recommend use of laboratory tests and advise clinicians of their limitations in evaluation of patients with suspected inflammatory bowel disease
• Interpret results of intestinal/pancreatic hormone testing in light of other known causes for abnormal hormone levels
Competency Area: Endocrine Function Tests

- Select appropriate tests for evaluation of thyroid function, and recommend additional tests in select circumstances (hypothyroidism, hyperthyroidism, acute illness, pregnancy) (THYROID)
- Establish appropriate reference intervals for TSH in the general population, and if caring for pediatric and obstetric patients, age and trimester-specific reference intervals (THYROID)
- Interpret patterns of thyroid function abnormality including thyroid antibodies (THYROID)
- Consult with clinicians on interpretation of Thyroglobulin levels in patients with thyroid cancer and detectable anti-thyroglobulin (THYROID)
- Provide expertise in laboratory testing for medullary thyroid carcinoma (THYROID)
- Recommend appropriate tests for evaluation of suspected Cushing’s syndrome, adrenal insufficiency, hyperaldosteronism, or pheochromocytoma, and advise on limitations of testing in the setting of acute illness or drug interferences (ADRENAL)
- Consult with clinicians on use of genetic tests in evaluation of patients with pheochromocytoma (ADRENAL)
- Recommend appropriate tests for evaluation of hyper- and hypocalcemia (PARATHYROID)
- Evaluate the uses and limitations of intraoperative PTH measurements (PARATHYROID)
- Recommend appropriate tests for evaluation of suspected hyper- or hypopituitarism (PITUITARY)
- Distinguish macro-prolactin from other causes of elevated prolactin (PITUITARY)
- Recognize the strengths and weaknesses of testing methodologies and algorithms used to diagnose diabetes (DIABETES/GLUCOSE)
- Recommend tests for identification of type of diabetes if clinically necessary (DIABETES/GLUCOSE)
- Interpret results of hemoglobin A1c in light of other factors (renal failure, alcohol abuse, hemoglobinopathies, abnormal red cell survival) that can affect results (DIABETES/GLUCOSE)
- Recommend appropriate tests to evaluate patients with hypoglycemia not due to known diabetic medication (DIABETES/GLUCOSE)
- Recognize the tests that assist in the diagnosis of metabolic syndrome (DIABETES/GLUCOSE)
- Recommend appropriate initial and follow-up tests to diagnose and monitor male hypogonadism (GONADAL FUNCTION)
- Recommend tests for evaluation of ovarian reserve and menopause (GONADAL FUNCTION)
- Recommend tests for evaluation of androgen excess in women (GONADAL FUNCTION)
- Recommend tests to support assisted reproductive technology and fertility assessment (GONADAL FUNCTION)
- Recommend tests for the evaluation of sexual maturity and puberty (GONADAL FUNCTION)

Competency Area: Tumor Markers

- Recognize the biases (lead time, length, over-diagnosis) that can occur with cancer screening and that may falsely lead to perception of screening benefit
- Communicate with clinicians the issues related to use of PSA screening for prostate cancer, and assist in development of recommendations for appropriate patient counseling and use of PSA in screening
- Recommend appropriate tumor markers (such as CEA, CA 19-9, CA 15-3/27.29, CA125, thyroglobulin, calcitonin) for monitoring of patients with specific malignancies, and advise clinicians of method-specific differences in test results and need to re-baseline patients when methods are changed
- Recommend tests (AFP, AFP-L3, DCP/PIVKA-II) that may be of benefit in screening for hepatocellular carcinoma in high-risk patients
- Recognize the effect of different molecular forms detected by beta-HCG assays and issues these may introduce into use of HCG measurements in monitoring of patients with gestational trophoblastic neoplasia
Competency Area: Hematology-related Chemistry Tests

- Interpret patterns of change in serum iron studies including transferrin receptors and hepcidin and advise clinicians of situations when iron tests may be misleading (acute liver injury, recent transfusion, dialysis) and should be deferred
- Recognize the limitations of B12 (and folate) assays in diagnosis of B12 deficiency and suggest additional tests (intrinsic factor blocking antibodies, methylmalonic acid, homocysteine) that may assist in diagnosis
- Recommend tests that are useful for recognition of hemolytic anemia and for identification of its cause when present
- Interpret patterns of hemoglobin electrophoresis (or ion-exchange HPLC), along with red blood cell morphology and clinical features, to identify common hemoglobinopathies and recommend additional testing (ie, globin chain analysis, analysis at different pH, hemoglobin A2, hemoglobin F, and hemoglobin solubility test) for definitive identification of hemoglobin variants

Competency Area: Proteins

- Recognize the importance of total protein and albumin for the identification of abnormalities in serum proteins
- Apply understanding of intended (paraprotein identification) and artifactual (eg, immune complexes, prozone, ladder pattern) phenomena to properly interpret immunofixation electrophoreses (IFE) of serum, urine, and CSF
- Recognize and report serum, urine, and CSF protein electrophoresis pattern abnormalities resulting from congenital, and acquired medical non-paraprotein associated defects or diseases
- Recommend additional testing (such as free light chain analysis, quantitative measurement of heavy/light chains, IFE or immunosubtraction, based on initial electrophoretic technique used) for diagnosis and monitoring of monoclonal gammopathy
- Recommend appropriate assay for CRP measurement (hs-CRP for cardiac risk assessment, other CRP assays only for the evaluation of inflammatory disorders)
- Utilize knowledge of the effects of various conditions (acute inflammation, estrogen use) on select specific protein assays such as ceruloplasmin, alpha-1-antitrypsin, haptoglobin, and beta-2-microglobulin; and recommend to clinicians appropriate settings for use of these assays in diagnosis (and prognosis) of related disorders
- Provide diagnostic and prognostic information about procalcitonin and sepsis

Competency Area: Pregnancy-related Tests

- Communicate the appropriate, relative usefulness of serum and urine HCG assays to either confirm or exclude early pregnancy
- Select serum HCG assay(s) appropriate for the clinical indication (usually pregnancy and / or tumor marker)
- Counsel caregivers regarding interpretation of indeterminate or persistently positive HCG results in the clinically non-pregnant, possibly pregnant, ectopic pregnancy, or post-pregnancy patient
- Select a laboratory for chromosomal, neural tube, and other genetic abnormality screening that provides chemically accurate, properly statistically described (multiple of median), and clearly reported results and includes all required elements
- Select, and if necessary, validate, and communicate clinical performance attributes of a fetal lung maturity test
- Describe the contemporary (currently evolving) approach to screening or diagnosing gestational diabetes
- Communicate to caregivers regarding the clinical performance of tests for preterm labor
- Describe common pregnancy induced changes in chemical and immunoassays

Competency Area: Neonatal-related Tests

- Access and describe your state’s newborn screening program and analytes; and provide support for confirmatory tests when needed
- Assist your newborn screening coordinator and/or caregiver in assuring high quality newborn screening within your sphere of practice
- Recognize that some inherited diseases such as galactosemia and salt-wasting CAH may clinically appear before newborn screening results are reported; and is a potentially lethal medical emergency
• Assist interpretation of properly collected umbilical cord blood gases
• Assist the recognition and management of neonatal hyperbilirubinemia by understanding current age (hours) related guidelines and supporting transcutaneous bilirubin measurement (if available)
• Ensure proper phlebotomy procedures exist for collection of highest quality capillary specimens (including blood gas specimens)
• Support as appropriate, newborn glucose testing for detection and treatment of hypoglycemia

Competency Area: Pediatric-related Tests
• If sweat testing is performed, understand and ensure adherence to guidelines
• Distinguish the diagnostic significance between sweat osmolality and properly performed sweat electrolyte testing
• Counsel caregivers regarding borderline abnormal chemical results which may reflect the limitations of pediatric reference range determinations and reporting
• Select methods for pediatric testing that require smaller specimen volumes
• Select methods that provide reliable results for values observed in this age group (for example, mass spectrometric methods for testosterone and estradiol instead of immunoassays)
• Ensure appropriate selection of calculated measures paired with appropriate methodology (eg, Schwartz EGFR and enzymatic creatinine)
• Assist caregivers with assessment of possible inherited metabolic disorders (usually, by recommending an appropriate specialist consultant) and recognize that these may not present until later in life

Competency Area: Point-of-Care Testing
• Develop criteria, in cooperation with medical staff, for evaluating requests for point of care testing
• Determine that point of care tests have acceptable accuracy and precision to meet stated clinical needs
• Recognize the strengths and limitations specific to point of care testing
• Communicate with clinical staff regarding the pros and cons of specific point of care testing requested for use (turnaround time, cost, analytical performance, competency and proficiency testing requirements, quality control requirements) to allow informed decisions to be made
• Oversee management of point-of-care testing so that all clinical and regulatory requirements are met
• Communicate with licensed providers on competency requirements for provider-performed microscopy and assist in documentation of parallel testing if needed

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Competency: Cytogenetics (To Be Developed)
Competency: Cytopathology

Competency Definition:
Use best practices in establishing laboratory evaluation and reporting of Cytopathology specimens. These practices include: specimen collection, specimen preparation and processing; cellular evaluation; integration of the morphologic findings with the patient’s clinical history, physical findings and imaging studies; requesting ancillary studies when appropriate and being able to incorporate these findings into the interpretation, treatment recommendations; concise communication for treatment purposes; and use of quality assurance practices to assure accurate interpretation and optimum patient care.

Sub-competencies:
1. Gynecological Cytology
2. Fine Needle Aspiration (FNA) Cytology
3. Non-Gynecological Cytology (NGC)

Sub-competency: Gynecological Cytology

Sub-competency Definition:
Use standard practices for the collection, acceptance, processing and staining of gynecologic cytology samples; use criteria for the evaluation of inflammatory, and reactive patterns as well as pre-neoplastic and neoplastic lesions of the cervix and uterus; issue descriptive interpretations reflecting standard terminology for gynecologic cytology; recommend patient management based upon evidenced-based patient management guidelines and use quality assurance tools to maximize accuracy of the Pap test and optimize patient care.

Competency Areas:
A. Obtaining the Pap Test
B. Specimen Processing/ Staining
C. Cytologic Screening
D. Interpretation
E. Reporting
F. Human Papillomavirus (HPV)
G. Patient Management
H. Quality Assurance

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Obtaining the Pap Test
- Identify the important factors for patient preparation prior to obtaining an optimal Pap test
- Identify patient variables that may affect the quality of a Pap test
- Describe the limitations and advantages of different specimen types (ie, conventional or liquid based)
- Describe the limitations and advantages of various sampling devices
- Explain the required components of a Pap test requisition
- Describe adequate sample identification
- Describe reasons for Pap test rejection and the process of rejection documentation

Competency Area: Specimen Processing/ Staining
- Describe the principles of liquid-based cytology and the differences between the available liquid-based preparations
- Identify the components of the Papanicolaou stain and explain the mechanism of action of each component
- Assess and document stain quality
• Validate automated instruments (e.g., automated stainers, coverslippers or image assisted screening devices) in the cytology laboratory
• Explain procedures and methods to optimize specimen processing
• Identify the differences in staining methods required for manual versus image assisted screening devices

Competency Area: Cytologic screening
• Identify the proper procedure for manual screening of Pap tests
• Identify the procedure for automated or image assisted screening of Pap tests; the appropriate triage of slides subjected to image guided screening; and procedure for full manual review of applicable cases
• Explain the criteria for quality indicators and specimen adequacy in conventional and liquid preparations
• Differentiate between normal cellular changes, microorganisms and pre-neoplastic/neoplastic cellular abnormalities
• Articulate the principles of different image assisted screening devices
• Recognize the limitations of image assisted screening and automated screening
• Describe the difference between locator and interpretive skills
• Recognize the requirements for work load recording for manual and image assisted Pap tests as defined by CLIA 88 and subsequent governmental regulations
• Identify the differences between random rescreening (including high risk cases) and targeted re-screening of workload and what re-screening is required by governmental regulations

Competency Area: Interpretation
• Identify the normal cells from the vagina, cervix, transformation zone, endocervix and endometrium on a Pap test
• Interpret benign changes and organisms seen on Pap tests
• Apply the criteria for interpretation of epithelial cell abnormalities of squamous lesions and glandular cells as described by the Bethesda System for Reporting Cervical Cytology
• Identify and interpret epithelial cell abnormalities of squamous and glandular cells as described by the Bethesda System for Reporting Cervical Cytology

Competency Area: Reporting
• Explain the required elements of a Pap test report
• Use descriptive terminology for reporting results, such as those used in the Bethesda System for Reporting Cervical Cytology
• Identify the signature/identifiers that are required to be on the Pap test report and the information that must be available in the laboratory
• Explain the requirements for electronic signature and security for Pap tests
• Articulate educational notes and recommendations when needed in the report
• Recognize the requirements for proper patient privacy issues as outlined by HIPPA regulations

Competency Area: Human Papillomavirus (HPV)
• Identify the pathophysiology and the spectrum of disease caused by HPV
• Explain the clinical recommendations for HPV vaccination and the differences between available HPV vaccines
• Identify the laboratory methods used to detect HPV
• Explain the differences between testing methods for High Risk (HR) HPV
• Describe the advantages and limitations of HR HPV testing in various age groups
• Select the correct use of HR HPV testing as recommended by evidence based guidelines
• Recommend the appropriate HPV test for specific patients
• Identify appropriate HR HPV proficiency testing programs for the various methods used for HPV detection in the laboratory
Competency Area: Patient Management

- Explain the use of screening Pap tests in the general population
- Describe the application of cervical cancer screening in special populations (eg, Immunosuppressed patients, adolescents, pregnant and post-menopausal women)
- Identify the recommended clinical follow up for unsatisfactory Pap tests as defined by ASCCP guidelines
- Identify the recommendations for patient management as outlined by evidence based guidelines
- Describe the limitation and risks of cervical cancer screening in adolescents
- Describe the limitations of the atrophic Pap test and options for follow up
- Integrate the results of HR HPV testing, clinical presentation and Pap test results to create a patient specific recommendation

Competency Area: Quality Assurance

- Outline the components of the laboratory that are part of a valid quality assurance program in gynecologic cytology
- Describe the requirements for daily review of random "negative" Pap tests (10% negative review)
- Explain the value of retrospective review, especially following an interpretation of a new high grade intraepithelial lesion, cyto- histologic correlation and clinical correlation as part of a quality assurance program
- Recognize the storage and retrieval requirements of federal and state regulations for Pap test slides and records
- Identify appropriate tools to use for performance evaluation of cytotechnologist and pathologist including work load, bench marking information, inter and intra-laboratory comparison, and interpretive rates
- Explain the responsibilities of the technical supervisor and general supervisor in establishing work load limits for cytotechnologists
- Explain the responsibilities of the technical supervisor and general supervisor in establishing work load limits for cytotechnologists
- Identify benchmarks to use for the evaluation of competency assessment and laboratory performance
- Identify the requirements defining an acceptable inter-laboratory comparison educational program in gynecologic cytology
- Define the qualifications that define a CMS approved gynecologic cytology proficiency testing
Competency: Cytopathology
Sub-competency: Fine Needle Aspiration (FNA) Cytology

Sub-competency Definition:
Use best practices for the collection, acceptance, processing, and staining of fine needle aspiration (FNA) cytology specimens; apply organ-specific criteria for the microscopic evaluation of benign, borderline, and malignant lesions; select appropriate ancillary testing; integrate morphologic findings with clinical, imaging and ancillary studies to formulate cytopathology interpretations; issue interpretive reports with general diagnostic categorization (benign / atypical / suspicious / malignant / insufficient) along with a specific diagnosis or a description and differential diagnosis; utilize quality assurance tools to maximize accuracy of FNA interpretations and optimize patient care; if performing FNAs, educate patient on FNA and optimally perform the procedure.

Competency Areas:
A. Patient Interaction
B. Performing a Palpable FNA
C. Performing an Ultrasound-guided FNA
D. Sample Handling
E. Interpretation
F. Reporting
G. Patient Management
H. Quality Assurance

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Patient Interaction
- Establish rapport with patient
- Correlate patient’s chief complaint with clinical history, prior imaging studies and pertinent laboratory test results
- Perform physical examination and record findings
- Evaluate the patient to determine if an FNA procedure is appropriate
- Make recommendation for FNA based on patient evaluation
- Explain the FNA procedure to the patient, including risks and benefits, and document patient consent

Competency Area: Performing a Palpable FNA
- Ensure patient identifiers are on FNA materials (ie, slides, rinse tubes)
- Demonstrate knowledge of methods of patient positioning to best expose the intended target lesion
- Demonstrate knowledge of methods to cleanse the biopsy site and apply local anesthetic
- Demonstrate methods to stabilize the target lesion with palpation
- Demonstrate knowledge of sampling techniques (ie, needle alone, needle and syringe without suction, needle, syringe and syringe holder to apply negative pressure)
- Perform needle placement by palpation with adequate needle excursions in the target lesion
- Determine how results of intraprocedural adequacy evaluation may influence triage of the sample and next steps in the FNA procedure
- Specify post-biopsy care and potential side effects

Competency Area: Performing an Ultrasound-Guided FNA
- Ensure adequate patient identification on FNA samples and ultrasound images
- Demonstrate methods of patient positioning to best expose the intended target lesion
- Adjust ultrasound machine parameters for ideal visualization of target lesion
- Identify sonographic criteria favoring benign lesions
- Identify sonographic criteria favoring indeterminate or malignant lesions
- Interpret sonographic findings to classify target lesion as benign, indeterminate or malignant, including size and vascularity
• Identify methods to cleanse the biopsy site and apply local anesthetic
• Demonstrate the tangential approach and perpendicular approach for ultrasound-guided FNA with adequate needle excursions in the target lesion
• Determine how results of intraprocedural adequacy evaluation may influence next steps in the FNA procedure
• Specify post-biopsy care
• Demonstrate ability to archive and retrieve ultrasound images within appropriate requirements

**Competency Area: Sample Handling**
• Describe the methods for making smears and performing needle rinses from an FNA sample (include slide labeling, smear technique and fixatives)
• Demonstrate slide preparation techniques
• Identify differences in air-dried and wet-fixed slide staining methods and identify when each stain might be the preferred choice
• Perform specimen adequacy assessment
• Explain the method used for immediate assessment for adequacy and sample composition
• Describe the collection method of FNA material for cell block preparation (transport media/fixative)
• Identify the proper procedure for submission of FNA material for flow cytometry, microbiologic culture, cytogenetics, FISH or electron microscopy
• Identify the proper procedure for optimal handling of bloody specimens and scant specimens

**Competency Area: Interpretation**
• Apply criteria for adequacy evaluation in the setting of immediate intra-procedural assessment and for final assessment of adequacy
• Identify normal cells from common anatomic sites sampled by FNA, including thyroid, salivary gland, lymph nodes, breast, lung, liver, pancreas, kidney, adrenal, soft tissue
• Interpret benign changes
• Apply the criteria for malignancy
• Identify and interpret abnormal cellular findings, including cancer
• Describe when special procedures, including immunocytochemistry and/or special stains, are appropriate to render a final diagnosis
• Describe common pitfalls in diagnosis

**Competency Area: Reporting**
• Explain the standard elements of a FNA report
• Use standardized terminology for reporting results for those anatomic sites in which these have been developed, such as those used in the Bethesda System for Reporting Thyroid Cytopathology
• Create descriptive diagnoses that will clearly communicate cellular findings for those anatomic sites where there is no standardized terminology
• Identify the signature/identifiers that are required to be on the FNA report and the information that must be available in the laboratory
• Explain the requirements for electronic signature and security for FNA reports
• Articulate educational notes and recommendations when needed in the report
• Document physical exam and evaluation for FNA with appropriate linking language to FNA recommendation, for those reports where the pathologist performs and interprets the FNA

**Competency Area: Patient Management**
• Recommend appropriate patient follow-up by incorporating morphologic findings with clinical, imaging and ancillary studies, and following existing evidence-based guidelines (eg, NCI Guidelines for Reporting Thyroid FNA Cytology)
• Describe the limitations of FNA cytology and how patient management is affected
Competency Area: Quality Assurance

- Outline the components of the laboratory quality management program in FNA cytology
- Ensure all FNA cytology reports are signed by a pathologist
- Monitor FNA report turnaround times
- Implement measures to minimize FNA report turnaround times
- Communicate significant and unexpected FNA cytology findings in accordance with laboratory policy
- Correlate FNA cytology findings with histology when available
- Recognize the storage and retrieval requirements of federal and state regulations for FNA cytology slides and records
- Select appropriate tools to use for performance evaluation of cytotechnologists, pathologists, and the laboratory, including workload information, benchmarks, inter- and intra-laboratory comparison, and interpretive rates

Competency: Cytopathology
Sub-competency: Non-Gynecological Cytology (NGC)

Sub-competency Definition:
Utilize best practices for the collection, acceptance, processing and staining of non-gynecologic cytologic specimens; determine adequacy of non-gynecologic specimens according to the criteria related to the specific body site, apply the organ-specific criteria for the microscopic evaluation of benign, atypical, and malignant lesions; select appropriate ancillary testing when appropriate; integrate cytological findings with clinical, imaging and ancillary studies to formulate cytopathology interpretations; issue interpretive reports with general diagnostic categorization (unsatisfactory/benign/ atypical/ suspicious/malignant) along with a specific diagnosis or a descriptive and differential diagnosis; use quality assurance tools to maximize accuracy of non-gynecologic cytology interpretations and optimize patient care.

Competency Areas:
A. Obtaining the Sample
B. Specimen Processing/ Staining
C. Cytologic Screening
D. Ancillary Studies
E. Interpretation
F. Reporting
G. Patient Management
H. Quality Assurance

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Obtaining the Sample

- Select the most appropriate and most cost-effective method for sample collection according to lesion, body site and clinical findings
- Ensure maintenance of sample identity by secure patient identification, sample labeling, requisition form completion, and specimen transport
- Identify the need for additives to the sample (e.g., anticoagulants, mucolytics) based on the site, clinical history and sample appearance
- Identify appropriate transport and fixation procedures for samples that will be processed immediately, refrigerated, stored or sent to a remote site for analysis
- Demonstrate compliance with clinical laboratory standards (CLIA and revisions, CAP Guidelines)
- Provide written instructions to clinical services where specimens are collected
- Identify samples that may require special handling or ancillary testing
Competency Area: Specimen Processing/Staining

- Describe the methods for making manual and automated slide preparations from non-gynecologic cytology samples (including slide labeling, slide preparation techniques and fixation)
- Describe proper procedures for identification and submission of appropriate cytologic material for flow cytometry or microbiology
- Determine sample cellularity and appropriate techniques for concentration or dilution as needed
- Identify the components of commonly used cytologic stains (Papanicolaou and Romanowsky) and be able to explain the contribution of each component
- Explain procedures used to prevent cross contamination of samples
- Describe methods for cell-block preparation from non-gynecologic cytologic samples
- Assess and document the quality of stained completed specimens
- Select appropriate validation procedures for instrumentation in the cytopreparatory laboratory including: centrifuges, liquid-based preparation units, automated stainers, cover slipping machine, etc.
- Describe methods of and documentation used for instrument maintenance

Competency Area: Cytologic screening

- Maintain sample identity
- Demonstrate proper use of the clinical microscope for cytologic screening including consideration of regular maintenance
- Demonstrate skill at locating and identifying significant cytologic features from commonly sampled body sites
- Employ screening techniques that ensure complete visualization of the cellular sample on a given slide preparation
- Determine sample adequacy based on cellularity and quality of preparation
- Identify significant microbiological findings
- Distinguish between normal, reactive, degenerative and neoplastic findings
- Identify samples that may require ancillary testing

Competency Area: Ancillary studies

- Relate the principles regarding standard immunologic, cytogenetic and molecular assays
- Specify methods used to prepare cytologic samples for cytochemical, immunologic, cytogenetic and molecular assays
- Support the choice of ancillary methodologies with current evidence-based studies
- Utilize only appropriately validated tests
- Communicate the outcomes and significance of ancillary studies to support clinical care
- Use appropriate ancillary studies to support a diagnosis and avoid extraneous studies in order to promote good systems-based practice and cost-effective care

Competency Area: Interpretation

- Determine the adequacy of the non-gynecologic specimens according to the criteria related to the specific body site
- Recognize normal cells from commonly sampled anatomic sites in non-gynecologic cytology
- Distinguish benign cellular and non-cellular changes from atypical, suspicious and malignant cytologic features
- Classify abnormal cytologic findings into atypical, suspicious and malignant categories
- Correlate the cytologic findings with the type of specimen and the clinical setting in order to avoid diagnostic pitfalls
- Recognize the requirements for proper patient privacy issues as outlined by HIPPA regulations

Competency Area: Reporting

- Select a reporting format that is user-friendly, concise and easy to read for the clinician or other individuals responsible for the care of the patient
- Incorporate the required identifiers, information and signature into the non-gynecologic report
- Use standardized diagnostic general categories (unsatisfactory/benign/atypical/suspicious/malignant) for reporting results
• Create descriptive diagnoses (beyond the general diagnostic categories) that will clearly communicate cytological findings
• Convey, when appropriate, the uncertainty of diagnosis and the need for further investigations
• Explain the requirements for electronic signature and security for non-gynecologic reports
• Recognize when it is necessary to consult another pathologist for a second opinion
• Articulate educational notes and recommendations when appropriate in the report

Competency Area: Patient Management
• Recommend appropriate patient follow-up by correlation of morphologic findings with clinical, imaging and ancillary studies
• Integrate existing evidence-based guidelines into the formulation of follow-up recommendations
• Comment on the limitations of non-gynecologic cytology according to body sites and to special clinical considerations
• Communicate the need for further investigations when the cytological diagnosis is uncertain/unclear

Competency Area: Quality Assurance
• Outline the components of the laboratory quality management program in non-gynecologic cytology
• Ensure that all non-gynecologic cytology specimens are screened by a cytotechnologist
• Ensure all non-gynecologic cytology reports are signed by a pathologist
• Monitor non-gynecologic report turnaround times
• Implement measures to minimize non-gynecologic report turnaround times
• Communicate significant and unexpected non-gynecologic cytology findings in accordance with laboratory policy
• Correlate non-gynecologic cytology findings with histology when available
• Recognize the storage and retrieval requirements of federal and state regulations for non-gynecologic cytology slides and records
• Select appropriate tools to use for performance evaluation of cytotechnologists, pathologists, and the laboratory, including workload information, benchmarks, inter- and intra-laboratory comparison, and interpretive rates
• Demonstrate skill in supervision of individuals who collect samples, process samples, perform primary screening of samples and prepare samples for ancillary testing

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Supporting Committee(s) Cytopathology Committee
Competency: Dermatopathology (To Be Developed)
Competency: Endocrine Pathology

Competency Definition:
Employs best practices both performing and interpreting laboratory testing in the diagnosis of endocrine disorders; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating laboratory results and imaging findings with morphologic, immunophenotypic, and cytogenetic/molecular findings; understanding how specific diagnoses affect treatment and outcome; and accurate reporting and communication to ensure accurate and comprehensive diagnosis and optimal patient care.

Sub-competencies:
1. Adrenal and Paraganglioma Pathology
2. Inherited Endocrine Disease/Tumor Syndromes
3. Neuroendocrine Tumor Pathology
4. Parathyroid Pathology
5. Pathology of Diabetes
6. Pituitary Pathology
7. Thyroid Pathology

Sub-competency: Adrenal and Paraganglioma Pathology

Sub-competency Definition:
Interprets laboratory data including biochemical, morphologic, and molecular findings to diagnose adrenal and paraganglioma pathology and correlates this data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses.

Competency Areas:
A. Clinicopathologic Correlation
B. Chemical Pathology
C. Cytology
D. Morphology
E. Ancillary Studies
F. Treatment Implications
G. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Clinicopathologic Correlation
- Diagnose adrenal cortical hyperfunction and hypofunction and recognize the morphologic features of adrenal pheochromocytoma and paraganglioma, including features distinguishing these from other disease entities
- Recognize radiologic features of adrenal lesions

Competency Area: Chemical Pathology
- Implement biochemical tests for adrenal cortical tumors, pheochromocytoma, and paraganglioma
- Interpret biochemical tests for adrenal cortical tumors, pheochromocytoma, and paraganglioma

Competency Area: Cytology
- Diagnose adrenal lesions from cytologic aspirates
- Distinguish adrenal lesions and paragangliomas from other diseases
**Competency Area: Morphology**
- Recognize adrenal lesions, adrenal cortical tumors, pheochromocytoma, and paragangliomas
- Diagnose adrenal lesions, adrenal cortical tumors, pheochromocytoma, and paragangliomas

**Competency Area: Ancillary Studies**
- Apply histochemistry tests in adrenal lesions and paragangliomas
- Utilize appropriate immunohistochemistry tests for adrenal tumors and paragangliomas
- Interpret electron microscopic characteristics of adrenal cortical and medullary tumors and paragangliomas
- Assess the molecular genetics of distinct endocrine syndromes causing adrenal diseases and paragangliomas
- Interpret molecular markers for diagnosis, treatment, and prognosis of adrenal tumors and paragangliomas

**Competency Area: Treatment Implications**
- Correlate morphological findings of these tumors with the molecular findings to best identify treatment options
- Recognize treatment implications of the diagnosis of adrenal lesions and paragangliomas

**Competency Area: Reporting and Communication**
- Follow published recommendations for reporting adrenal disorders and paragangliomas
- Comply with synoptic reporting guidelines for adrenal cortical carcinoma
- Generate clear, concise, and accurate reports that effectively communicate adrenal testing results and treatment implications to the patient’s health care team
- Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

**Competency: Endocrine Pathology**

**Sub-competency: Inherited Endocrine Disease/Tumor Syndromes**

**Sub-competency Definition:**
Interpret laboratory data including biochemical, morphologic, and molecular findings to diagnose inherited endocrine disease/tumor syndromes and correlates this data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses.

**Competency Areas:**
A. Clinicopathologic Correlation
B. Chemical Pathology
C. Morphology
D. Ancillary Studies
E. Treatment Implications
F. Reporting and Communication
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Clinicopathologic Correlation
- Recognize endocrine autoimmune diseases and polyendocrine autoimmune syndromes
- Identify familial endocrine tumor syndromes

Competency Area: Chemical Pathology
- Implement testing for hormone-secreting tumors, testing for selective or generalized hormonal insufficiencies, and serology for autoimmune endocrine disorders
- Interpret testing for hormone-secreting tumors, testing for selective or generalized hormonal insufficiencies, and serology for common autoimmune endocrine disorders

Competency Area: Morphology
- Recognize unique features that distinguish familial endocrine tumor syndromes, and recognize associated diseases
- Recognize features that predict familial endocrine autoimmune diseases and polyendocrine autoimmune syndromes

Competency Area: Ancillary Studies
- Assess the molecular genetics of distinct inherited endocrine diseases and familial tumor syndromes
- Utilize the appropriate immunohistochemistry tests in inherited endocrine disease/tumor syndromes

Competency Area: Treatment Implications
- Recognize critical laboratory results for inherited endocrine disease/tumor syndromes for clinicians’ immediate knowledge
- Recognize treatment implications of diagnosis of familial endocrinopathies and familial tumor syndromes to patient and family

Competency Area: Reporting and Communication
- Follow published recommendations for reporting of familial endocrine disorders and familial tumor syndromes
- Comply with reporting guidelines for reporting of familial endocrine disorders
- Generate clear, concise, and accurate reports that effectively communicate testing results and implications of familial endocrinopathies and tumor syndromes to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams
Competency: Endocrine Pathology
Sub-competency: Neuroendocrine Tumor Pathology

Sub-competency Definition:
Interprets laboratory data including biochemical, morphologic, and molecular findings to diagnose neuroendocrine tumors and correlates these data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses.

Competency Areas:
A. Chemical Pathology
B. Clinicopathologic Correlation
C. Cytology
D. Morphology
E. Ancillary Studies
F. Treatment Implications
G. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Chemical Pathology
• Employ biochemical markers for neuroendocrine lesions and tumors
• Correlate biochemical findings with clinical features in patients with neuroendocrine lesions and tumors

Competency Area: Clinicopathologic Correlation
• Interpret radiologic features of neuroendocrine tumors
• Correlate morphologic and immunohistochemical features with clinical findings of neuroendocrine tumors

Competency Area: Cytology
• Recognize neuroendocrine tissues and lesions in cytology aspirates
• Classify neuroendocrine tissues and lesions in cytology aspirates

Competency Area: Morphology
• Diagnose neuroendocrine tumors and precursor lesions in diverse tissues
• Subclassify neuroendocrine tumors and precursor lesions in diverse tissues

Competency Area: Ancillary Studies
• Apply histochemistry tests in neuroendocrine diseases to best understand clinical and pathological correlation
• Interpret appropriate immunohistochemistry tests in neuroendocrine tumors
• Recognize electron microscopic characteristics of neuroendocrine tumors
• Determine the molecular genetics of distinct neuroendocrine diseases and familial syndromes
• Interpret molecular markers for diagnosis, treatment, and prognosis of neuroendocrine tumors

Competency Area: Treatment Implications
• Recognize critical neuroendocrine laboratory results and immediately communicate to clinicians
• Recognize treatment implications of neuroendocrine tumors

Competency Area: Reporting and Communication
• Follow published recommendations for classification, reporting, staging, and grading of neuroendocrine tumors
• Comply with synoptic reporting guidelines for neuroendocrine tumors in various sites
• Generate clear, concise, and accurate reports that effectively communicate testing results and treatment implications to the neuroendocrine tumor patient’s health care team
• Clearly communicate critical/significant diagnoses requiring immediate action
• Appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
• Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
• Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency: Endocrine Pathology
Sub-competency: Parathyroid Pathology

Sub-competency Definition:
Interprets laboratory data including biochemical, morphologic, and molecular findings to diagnose parathyroid disorders and correlates this data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses.

Competency Areas:
A. Chemical Pathology
B. Clinicopathologic Correlation
C. Cytology
D. Morphology
E. Ancillary Studies
F. Treatment Implications
G. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Chemical Pathology
• Implement testing methods for calcium/PTH abnormalities
• Interpret testing methods for calcium/PTH abnormalities

Competency Area: Clinicopathologic Correlation
• Interpret imaging modalities applied in parathyroid lesions
• Correlate the imaging findings (especially radiolabelled scintigraphic studies) with clinical findings

Competency Area: Cytology
• Recognize parathyroid tissue in cytologic aspirates
• Distinguish parathyroid lesions from other diseases

Competency Area: Morphology
• Distinguish diverse parathyroid lesions
• Diagnose a diverse array of parathyroid lesions

Competency Area: Ancillary Studies
• Apply histochemistry tests in parathyroid diseases for diagnosis, prognostic indicators, and for treatment
• Utilize appropriate immunohistochemistry tests in parathyroid lesions
• Interpret electron microscopic characteristics of parathyroid tumors
• Assess the molecular genetics of distinct parathyroid diseases and familial syndromes
• Interpret molecular markers for diagnosis, treatment, and prognosis of parathyroid tumors
Competency Area: Treatment Implications
- Recognize implications of intraoperative diagnosis and intraoperative PTH assay
- Recognize the implications of diagnosis of parathyroid neoplasms such as adenoma, atypical adenoma, and carcinoma that may require specific management approaches

Competency Area: Reporting and Communication
- Follow published recommendations on reporting of parathyroid lesions
- Generate clear, concise, and accurate reports that effectively communicate parathyroid testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency: Endocrine Pathology
Sub-competency: Pathology of Diabetes

Sub-competency Definition:
Interprets laboratory data including biochemical, morphologic, and molecular findings to diagnose diabetic disorders and correlates this data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses

Competency Areas:
A. Clinicopathologic Correlation
B. Chemical Pathology
C. Morphology
D. Treatment Implications
E. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Clinicopathologic Correlation
- Distinguish the various types of diabetes mellitus including possible complications
- Recognize the specific findings with emphasis on diabetic changes in diverse organs

Competency Area: Chemical Pathology
- Implement testing methods for diabetes, eg, Glucose - random, Glucose - fasting, Glucose tolerance test - oral, Hemoglobin A1C, Point-of-care glucose
- Interpret testing methods for diabetes

Competency Area: Morphology
- Distinguish the various manifestations and complications of diabetes mellitus
- Recognize pathological changes associated with diabetes mellitus

Competency Area: Treatment Implications
- Recognize critical diabetic results and immediately communicate to clinicians
- Recognize treatment implications for diabetes mellitus
**Competency Area: Reporting and Communication**
- Follow published recommendations in pathology reporting formatting
- Comply with reporting surgical pathology guidelines for a clear diagnosis
- Generate clear, concise, and accurate reports that effectively communicate diabetes testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

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**Competency: Endocrine Pathology**

**Sub-competency: Pituitary Pathology**

**Sub-competency Definition:**
Interprets laboratory data including biochemical, morphologic, and molecular findings to diagnose pituitary disorders and correlates this data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses.

**Competency Areas:**
A. Clinicopathologic Correlation
B. Chemical Pathology
C. Morphology
D. Ancillary Studies
E. Treatment Implications
F. Quality Assurance
G. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Clinicopathologic Correlation**
- Recognize clinical and biochemical features of pituitary tumors, pituitary hyperfunction and hypofunction, including features distinguishing these from other tumors
- Recognize radiologic features of diverse pituitary lesions

**Competency Area: Chemical Pathology**
- Implement dynamic testing for hormone-secreting pituitary tumors, testing for selective or generalized pituitary gland failure
- Interpret dynamic testing for hormone-secreting pituitary tumors, testing for selective or generalized pituitary gland failure

**Competency Area: Morphology**
- Recognize pituitary adenomas and nonneoplastic pituitary diseases
- Subclassify pituitary adenomas and nonneoplastic pituitary diseases

**Competency Area: Ancillary Studies**
- Utilize appropriate histochemistry tests in pituitary diseases
- Interpret appropriate immunohistochemistry tests in pituitary lesions
- Interpret electron microscopic characteristics of pituitary tumors
- Assess the molecular genetics of distinct pituitary diseases and familial syndromes
- Apply molecular markers for diagnosis, treatment, and prognosis of pituitary tumors
- Interpret molecular markers for diagnosis, treatment, and prognosis of pituitary tumors

**Competency Area: Treatment Implications**
- Recognize critical pituitary laboratory results and immediately communicate to clinicians
- Recognize treatment implications of pituitary lesions

**Competency Area: Quality Assurance**
- Identify antibody specificities and cross reactivities that impact pituitary tumor classification
- Correlate clinical, morphological, and radiological findings with pathology reporting

**Competency Area: Reporting and Communication**
- Follow published recommendations for use of ancillary studies in pituitary pathology
- Comply with synoptic reporting guidelines for pituitary tumors
- Generate clear, concise, and accurate reports that effectively communicate pituitary testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

**Competency: Endocrine Pathology**

**Sub-competency: Thyroid Pathology**

**Sub-competency Definition:**
Interprets laboratory data including biochemical, morphologic, and molecular findings to diagnose thyroid disorders and correlates this data with clinical and imaging findings in a concise, cogent report that is accurately and efficiently conveyed to the clinician and/or patient, applying best principles of practice and understanding the clinical implications for treatment of specific diagnoses.

**Competency Areas:**
A. Chemical Pathology
B. Clinicopathologic Correlation
C. Ancillary Studies
D. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Chemical Pathology**
- Interpret thyroid chemistry, serology panels, and ultrasensitive TSH
- Correlate chemical findings to morphologic and molecular features
Competency Area: Clinicopathologic Correlation
- Identify thyroid pathology by fine needle aspiration and cytology interpretation
- Create integrated pathology report with chemical, morphologic, molecular findings and include comment about treatment implications
- Recognize morphologic characteristics of diverse thyroid lesions
- Correlate imaging findings with clinical, biochemical, and morphologic features of thyroid lesions

Competency Area: Ancillary Studies
- Apply histochemistry tests in thyroid diseases for diagnosis, prognostic indicators, and for treatment
- Utilize appropriate immunohistochemistry tests in thyroid lesions
- Interpret electron microscopic characteristics of thyroid tumors
- Assess the molecular genetics of distinct thyroid diseases and familial syndromes

Competency Area: Reporting and Communication
- Classify cytology lesions following NCI Thyroid Fine Needle Aspiration Guidelines
- Comply with CAP synoptic reporting guidelines for thyroid cancers
- Generate clear, concise, and accurate reports that effectively communicate thyroid testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis, and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

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Supporting Committee(s)
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Competency: Forensic Pathology (To Be Developed)
Competency: Gastrointestinal Pathology

Competency Definition:
Applies best practices in interpretation of biopsies, endoscopic and surgical resection specimens; and appropriately incorporate clinical, endoscopic, laboratory and radiological/imaging information to diagnose benign, inflammatory/infectious, degenerative, and neoplastic conditions of the gastrointestinal tract.

Sub-competencies:
1. Appendix
2. Esophagus
3. Molecular Oncology
4. Stomach
5. Small Intestine
6. Large Intestine and Rectum

Sub-competency: Appendix

Sub-competency Definition:
Employs best practices in diagnosing and reporting diseases of the appendix. These best practices apply to specimen collection, grossing, tissue processing, interpretation, and communication including: integration of morphologic findings and the results of ancillary studies, as appropriate, with available clinical and radiologic information; appreciation of the prognostic and therapeutic import of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary health care team.

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Differential Diagnosis
D. Treatment Implications
E. Reporting and Communication
F. Ancillary Studies

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types

- Apply a minimum set of histologic criteria in the diagnosis of acute appendicitis (eg, neutrophilic infiltration of the muscularis propria), understand its broad etiologic differential diagnosis, and recognize that the etiopathogenesis of many cases is uncertain
- Recognize the clinical setting in which interval (delayed) appendectomy is undertaken and the histologic features seen in these specimens
- Recognize the highly prevalent nature of neurotization of the appendix/fibrous obliteration, likely as a result of repeated low-grade insults, and its general lack of clinical significance
- Recognize that neuroendocrine tumors are the most common appendiceal neoplasm, with most cases detected incidentally and presenting in the tip
- Recognize that most instances of pseudomyxoma peritonei arise in association with a ruptured low-grade appendiceal mucinous neoplasm; distinguish this biology from that seen with appendiceal adenocarcinoma
- Recognize that the appendix may be involved by chronic active inflammation in idiopathic inflammatory bowel disease
- Recognize unusual findings in routine appendectomy specimens (eg, luminal parasites, adenovirus, spirochetosis, and Müllerian tissue)
Competency Area: Specimen Handling
- Ensure correct specimen identity by secure patient identification, specimen labeling, completion of requisition form, etc., according to local laboratory practice
- Incorporate clinical and radiologic information in specimen grossing
- Advise surgeon on appropriate use of frozen section
- Ink the external appendiceal surface of mucinous lesions, and carefully examine for evidence of rupture/extraluminal mucin
- Evaluate luminal contents for fecalith, polyp, diverticulum, mucin, and parasites
- Select appropriate tissue sections for subsequent histologic examination, including, at a minimum, the proximal (mucosal) margin, representative cross sections of any lesion(s), and a longitudinal section through the tip
- Recognize indications for entirely submitting an appendectomy specimen (eg, mucinous lesions, absence of significant inflammation on H&E slides in clinical acute appendicitis)
- Identify twelve (12) or more lymph nodes in specimens including a regional lymphadenectomy for malignancy (eg, right hemicolecctomy for appendiceal adenocarcinoma)
- Advise appropriate collection and handling of specimens for additional studies (eg, aerobic and anaerobic bacterial cultures), as needed

Competency Area: Differential Diagnosis
- Distinguish inflammatory mucocele from mucinous neoplasms; recognize that appendiceal diverticular disease may be associated with either inflammatory mucocele or low-grade appendiceal mucinous neoplasm
- Differentiate low-grade appendiceal mucinous neoplasm from conventional adenoma, hyperplastic poly, sessile serrated adenoma/polyp, and appendiceal adenocarcinoma
- Separate tubular, clear cell/lipid rich, and goblet cell carcinoids from each other and from metastatic adenocarcinoma
- Apply published criteria to distinguish "pure" goblet cell carcinoid (GCC) from adenocarcinoma ex GCC (aka mixed adenoneuroendocrine carcinoma)
- Adjudicate the differential diagnosis of "granulomatous appendicitis" including, usually, interval (delayed) appendectomy and Yersinia infection and, less commonly, Crohn’s disease or mycobacterial infection, making use of clinical correlation and special stains for microorganisms

Competency Area: Treatment Implications
- Recognize the impact of the presence of tumor at the proximal (mucosal) margin in a simple appendectomy as regards the decision to re-operate
- Recognize the importance of disease biology in determining the choice of ileocelectomy (eg, in low-grade appendiceal mucinous neoplasm with a positive mucosal margin at appendectomy) vs. right hemicolectomy (eg, in appendiceal adenocarcinoma and well-differentiated neuroendocrine tumor > 2 cm) in re-operated patients
- Recognize the importance of tumor size and the unsettled importance of lymph-vascular invasion and mesoappendiceal involvement in determining the need for right hemicolectomy in patients with well-differentiated neuroendocrine tumors
- Recognize the unsettled debate regarding the adequacy of simple appendectomy as treatment of low-stage goblet cell carcinoid
- Recognize the importance of the presence of acellular extra-appendiceal mucin (low-risk) and extra-appendiceal neoplastic epithelium (high-risk) as regards recurrence and development of pseudomyxoma peritonei in patients with low-grade appendiceal mucinous neoplasms
- Recognize the critical distinctions in the management of pseudomyxoma peritonei vs. appendiceal adenocarcinoma not involving the peritoneum
- Recognize the importance of accurate TNM (tumor, node, metastasis) staging of appendiceal adenocarcinoma as regards the decision to recommend adjuvant chemotherapy
**Competency Area: Reporting and Communication**

- Generate accurate, clear, and concise reports that effectively communicate results and therapeutic implications to the patient’s health care team
- Employ synoptic reporting for appendiceal adenocarcinomas and neuroendocrine neoplasms (eg, CAP Cancer Protocols)
- Perform TNM staging of appendiceal adenocarcinomas and neuroendocrine neoplasms according to current American Joint Committee on Cancer (AJCC)/International Union for Cancer Control (UICC) guidelines as specified in Chapter 13 of the 7th edition of the AJCC Cancer Staging Manual (NOTE: high-grade neuroendocrine carcinomas and goblet cell carcinoids are more aggressive than well-differentiated neuroendocrine tumors and are staged as carcinomas)
- Utilize current World Health Organization (WHO) terminology for appendiceal neoplasms and grading criteria for neuroendocrine neoplasms (including Ki-67 proliferation index and mitotic rate) as specified in the WHO 2010 Gastrointestinal “Blue Book”
- Integrate results of ancillary testing into the final diagnosis
- Communicate significant and unexpected findings (eg, presence of AFB, frozen section/permanent section discordance) and anticipated delays in diagnosis, and document these preliminary communications (including physician notified and date) in the final report
- Articulate educational notes and recommendations as needed
- Demonstrate willingness and ability to discuss results with the multidisciplinary health care team

**Competency Area: Ancillary Studies**

- Perform special stains for microorganisms in appropriate diagnostic contexts (eg, AFB and fungal stains in “granulomatous appendicitis”)
- Perform other special stains in appropriate diagnostic contexts when the H&E is not sufficient (eg, mucin histochemistry in the differential diagnosis of goblet cell carcinoid vs. clear cell/lipid rich carcinoid)
- Perform immunohistochemical stains judiciously in appropriate diagnostic contexts (eg, CDX2 and WT-1 to distinguish neoplastic mucinous epithelium from reactive mesothelial cells, as needed)
- Recognize the limited application of hormone immunohistochemistry (eg, for serotonin, insulin, glucagon, etc.) in the diagnosis of neuroendocrine tumors and that the detection of hormone expression does not equate with clinically apparent functionality
- Recognize the limited application of mismatch repair (MMR) protein immunohistochemistry/microsatellite instability testing in appendiceal adenocarcinoma, given the infrequency of MMR deficiency at this anatomic site

**Competency: Gastrointestinal Pathology**

**Sub-competency: Esophagus**

**Sub-competency Definition:**
Applies best practices in interpretation of esophageal biopsies, endoscopic and surgical resection specimens; and appropriately incorporates clinical, endoscopic, laboratory and radiological/imaging information to diagnose benign, inflammatory/infectious, degenerative and neoplastic conditions of the esophagus.

**Competency Areas:**
A. Disease Types
B. Specimen Handling
C. Differential Diagnosis
D. Clinical Implications
E. Reporting and Communication
F. Procedures
G. Ancillary Studies
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types

- Recognize the anatomic alterations and structural elements, such as types of epithelial lining and tissues, seen in developmental abnormalities and acquired deformations of the esophagus
- Identify common fungal and viral infections, such as Candida, herpes simplex, cytomegalovirus, and less commonly encountered pathogens such as tuberculosis and syphilis
- Diagnose specific forms of esophagitis, such as eosinophilic esophagitis and reflux esophagitis, by histologic features and correlation with clinical findings
- Recognize other inflammatory conditions affecting the esophagus, such as Crohn’s disease and sarcoidosis, and iatrogenic and traumatic injuries such as medication-induced ulcers
- Differentiate tumor-like conditions of the esophagus, such as diverticula, webs, xanthoma, and idiopathic muscular hypertrophy, from malignancies
- Diagnose carcinomas of the esophagus and their associated pre-invasive lesions, such as identifying Barrett’s Esophagus and classifying associated glandular dysplasia, and recognizing squamous cell carcinoma and associated changes of the squamous dysplasia-carcinoma sequence
- Diagnose and apply appropriate grading and staging schemes to non-epithelial neoplasms that occur in the esophagus
- Diagnose and classify esophageal polyps, such as squamous papilloma, heterotopias, and inflammatory and hyperplastic polyps
- Identify the etiology and histologic features of vascular disorders of the esophagus
- Recognize the histologic changes and clinical symptoms that may be seen in systemic diseases, such as amyloidosis, systemic sclerosis, polymyositis, and dermatomyositis

Competency Area: Specimen Handling

- Manage or oversee gross examination of endoscopic mucosal and submucosal resection specimens to optimize histologic examination and assure appropriate evaluation of margins
- Implement a process for gross (macroscopic) examination and sectioning of esophageal resection specimens for carcinoma, with or without preoperative neoadjuvant treatment, to ensure inclusion of all relevant staging and prognostic information
- Request additional tissue when technical artifact and/or limited sampling hamper diagnosis
- Evaluate frozen sections of gastric specimens for identification of lesions and margin status
- Communicate with gastroenterologists to implement ways to improve or optimize quality of tissue samples obtained for histologic evaluation, such as orientation of pinch biopsy specimens in the endoscopy suite or implementation of more complete biopsy protocols
- Employ the optimal biopsy and fixation strategy for endoscopic work-up of bullous disorders of the esophagus
- Employ optimal collection techniques and transport media selection for flow cytometry work-up of possible hematolymphoid disorders
- Recommend appropriate fixatives for routine histology versus special handling, such as electron microscopy

Competency Area: Differential Diagnosis

- Identify and quantitate increased intraepithelial eosinophils, and interpret this finding in context of an appropriate differential diagnosis, such as eosinophilic esophagitis versus reflux esophagitis
- Classify esophageal adenocarcinoma versus gastric adenocarcinoma for purposes of AJCC staging
- Generate a differential diagnosis for granulomatous disease in the esophagus, utilizing special stains in the work-up as indicated
- Generate a differential diagnosis for uncommon neoplasms of the esophagus, such as small cell carcinoma and spindle cell carcinoma
- Distinguish primary esophageal tumors from non-esophageal malignancies, such as metastatic melanoma or lung cancer
- Diagnose non-epithelial neoplasms of the esophagus, distinguishing GIST from leiomyoma and other mimics
• Apply differential diagnostic considerations for iatrogenic and traumatic lesions, such as those due to medications, radiation, corrosive substance ingestion, and mechanical injury
• Distinguish between benign and malignant inflammatory infiltrates
• Distinguish between reactive epithelial changes, low-grade dysplasia, high-grade dysplasia, and intramucosal adenocarcinoma in Barrett’s esophagus and know when to apply the indefinite for dysplasia category

**Competency Area: Clinical Implications**

• Recognize the long-term sequelae of inflammatory esophageal conditions, including reflux esophagitis and achalasia
• Communicate the assessment of HER2 status in esophageal adenocarcinoma, with recognition of the impact of findings on clinical treatment options
• Recognize the clinical implication of diagnosis of Barrett’s esophagus and associated dysplasia and its impact on surveillance and treatment
• Compare the definition of Barrett’s esophagus used in North America (Canada and US) with that used in Japan and UK
• Ensure accurate TNM staging of esophageal carcinoma and understand the clinical use of such information
• Recognize the different clinical implications of a diagnosis of reflux esophagitis and eosinophilic esophagitis
• Recognize the clinical implications of finding HPV in squamous papillomas

**Competency Area: Reporting and Communication**

• Generate accurate, clear, and concise reports that communicate results and therapeutic implications with the patient’s healthcare team
• Employ synoptic reporting for esophageal carcinomas and gastrointestinal stromal tumors (eg, CAP cancer protocols) utilizing World Health Organization (WHO) terminology, as appropriate
• Perform TNM staging of esophageal carcinomas and gastrointestinal stromal tumors according to the guidelines specified in the current edition of the AJCC TNM Cancer Staging Manual
• Utilize current WHO (or other international accepted terminology) to classify and grade esophageal cancer
• Integrate results of ancillary testing into the final diagnosis
• Communicate significant or unexpected findings and anticipated delays in diagnosis, and document these preliminary communications in the final report
• Demonstrate willingness, accessibility, and ability to discuss results with a multidisciplinary healthcare team, including participation in appropriate conferences and tumor boards
• Apply appropriate terminology for tumor regression after neoadjuvant therapy
• Apply accepted terminology when reporting cases of Barrett’s esophagus and associated dysplasia
• Follow the appropriate ethical protocol to communicate hereditable syndromes
• Consult (other) subspecialty experts as appropriate on problematic cases
• Ensure that patient confidentiality is maintained while communicating and reporting patient results to the provider

**Competency Area: Procedures**

• Employ an optimal biopsy and fixation strategy for endoscopic work-up of bullous disorders of the esophagus
• Employ a strategy for gross examination and sectioning of esophageal resection specimens for carcinoma with or without neoadjuvant treatment
• Utilize the American College of Gastroenterology guidelines for examining specimens from patients with Barrett’s neoplasia
• Apply algorithms for HER2 testing in esophageal adenocarcinoma, utilizing immunohistochemistry and fluorescence in situ hybridization as recommended by standard-setting organizations such as the National Comprehensive Cancer Network (NCCN) or FDA
• Recommend appropriate molecular testing methods for GI stromal tumors
Competency Area: Ancillary Studies

- Apply appropriate special histological stains (eg, PAS, methenamine silver stain) for detection of fungi in esophageal specimens
- Recognize the clinical settings that suggest the need for special studies for viral pathogens and utilize the appropriate special methods for their detection
- Employ an appropriate panel of immunohistochemical studies to assist in the diagnosis of non-epithelial neoplasms, poorly differentiated carcinomas, and metastatic tumors to the esophagus
- Score immunohistochemical studies for HER2 performed on an esophageal adenocarcinoma according to site-specific guidelines, and recommend cases that need HER2 fluorescence in situ hybridization studies
- Employ special mucin stains that may be used in detecting Barrett’s esophagus, when appropriate
- Communicate results of HER2 FISH studies in esophageal adenocarcinoma, including HER2/CEP17 ratio and absolute HER2 number
- Determine appropriate positive and negative controls for each histochemical and immunohistochemical stain employed in the laboratory
- List the immunofluorescent (IF) stains indicated in the differential diagnosis of bullous lesions of the esophagus and the media indicated for collecting/holding biopsies for IF

Competency: Gastrointestinal Pathology
Sub-competency: Molecular Oncology

Sub-competency Definition:
Applies best practices in specimen handling and clinical indications for a molecular test, identifies applicable tests and recognizes their limitations, understands treatment and other clinical implications, and ensures delivery of an accurate and concise report to oncologists/surgeons in a timely and effective manner.

Competency Areas:
A. Clinical Indications for Testing
B. Specimen Handling
C. Testing Methods
D. Clinical Implications
E. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Clinical Indications for Testing

- Determine microsatellite instability (MSI) status of all colorectal cancers OR colorectal cancers from patients diagnosed at
- Determine if RAS (KRAS/NRAS) is mutated for stage IV colorectal cancer and recommend testing for BRAF mutation if RAS is not mutated
- Determine the presence/absence of HER2 overexpression/amplification in advanced or metastatic gastric or gastro-esophageal junction cancer
- Recommend testing for mutations in the KIT and PDGFRA genes in advanced or metastatic gastrointestinal stromal tumors when tyrosine kinase inhibitors are considered

Competency Area: Specimen Handling

- Recognize the need for established laboratory procedures/protocols for handling tissue and specimen for potential future nucleic acid or ancillary testing
- Ensure that samples are processed correctly, avoiding decalcification and under/over fixation, so that reliable and accurate diagnosis and test results can be obtained
• Recognize the importance of blocks selection with sufficient tumor cells based on limits of detection (the minimal percentage of neoplastic cells that are present in a sample) for DNA-based molecular tests and ensure that they are voided of any extraneous/floater tissue
• Identify an area(s) of the sample for macrodissection/microdissection that will allow you to obtain a sufficient percentage of tumor cells for molecular testing if further dissection is required
• Provide an estimate of the percentage of neoplastic cells present in the tissue section or selected area used for testing
• Ensure that a normal tissue/blood sample is submitted with the tumor sample for MSI testing
• Ensure that sufficient tumor tissue is tested for HER2 overexpression/amplification in gastric or gastro-esophageal junction cancer due to tumor heterogeneity
• Recognition of the importance of using 10% neutral buffered formalin for HER2 studies

Competency Area: Testing Methods
• Utilize immunohistochemistry (IHC) or MSI testing by PCR or both to screen for MSI-high colorectal cancers
• Recognize that both IHC and MSI testing by PCR have a 5%-10% false-negative rate, identify common pitfalls of each, and repeat or recommend alternative testing when necessary
• Recognize the need for additional testing (testing for BRAF V600E mutation and/or hypermethylation of MLH1 promoter) for MSI-high colorectal cancers to differentiate Lynch Syndrome-related colorectal cancer from sporadic MSI-high tumor
• Recognize the several test methods that can be employed for detecting RAS or BRAF mutations, including Sanger sequencing, pyrosequencing, allele-specific PCR, PCR and single-base extension, next generation sequencing, and immunohistochemistry for BRAF mutation
• Recognize advantages and disadvantages of the different methods for detecting RAS or BRAF
• Employ techniques such as Sanger sequencing with/without combination of restriction enzyme digestion of PCR product to detect KIT/PDGRFA mutations in gastrointestinal stromal tumors
• Detect HER2 protein overexpression by IHC and HER2 gene amplification by fluorescence in situ hybridization (FISH) in gastric and gastro-esophageal cancers
• Recognize the differences in HER2 overexpression between breast and gastric/gastro-esophageal junction cancers
• Recognize the differences in HER2 expression between biopsy and resection specimen in gastric/gastro-esophageal junction cancers

Competency Area: Clinical Implications
• Recognize clinical implications of MSI testing, such as prognosis, prediction of response to 5-FU and irinotecan therapy, detection of Lynch Syndrome, and impact on family members who will require screening
• Identify RAS(KRAS/NRAS)-wild type (and possibly BRAF-wild type) stage IV colorectal cancers that respond to cetuximab or panitumumab
• Understand that the presence or absence of mutations in specific regions of the KIT and PDGFRA genes are correlated with response or resistance to certain tyrosine kinase inhibitors
• Recognize that patients with a HER-2 positive (3+ immunohistochemical staining or FISH+) advanced gastric or gastro-esophageal junction cancer may benefit from treatment with trastuzumab, a recombinant humanized IgG1 monoclonal anti-HER2 antibody

Competency Area: Reporting and Communication
• Specify the genes, loci, or mutation types tested and the method used to analyze the sample and its limitations
• Integrate the test results with clinical history, morphologic findings, and results of other ancillary studies, and establish algorithm to recommend appropriate follow-up testing if necessary
• Provide accurate, clear and concise interpretation of the result(s) obtained and incorporate any relevant, up-to-date advice including the potential use of targeted therapy in mutation positive tumors
• Demonstrate willingness, accessibility, and the ability to discuss results with the patient’s healthcare team
• Follow appropriate ethical protocols to communicate heritable syndromes and recognize the national, state and local regulatory and/or ethical requirements for consent, ordering and performance of genetic testing
Competency: Gastrointestinal Pathology
Sub-competency: Stomach

Sub-competency Definition:
Employs best practices in diagnosing and reporting diseases of the stomach. These best practices apply to specimen handling, gross examination, tissue processing, interpretation of morphologic findings, and communication with other health care professionals, and include integration of morphologic findings with results of ancillary studies, as appropriate, with available clinical and radiologic information; understanding the clinical implications of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary healthcare team.

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Testing Methods
D. Ancillary Studies
E. Differential Diagnosis
F. Clinical Implications
G. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Diagnose gastritis, including H. pylori gastritis and special forms of gastritis such as lymphocytic, collagenous, eosinophilic gastritis, and atrophic gastritis due to autoimmune gastritis
- Diagnose other inflammatory disorders of the stomach such as reactive gastropathy, involvement of the stomach by inflammatory bowel disease, and systemic disorders such as sarcoidosis
- Distinguish vascular disorders of the stomach, including gastric antral vascular ectasia, portal hypertensive gastropathy, and Dieulafoy’s lesion using morphologic, endoscopic, and clinical findings
- Identify histologic findings of gastric ulcers and medication-related injuries, including iron, NSAIDs, Kayexalate, and correlate with etiology
- Differentiate tumor-like lesions of the stomach (such as gastritis cystica profunda, pancreatic rest, and foveolar hyperplasia) from malignancies
- Diagnose epithelial neoplasms of the stomach and identify changes of the metaplasia-dysplasia-carcinoma sequence
- Diagnose mesenchymal neoplasms of the stomach and apply appropriate grading and staging schemes to gastrointestinal stromal tumors arising in the stomach
- Distinguish between primary gastric carcinoma and histologic mimics (metastatic tumors, pseudosignet ring cell change, etc.)
- Diagnose and classify common lymphoid neoplasms involving the stomach such as follicular lymphoma, MALT and mantle zone lymphoma and know when to consult or refer other suspicious lymphoid lesions
- Recognize the controversy surrounding the distinction of intestinal metaplasia of the distal esophagus and the gastric cardia
- Classify and distinguish from malignant lesions all gastric polyps including fundic gland polyp, hyperplastic polyp, hamartomatous polyp, and inflammatory fibroid polyp
- Classify and grade neuroendocrine proliferations and tumors

Competency Area: Specimen Handling
- Employ optimal collection strategy and media selection for flow cytometry analysis of possible hematolymphoid disorders
- Recommend appropriate fixatives for routine histology versus techniques requiring special processing, such as for electron microscopy
Manage or oversee gross examination of endoscopic mucosal and submucosal resection specimens to optimize histologic examination and assure appropriate evaluation of margins

Implement a strategy for gross examination and sectioning of gastric resection specimens for carcinoma, with or without preoperative neoadjuvant treatment, to ensure inclusion of all relevant staging and prognostic information

Request additional tissue when technical artifact and/or limited sampling hamper diagnosis

Communicate with gastroenterologists to implement ways to improve or optimize quality of tissue samples obtained for histologic evaluation, such as orientation of pinch biopsy specimens in the endoscopy suite or implementation of more complete biopsy protocols

Evaluate frozen sections of gastric specimens for identification of lesions and margin status

Competency Area: Testing Methods

Recommend appropriate molecular testing methods for gastrointestinal stromal tumors

Recognize utility of cultures in gastric specimens

Recognize the role of fine needle aspiration in endoscopic ultrasound-guided diagnosis of submucosal lesions

Apply algorithms for HER2 testing in gastric adenocarcinoma, utilizing immunohistochemistry and fluorescence in situ hybridization as recommended by standard-setting organizations such as the National Comprehensive Cancer Network (NCCN) or FDA

Competency Area: Ancillary Studies

Apply appropriate histochemical or immunochemical stains for detection of Helicobacter pylori organisms in gastric specimens

Recognize the clinical settings that might indicate a need for special studies for viral, fungal, and non-H. pylori bacterial pathogens, and utilize the appropriate special methods for their detection

Use appropriate special studies (gastrin or other immunohistochemical stains) to assist in the diagnosis of atrophic gastritis, neuroendocrine cell hyperplasia, and intestinal metaplasia

Employ an appropriate panel of immunohistochemical studies to assist in the diagnosis of non-epithelial neoplasms, poorly differentiated carcinomas, and metastatic tumors to the stomach

Score immunohistochemical studies for HER2 performed on a gastric carcinoma according to site-specific guidelines, and recommend cases that need HER2 fluorescence in situ hybridization studies (FISH)

Evaluate and interpret the results of HER2 FISH studies in gastric adenocarcinoma, including HER2/CEP17 ratio and absolute HER2 number

Employ a panel of immunohistochemical studies to evaluate lymphoid lesions and diagnose/classify the most commonly encountered lymphoid neoplasms

Determine appropriate positive and negative controls for each histochemical and immunohistochemical stain employed in the laboratory

Grade neuroendocrine tumors using mitotic rate or Ki67 immunohistochemistry according to current guidelines

Competency Area: Differential Diagnosis

Classify chronic gastritis and its variants, including lymphocytic gastritis, collagenous gastritis, and eosinophilic gastritis, using accepted grading schemes such as the updated Sydney system, when appropriate

Diagnose non-epithelial neoplasms of the stomach, distinguishing GIST (gastrointestinal stromal tumors) from schwannoma and other mimics

Distinguish inflammatory bowel disease involving the stomach from other inflammatory conditions

Generate a differential diagnosis for granulomatous gastritis

Evaluate the range of findings in graft versus host disease, with generation of an appropriate differential diagnosis based on histologic and clinical findings

Classify gastric adenocarcinoma versus gastroesophageal junction adenocarcinoma and esophageal adenocarcinoma for purposes of AJCC staging
• Distinguish between ultra-short segment Barrett’s esophagus and intestinal metaplasia of the stomach
• Generate a differential diagnosis of medication-induced injury in the stomach
• Distinguish between vascular lesions of the stomach using clinical, endoscopic and histologic findings
• Use clinical, laboratory, and histologic findings to distinguish eosinophilic gastroenteritis from other inflammatory conditions involving the stomach
• Distinguish gastric neoplasia versus its mimics (dysplasia from reactive change, signet ring cells from pseudo-signet ring cells)
• Distinguish between and classify neuroendocrine cell hyperplasia, dysplasia, and neoplasia according to accepted criteria
• Distinguish between hyperplastic, fundic gland, hamartomatous, and less common gastric polyps
• Distinguish between benign and malignant inflammatory infiltrates

Competency Area: Clinical Implications
• Recognize the long-term sequelae and natural history of Helicobacter pylori gastritis, including ulcerations, atrophy, and neoplasia
• Correlate molecular findings in GIST (gastrointestinal stromal tumor) with clinical implications for treatment
• Estimate risk of developing adenocarcinoma in association with intestinal metaplasia
• Recognize the clinical impact of endoscopic mucosal resection findings
• Incorporate knowledge of clinical/etiologic setting in assessing the risk of progression for gastric neuroendocrine tumors
• Ensure adequate lymph node retrieval in gastric adenocarcinoma resection specimens, taking into account the type of lymph node dissection performed
• Ensure accurate TNM staging of gastric adenocarcinoma to guide adjuvant therapy
• Communicate assessment of HER2 status in gastric adenocarcinoma, with recognition of impact of findings on clinical treatment options

Competency Area: Reporting and Communication
• Generate accurate, clear, and concise reports that effectively communicate results and therapeutic implications to the patient’s healthcare team
• Employ synoptic reporting for gastric adenocarcinomas, neuroendocrine neoplasms, and gastrointestinal stromal tumors (eg, CAP Cancer Protocols)
• Perform TNM staging of gastric adenocarcinomas, neuroendocrine neoplasms, and gastrointestinal stromal tumors according to the guidelines specified in the current edition of the AJCC (American Joint Committee on Cancer) TNM Cancer Staging Manual
• Utilize current World Health Organization (WHO) (or other internationally accepted terminology) to classify and grade gastric cancer, including carcinomas and well-differentiated neuroendocrine tumors
• Use recommended terminology to describe the histologic findings in biopsies from the distal esophagus, gastroesophageal junction, and gastric cardia
• Integrate results of ancillary testing into the final diagnosis
• Communicate significant or unexpected findings and anticipated delays in diagnosis, and document these preliminary communications in the final report
• Demonstrate willingness, accessibility, and ability to discuss results with a multidisciplinary healthcare team, including participation in appropriate conferences and tumor boards
• Apply appropriate terminology for tumor regression after neoadjuvant therapy
• Follow appropriate ethical protocols to communicate heritable syndromes
• Consult (other) subspecialty experts as appropriate on problematic cases
Competency: Gastrointestinal Pathology
Sub-competency: Small Intestine

Sub-competency Definition:
Applies best practices in interpretation of biopsies and surgical resection specimens. Appropriately incorporates clinical, endoscopic, laboratory and radiological/imaging information to diagnose benign, inflammatory/infectious, degenerative, and neoplastic conditions of the small intestine.

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Testing Methods
D. Differential Diagnosis
E. Treatment Implications
F. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Recognize the clinical symptoms, endoscopic and histological findings for vascular abnormalities of the small intestine (eg, Angiodysplasia, arteriovenous malformation, Dieulafoy's abnormality, infarcts, ischemia)
- Identify the symptoms, causes, and histologic findings of primary and secondary neuromuscular disorders
- Recognize the histologic, gross/endoscopic, and microscopic appearance of the small intestine mucosa in fungal, viral, mycobacterial, parasitic and helminthic infections (eg, CMV, giardiasis adenovirus, Cytomegalovirus and adenovirus, Whipple disease)
- Recognize clinical and histologic features to suggest immunodeficiencies and autoimmune enteropathy
- Recognize clinical, endoscopic, and histologic features to suggest peptic injury
- Recognize features of drug-induced injury to the small intestine (ie, NSAIDs, mycophenolate)
- Define the clinical, serologic, and histologic features that can be seen in, along with possible complications of, celiac disease
- Identify the common clinical presentation and histologic changes of erosive/ ulcerating disease
- Recognize histologic features of graft-versus-host disease
- Recognize histologic features of acute cellular and antibody mediated rejection in small bowel allografts
- Identify the histologic features of the types of neoplastic and nonneoplastic polyps that can occur in the small intestine
- Discuss the epidemiology and the clinical, radiological, and endoscopic findings that may suggest a nonepithelial neoplasm (eg, granular cell tumor, leiomyoma, GIST, lymphangioma, lymphoma, melanoma, lipoma, hemangioma, Kaposi sarcoma, sarcoma, Schwannoma)
- Recognize features of a neuroendocrine neoplasm and recommend appropriate supportive stains, if needed
- Identify the features of small intestinal involvement by chronic inflammatory bowel disease (Crohn's disease)
- Discuss the common sites of heterotopia involving the small intestine and setting in which it may be encountered

Competency Area: Specimen Handling
- Employ the optimal biopsy and fixation strategy for endoscopic work-up of celiac sprue
- Manage endoscopic mucosal and submucosal resection specimens appropriately for histologic examination, including evaluation of margins
- Examine grossly and section small intestinal and ampullary resection specimens appropriately for accurate diagnosis, grading, and staging of neoplasms with or without preoperative neoadjuvant treatment
- Perform gross examinations of small intestinal resection specimens with non-neoplastic diseases, (ie, idiopathic inflammatory bowel disease, infarct/ischemia, and trauma) and section them appropriately to document the extent and severity of the pathological process
- Recognize situations in which special specimen processing may be necessary (eg, electron microscopy for suspected microvillous inclusion disease, frozen/fresh tissue for enzyme analysis)
Competency Area: Testing Methods

- Recommend serologic testing for antibodies, when appropriate, based on clinical-pathologic correlative questions
- Utilize cytogenetics for the work-up of mesenchymal neoplasms of the small intestine
- Employ special histochemical stains, immunohistochemical stains, and other tests (electron microscopy) to confirm a diagnosis of microvillus inclusion disease
- Use immunohistochemical or histochemical stains to increase detection of mast cells
- Use immunohistochemical staining menus and flow cytometry for the diagnosis and classification of hematolymphoid neoplasms
- Utilize stains assessing the cell cycle (such as Ki67) to appropriately grade neuroendocrine neoplasms
- Use immunohistochemical staining menus to differentiate primary from secondary tumors involving the small intestine
- Employ special histologic and immunohistochemical stains to detect bacterial, mycobacterial, fungal, viral, and parasitic infectious agents
- Use special histologic stains for the diagnosis of amyloidosis

Competency Area: Differential Diagnosis

- Identify common artifacts that may be seen in small intestinal biopsies and the diseases they may mimic
- Differentiate true invasion in epithelial tumors from its histologic mimics
- Use differential diagnostic considerations to diagnose vascular abnormalities in the small intestine
- Apply differential diagnostic considerations for erosive/ulcerative injury to diagnose appropriately
- List the differential diagnostic considerations for increased intraepithelial lymphocytes (eg, Celiac, Crohn’s disease, bacterial overgrowth, drug effect, collagenous and lymphocytic colitis)
- List the differential diagnostic considerations for increased intraepithelial eosinophils
- List the differential diagnostic considerations for malabsorption/steatorrhea
- Outline the range of findings and differential diagnostic considerations that can be seen with graft-versus-host disease of the small intestine
- Describe the range of findings and differential diagnostic considerations for diagnosing acute cellular and antibody mediated rejection in small intestinal allografts
- Provide a differential diagnosis for small intestinal crypt apoptosis
- List the differential diagnostic considerations for granulomas in the small intestine
- Identify and assess severity of villous blunting (mild, moderate and marked)
- Identify intraepithelial lymphocytosis and provide a differential diagnosis for cases with these findings
- Provide a differential diagnosis for subepithelial mesenchymal or spindle-cell neoplasms of the small intestine
- Provide a differential diagnosis for epithelial/epithelioid neoplasms of the small intestine
- Compare the changes in histology expected in acute, chronic intermittent, and healed ischemic damage
- Report the differential diagnoses associated with foveolar metaplasia with or without activity at different anatomic sites

Competency Area: Treatment Implications

- Recognize long-term sequelae following corrosive injury, radiation changes, thermal burns, and ulcers from medication effect and due to chemotherapy
- Recommend genetic testing and or genetic counseling based on rendered diagnoses, as appropriate
- Recognize the risk of synchronous and metachronous tumors in patients in whom a hamartomatous polyp is identified
- Recognize the treatment implications of the mutation status of gastrointestinal stromal tumors
- Recognize syndromic associations with neuroendocrine neoplasms of the small bowel

Competency Area: Reporting and Communication

- Suggest to the gastroenterologist additional clinical features that may need to be considered in the work-up of a disorder
- Utilize the accepted terminology for reporting UICC/ AJCC TNM staging of malignant neoplasms, as appropriate
• Recognize critical results necessitating immediate contact with clinicians (e.g., infection in an immunocompromised host, GVHD, small bowel transplant rejection, new/unsuspected diagnosis of malignancy)
• Provide appropriate comments and recommendations for cases in which findings are not specific, but rather which raise a differential diagnosis that requires additional testing or work-up
• Define a process for implementing the appropriate timing of reporting results
• Provide the appropriate histologic grade for cases of small intestinal transplant rejection
• Provide grading information for neuroendocrine neoplasms using accepted classification schemata

Competency: Gastrointestinal Pathology
Sub-competency: Large Intestine and Rectum

Sub-competency Definition:
Applies best practices in interpretation of biopsies and surgical resection specimens. Appropriately incorporates clinical, endoscopic, laboratory and radiological/imaging information to diagnose benign, inflammatory/infectious, degenerative, neoplastic, and syndrome-related conditions of the large intestine.

Competency Areas:
A. Disease Types
B. Specimen Handling
C. Testing Methods
D. Differential Diagnosis
E. Treatment Implications
F. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
• Recognize the features of invasive carcinoma in endoscopic biopsies, polypectomies, and resection specimens
• Recognize the endoscopic and histological findings for the various patterns of chronic inflammatory bowel disease (i.e., Crohn’s disease, ulcerative colitis, indeterminate colitis, and fulminant colitis)
• Identify the common clinical presentation and spectrum of histologic changes of microscopic colitis (lymphocytic and collagenous colitis)
• Identify the common clinical presentation and histologic features of pseudomembranes in biopsy and resection specimens
• Identify the clinical setting and histologic findings that suggest mucosal prolapsed
• Recognize the spectrum of morphologic changes that occur in drug-induced colonic injury (i.e., NSAIDs)
• Recognize histologic features of graft-versus-host disease
• Recognize the epidemiology and gross/microscopic changes in the large bowel caused by commonly encountered infectious agents (i.e., viral such as CMV and adenovirus, mycobacterial, cryptosporidium, spirochetes, bacterial, protozoal, and helminthic organisms)
• Recognize the clinical symptoms, endoscopic, histological findings, and common complications of diverticular disease
• Identify the histologic features of the types of polyps that can occur in the large intestine
• Describe the morphologic features of epithelial tumors/polyps that suggest inherited syndromes with and without associated increased cancer risk
• Recognize non-epithelial neoplasms (i.e., endometriosis, granular cell tumor, leiomyoma, GIST, lymphangioma, lymphoma, melanoma, lipoma, hemangioma, Kaposi sarcoma, sarcoma, and Schwannoma)
• Recognize features of neuroendocrine neoplasms
• Identify the histologic features that suggest ischemia
Competency Area: Specimen Handling

- Manage endoscopic mucosal, submucosal, and transanal resection specimens appropriately for histologic examination, including evaluation of margins
- Examine grossly and section large intestinal resection specimens appropriately from all anatomic sites for accurate diagnosis, grading, and staging for epithelial and nonepithelial neoplasms, with or without neoadjuvant treatment
- Describe assessment of the mesorectal envelope in rectal cancers (incomplete, nearly complete, complete)
- Perform gross examinations of large intestinal resection specimens with non-neoplastic diseases, including idiopathic inflammatory bowel disease, infarct/ischemia, diverticular disease, and trauma, and section them appropriately to document the extent and severity of the pathological process
- Describe appropriate specimen handling in cases of suspected hematolymphoid neoplasia involving the large intestine
- Describe strategies for managing technical limitations in specimens (ie, histologic/processing artifact, inadequate tissue)

Competency Area: Testing Methods

- Use immunohistochemical staining menus for the classification and diagnosis of primary and metastatic epithelial, non-epithelial, hematolymphoid neoplasms involving the large intestine
- Utilize immunohistochemical stains to assist in diagnosis and grading of neuroendocrine neoplasms
- Use an immunohistochemical approach to diagnose a mesenchymal neoplasm of the large intestine
- Use special histological and immunohistochemical stains to detect microorganisms in large intestinal specimens
- Use special histological and immunohistochemical stains to assist in the evaluation of specimens from patients with suspected neuromuscular abnormalities (ie, Hirschsprung’s disease, pseudoobstruction, etc.)
- Recommend flow cytometry appropriately in cases in which clinical and endoscopic features suggest a possible hematolymphoid neoplasm
- Interpret the results of Masson staining for use in the diagnosis of collagenous colitis
- Interpret immunohistochemical stains for DNA mismatch repair proteins and BRAF V600E mutation status that suggest germline mutations and epigenetic changes in colorectal carcinoma
- Correlate the results of molecular analyses for BRAF/KRAS mutations in primary/metastatic colorectal carcinoma with the impact on adjuvant therapy and prognosis
- Correlate the site of c-KIT mutations in GISTs with their neo-/adjuvant therapy implications

Competency Area: Differential Diagnosis

- Differentiate the clinical, endoscopic, gross, and microscopic features of ulcerative colitis, Crohn’s disease, and acute self-limited colitis
- Differentiate dysplasia in the setting of inflammatory disease from reactive epithelial changes
- List the differential diagnostic considerations for bloody diarrhea, nonbloody diarrhea, and constipation in light of the clinical scenario
- Outline the differential diagnostic considerations for increased intraepithelial and lamina propria eosinophils
- Generate a differential diagnosis for large intestinal crypt epithelial apoptosis
- List the differential diagnostic considerations for granulomas and their mimics in the large intestine
- Differentiate the clinical, endoscopic, gross, and microscopic features of epithelial lesions (ie, polyps and tumors)
- Generate a differential diagnosis for non-epithelial spindle cell and epithelioid neoplasms of the large intestine
- Compare the changes in histology expected in acute versus chronic intermittent or healed ischemic damage
- Differentiate the etiologies of pseudomembranes based on clinical, gross, and microscopic findings
- Identify common artifacts that may be seen in large intestinal biopsies and the diseases they may mimic
Competency Area: Treatment Implications
- Recognize sequelae following corrosive injury, radiation changes, medication effect, and chemotherapy
- Recognize the potential treatment implications of identifying dysplasia in colons affected by inflammatory bowel disease
- Report the salient features of invasive carcinomas arising within polyps necessary to guide further treatment
- Compare inherited tumor syndromes involving the colon and recognize the risk of developing synchronous and metachronous neoplasms in other organs
- Recognize the clinical, endoscopic and histologic features of advanced adenomas and the screening implications
- Utilize histologic criteria to stratify the risk of a gastrointestinal stromal tumor’s aggressive behavior

Competency Area: Reporting and Communication
- Recognize critical results necessitating immediate contact with clinicians (e.g., infection in an immunocompromised host, high-risk infections, GVHD, new/unsuspected diagnosis, suspected perforation)
- Provide appropriate comments and recommendations for cases in which findings are not specific, but rather which raise a differential diagnosis that requires additional testing or work-up
- Complete synoptic reports for colorectal neoplasms, as appropriate
- Utilize the accepted terminology for reporting the AJCC TNM staging of malignant neoplasms, as appropriate
- Use appropriate terminology to describe neuroendocrine neoplasms
- Integrate the results of ancillary studies (i.e., molecular) into a report for a colorectal neoplasm

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Competency: Genitourinary Pathology

Competency Definition:

Sub-competencies:
1. Urinary Passages (To be developed.)
2. Penile Pathology (To be developed.)
3. Prostate (To be developed.)
4. Kidney (To be developed.)
5. Testis Pathology

Sub-competency: Testis Pathology

Sub-competency Definition:
Employment of best practices in a judicious manner for evaluation and interpretation of laboratory, imaging, and pathology testing pertaining to the diagnosis and reporting of testicular disorders; recognition of specific diagnoses that result in alteration of treatment and outcome; and implementation of accurate reporting and communication to ensure provision of comprehensive diagnoses enabling a multidisciplinary team to provide consummate patient care.

Competency Areas:
A. Non-neoplastic Lesions
B. Neoplastic Lesions
C. Specimen Handling
D. Differential Diagnosis
E. Ancillary Studies
F. Treatment Implications
G. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Non-neoplastic Lesions

- Recognize and correlate the clinical significance of congenital disorders including cryptorchidism, anorchia, and testicular-splenic fusion
- Identify commonly encountered acquired testicular abnormalities such as testicular torsion, infarction, hydrocele, varicocele, and microlithiasis
- Detect and assess clinical implications of testicular involvement in systemic diseases including vasculitides and amyloidosis
- Diagnose and specify etiopathogenetic factors in testicular biopsies performed for male infertility, namely, hypospermatogenesis, maturation arrest, germinal cell aplasia, testicular changes associated with karyotypic abnormalities, tubular sclerosis and interstitial fibrosis (end-stage testis), and active spermatogenesis compatible with efferent duct obstruction
- Report findings of infectious processes identified in testicular and epididymal biopsies and/or resections encompassing bacterial, fungal, mycobacterial, viral, spirochete diseases and correlate with microbiologic and/or serologic testing for these diseases
- Evaluate histologic gonadal features and integrate results with karyotypic findings in cases with intersex syndromes; eg, male pseudohermaphroditism, persistent Mullerian duct syndrome, congenital adrenal hyperplasia, gonadal dysgenesis, true hermaphroditism, and androgen insensitivity syndrome
- Indicate effects of drugs and radiation in testicular biopsy, particularly for infertility or orchiectomy specimens
Competency Areas: Neoplastic Lesions

- Diagnose and differentiate between different types of pure and mixed germ cell tumors including seminoma, spermatocytic seminoma, embryonal carcinoma, yolk sac tumor, mature and immature teratoma, monodermal teratoma including carcinoid tumor, and trophoblastic tumors
- Recognize intratubular germ cell neoplasia with mimickers in testicular biopsies and resection specimens
- Diagnose benign testicular tumors- dermoid and epidermoid cysts
- Identify and document regression in testicular germ cell tumors detected in orchietomy specimens
- Diagnose sex cord stromal tumors of the testis - Leydig cell tumors, Sertoli cell tumors, large cell calcifying Sertoli cell tumor, adult and juvenile granulosa cell tumors, fibroma, thecoma, mixed, and unclassified sex cord stromal tumors
- Communicate clinical significance of particular diagnoses such as testicular neoplasia in Peutz Jeghers syndrome and Carney complex for therapeutic implications
- Identify diagnostic features in mixed germ cell- sex cord stromal tumors, particularly gonadoblastoma
- Recognize and report lesions of the rete testis and epididymis including adenomatous hyperplasia, adenoma, and adenocarcinoma
- Diagnose and categorize hematopoietic neoplasms involving testis and paratesticular regions including lymphoma, plasmacytoma, and leukemic infiltrate
- Diagnose tumors presenting as paratesticular lesions including adenomatoid tumor, mesothelioma, atypical lipomatous tumor (well differentiated liposarcoma), rhabdomyosarcoma, other sarcomas, and Mullerian type tumors (benign, borderline, and malignant)
- Diagnose and distinguish metastatic tumors in the testicular and paratesticular regions from primary testicular neoplasms

Competency Area: Specimen Handling

- Whenever feasible, preparation of imprint cytology/touch preparation smears at the time testicular biopsy should be performed especially for infertility assessment
- Utilize Bouins and Hollande fixatives for fixation of testicular biopsies to eliminate artifacts introduced by formalin
- Submit spermatic cord sections in an orchietomy specimen, including the spermatic cord margin, prior to incising the testis during evaluation of testicular tumors
- Obtain samples for special studies (flow cytometry, molecular and cytogenetic analysis) and electron microscopy prior to fixation in formalin
- Ensure serial sectioning of orchietomy specimen at 2-3 mm intervals and adequate fixation in a generous volume of fixative (10% neutral buffered formalin)
- Submit an adequate number of blocks from different appearing areas of tumor, including foci of hemorrhage and necrosis, with a minimum number of one block per centimeter of maximum tumor dimension and also incorporating tumor-parenchyma interface, non-neoplastic parenchyma, and testicular hilum

Competency Area: Differential Diagnosis

- Assess the lesion/tumor based on focused and pertinent differential diagnosis with proper utilization of immunohistochemical stains
- Incorporate the precise anatomic location of lesion/tumor (testicular parenchyma, epididymis, rete testis, spermatic cord, paratesticular) into the request and report to refine the differential diagnosis
- Utilize requisite ancillary tests to differentiate between the various entities in the differential diagnosis and arrive at a definitive diagnosis; perform triaging of ancillary testing in cases with limited material for analysis and interpretation
- Correlate clinical information and laboratory testing results with histologic features
- Address the limitations of subtyping or classification in small biopsy specimens
- Recognize the range of morphologic patterns encountered in the different subtypes of testicular and paratesticular neoplasms
- Ensure adequate interpretation of non-neoplastic testicular biopsies for infertility based on knowledge of histologic features of various stages of spermatocytic maturation
**Competency Area: Ancillary Studies**

- Ensure the requirements for specimen handling, appropriate specimen fixation intervals and assay validation are fulfilled
- Address the conditions in which decalcifying agents and fixatives other than buffered formalin can alter the results of IHC and ISH tests
- Correlate serum tumor marker test results [AFP (alpha-fetoprotein), LDH (lactate dehydrogenase) and β-HCG (beta-human chorionic gonadotropin)], and morphologic findings
- Recognize the utility and limitations of serum biomarker testing
- Select the correct panel of immunohistochemical stains to distinguish between the various tumors in the differential diagnosis
- Determine a course of action to address discrepancies in results between immunohistochemical staining and serum tumor marker levels in testicular tumors
- Establish a protocol for procurement and storage of fresh tumor/lesional tissue for flow cytometric evaluation and electron microscopy, if required in any case of testicular tumor

**Competency Area: Treatment Implications**

- Explain the basic treatment alternatives for testicular lesions and how pathology findings affect the choice
- Detect and report the pathologic factors that influence patient management and treatment options
- Demonstrate an understanding of manner in which different treatment options will affect outcome
- Integrate pathologic data and staging parameters with serum tumor marker data and resolve discordant results prior to treatment planning decisions
- Explain which patients are most likely to benefit from the addition of chemotherapy based on the histopathologic features and staging parameters

**Competency Area: Reporting and Communication**

- Employ established recommendations/guidelines for testicular reporting and appropriate AJCC tumor staging
- Identify pathologic prognostic factors for seminoma and non-seminomatous germ cell tumors
- Demonstrate consistent use of terminology (World Health Organization) in reports
- Review and integrate the results of all ancillary testing performed in the final diagnosis
- Generate clear, accurate, and complete reports that effectively communicate results and treatment implications to the health care team treating the patient
- Demonstrate willingness and ability to discuss diagnostic or treatment-related issues about testicular and paratesticular tumors and interpretation of testicular biopsy for assessment in infertility cases with clinicians and other members of the health care team
- Communicate critical diagnosis in an effective and timely manner such that immediate action may be instituted; appropriately indicate when there is going to be a delay in diagnosis

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N/A
Competency: Genomics

Competency Definition:
Genomics is the study and application of recombinant DNA, mitochondrial DNA, pathogen DNA/RNA, DNA sequencing methods, and bioinformatics to sequence, assemble, and analyze the function and structure of genomes. Genomics at the CAP: genomic medicine, molecular pathology, and clinical care based on genomic information. This includes the application and utility of large-scale genomic information management and data architecture in healthcare diagnostics in pursuit of efficient and cost-effective patient care and health outcomes at the level of individuals, institutions, populations, and communities. (Definition proposed by Gail Vance, MD, FCAP and CAP’s Genomics Strategy Workgroup - endorsed by Advisory Group.

Competency Areas:
A. Basic Genomics Concepts
B. Ethics, Legal and Social Issues
C. Quality Assurance and Regulatory
D. Sample Acquisition
E. Testing and Interpretation
F. Patient Management and Reporting

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Basic Genomics Concepts
- Distinguish between the components of the human genome including regulatory regions, exons, introns, repeated regions, centrosomes and telomeres
- Distinguish genotype versus phenotype
- Define the structural basis and clinical significance of inherited and acquired genetic variation such as point mutations, insertions, inversions, deletions, polymorphisms, copy number variants and structural chromosomal abnormalities
- Define the structural basis and clinical significance of silent, missense, nonsense, frameshift and splicing defect variants
- Differentiate somatic versus germline variation and modes of inheritance
- Define targeted gene panel, whole genome sequencing, whole exome and whole transcriptome sequencing

Competency Area: Ethics, Legal and Social Issues
- Recognize the importance of an informed consent process for genomic testing that promotes patient involvement in decision making and addresses issues related to limits of confidentiality, duty to disclose, duty to re-contact during phases of clinical testing and retention of electronic information
- Recognize the legal and regulatory issues related to acquisition, storage, analysis and re-analysis of genetic information
- Recognize the legal and regulatory issues related to the reporting of incidental findings to the patient and clinically significant results to other family members and third parties

Competency Area: Quality Assurance and Regulatory
- Ensure genomic tests have undergone adequate analytical and clinical validation and appropriate quality control and proficiency testing is in place
- Distinguish between FDA-cleared and laboratory-developed genomic testing and ensure the latter have been thoroughly validated by each local laboratory for both analytical and clinical utility
- Evaluate and utilize genomic testing guidelines published by regulatory bodies and professional societies (eg, CAP, CDC, CLSI, ACMG, AMP)
- Ensure compliance with governmental regulations that apply to acquisition, use, storage and transmission of genetic information (eg, HIPAA, GINA)
Competency Area: Sample Acquisition

- Ensure effective communication between the primary clinical team and the pathologist to facilitate appropriate specimen collection including the types, quantities, and handling requirements (including sample preservation)
- Establish processes for specimen identification, labeling, tracking and resolving potential sample mix-ups
- Specify criteria for determining whether specimens have been collected and handled appropriately to maintain specimen quality during acquisition, transport to the laboratory, and during subsequent storage of the sample or components isolated from the sample in the laboratory
- Ensure that laboratory areas used for receiving and processing specimens are separated from sources of molecular contamination such as post-PCR areas
- Specify the criteria for determining if cells of diagnostic interest are present in a specimen in sufficient quantities (particularly for oncology genomic testing)

Competency Area: Testing and Interpretation

- Specify clinical contexts in which genomic testing may be of diagnostic, prognostic or reproductive planning utility
- Evaluate whether the genomic test and interpretation method ordered for a patient sample is appropriate for the clinical context of the patient
- Analyze the cost of genomic testing within the context of providing the highest quality patient care while using resources responsibly
- Recognize the basic steps necessary to complete genomic testing in the laboratory
- Recognize the basic processes of sequence analysis and interpretation
- Recognize the limitations of genomic testing when interpreting results including the consequences of poorly covered target regions, insufficient nucleic acid input, low quality samples and sequencing errors
- Identify currently available tools and resources to evaluate genomic test results
- Interpret which findings in a genomic test are of sufficiently high data quality and clinical significance that they should be reported in the patient’s medical record

Competency Area: Patient Management and Reporting

- Communicate effectively with genetic counselors and referring physicians in an interdisciplinary team setting on pre- and post-test counseling
- Effectively integrate genomic results with clinical information and into other laboratory and pathology reports
- Apply appropriate guidelines and standard nomenclature when reporting genomic results
- Specify the rationale for variant interpretation, particularly for variants of uncertain significance, and likely pathogenic and non-pathogenic
- Recommend applicable ancillary studies, services and interventions in the context of the reported findings
- Utilize reporting as a platform to deliver added educational value for both providers and patients; incorporate concise yet instructive information related to the clinical diagnosis

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Competency: Gynecologic/Obstetric Pathology

Competency Definition:
Employs best practices in interpretation of biopsies, cytologic preparations and surgical resection specimens from the gynecologic tract; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating the morphologic, immunophenotypic and molecular findings with the patient's clinical information; understanding how specific diagnoses affect treatment; and how accurate reporting and communication ensure optimal patient care.

Sub-competencies:
1. Vulva and Vagina
2. Cervix and Uterus
3. Ovary, Fallopian Tube, and Peritoneum
4. Gestational Trophoblastic Disease
5. General Practices
Also relevant to this competency:
6. Pediatric Pathology \ Placental Pathology
7. Pediatric Pathology \ Perinatal Pathology

Sub-competency: Vulva and Vagina

Definition:
Employs best practices in diagnosing and reporting diseases of the vulva and vagina. These best practices apply to specimen handling, gross examination, tissue processing, interpretation of morphologic findings, and communication with other health care professionals. These practices include integration of morphologic findings with results of ancillary studies and, as appropriate, with available clinical and radiologic information; understanding the clinical implications of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary healthcare team.

Competency Areas
A. Disease Types
B. Ancillary Studies
C. Clinical Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Disease Types
- Recognize the most common histologic patterns associated with vulvar dermatoses and understand how to generate a differential diagnosis by integrating histologic pattern and clinical information
- Recognize histologic changes associated with infectious and non-infectious inflammatory vulvar and vaginal diseases
- Diagnose commonly recognized mesenchymal lesions of the vulva and vagina, including malignant tumors, benign or locally aggressive tumors (e.g., aggressive angiomyxoma, angiomyofibroblastoma, etc.), and pseudoneoplastic mesenchymal lesions (post-operative spindle cell nodule, nodular fasciitis, etc.)
- Differentiate between HPV-associated low and high-grade squamous intraepithelial lesions of the vulva and vagina, and their potential morphologic mimics
- Distinguish between conventional (HPV-associated) high-grade squamous intraepithelial lesion of the vulva and differentiated-type vulvar intraepithelial neoplasia
- Diagnose primary vulvar Paget disease and distinguish primary vulvar Paget disease from vulvar melanoma in situ and secondary involvement by Paget disease
• Diagnose rare, but clinically significant entities of the vulva and vagina, including malignant melanoma, metastases, germ cell tumors, and lymphoma/leukemia
• Diagnose the most commonly recognized invasive carcinomas of the vulva and/or vagina, including squamous cell carcinoma, transitional (urothelial) carcinoma, neuroendocrine carcinoma, myoepithelial carcinoma and Müllerian-type adenocarcinomas
• Diagnose commonly recognized benign, reactive and tumor-like epithelial lesions of the vulva and vagina

Ancillary Studies
• Recognize the diagnostic scenarios wherein immunohistochemistry may be most useful as well as the general limitations of diagnostic immunohistochemistry in vulvar and vaginal pathology
• Address discrepancies between expected results (immunohistochemistry, hormone receptors, molecular tests, etc.) and morphologic findings

Clinical Implications
• Describe the pathologic factors in vulvovaginal carcinomas and melanomas that influence patient management, treatment options, and patient outcomes
• Recognize that there is an evolving debate surrounding the use of sentinel lymph node mapping versus groin lymphadenectomy in the treatment of vulval squamous cell carcinoma

Competency: Gynecologic/Obstetric Pathology
Sub-competency: Cervix and Uterus
Sub-competency Definition:
Employs best practices in diagnosing and reporting diseases of the uterine cervix and corpus. These best practices apply to specimen handling, gross examination, tissue processing, interpretation of morphologic findings, and communication with other health care professionals. These practices include integration of morphologic findings with results of ancillary studies and, as appropriate, with available clinical and radiologic information; understanding the clinical implications of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary healthcare team.

Competency Areas:
A. Disease Types
B. Ancillary Studies
C. Clinical Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS
Disease Types
• Distinguish hyperplastic, metaplastic, and reactive changes from dysplastic/pre-neoplastic conditions of the squamous and glandular cervical epithelium
• Understand the biology of Human Papilloma Virus (HPV) and its role in the development of squamous dysplasia, adenocarcinoma in situ, and invasive cervical carcinoma
• Recognize and appropriately classify low-grade (CIN I) and high-grade (CIN 2 and 3) squamous intraepithelial lesions of the cervical squamous epithelium
• Identify adenocarcinoma in situ (usual type and variants) of the endocervix
• Diagnose types of cervical carcinoma typically associated with HPV (eg, squamous cell carcinoma, endocervical adenocarcinoma [usual type, villoglandular, intestinal type], adenosquamous carcinoma, neuroendocrine carcinoma) and those not typically associated with HPV (eg, mucinous carcinoma of gastric type, minimal-deviation adenocarcinoma, serous carcinoma, clear cell carcinoma, mesonephric carcinoma)
• Correctly measure the depth of invasion of carcinomas of the cervix
• Recognize the histologic features most commonly encountered in endometrial biopsies obtained for abnormal uterine bleeding (eg, endometrial polyp, effects of exogenous estrogen and progesterone, effect of relative estrogen excess/disordered proliferative endometrium, irregular shedding, metaplastic changes) and differentiate these conditions from pre neoplastic conditions of the endometrium
• Recognize and appropriately document a suboptimal quantity of endometrial tissue in biopsy specimens in postmenopausal women
• Identify the etiologic agents of inflammatory conditions of the endometrium (acute and chronic endometritis) and their respective histologic features
• Diagnose pre-neoplastic (atypical endometrial hyperplasia/EIN) and neoplastic conditions (eg, endometrioid adenocarcinoma and its variants, serous carcinoma, clear cell carcinoma, carcinosarcoma) arising in the endometrium
• Differentiate between type I and type II endometrial carcinomas based on the clinicopathologic differences
• Correctly evaluate features associated with patient outcome in endometrial carcinoma (eg, tumor grade and histologic type, depth of myometrial invasion, cervical stromal involvement, lymphovascular space invasion)
• Differentiate malignant mixed epithelial/stromal tumors (eg, adenosarcoma, carcinosarcoma) from their benign counterparts (eg, endometrial polyp, adenomyoma, atypical polyoid adenomyoma)
• Recognize the classic and variant histologic patterns of low-grade endometrial stromal neoplasms
• Apply criteria to distinguish stromal nodules from low-grade endometrial stromal sarcoma
• Recognize the features of high-grade endometrial stromal tumors and distinguish them from undifferentiated stromal sarcomas, including tumors with heterologous elements
• Apply criteria to distinguish benign smooth muscle tumors (usual, epithelioid and myxoid types) and its variants (eg, hydropic leiomyoma, mitotically active leiomyoma, cellular/highly cellular leiomyoma, bizarre leiomyoma, leiomyoma with hyalinization, lipoleiomyoma) from smooth muscle tumors of uncertain malignant potential and leiomyosarcoma
• Recognize how patient age, hormonal status, and pregnancy may affect appearance of morphologic findings and risk of subtypes of uterine and cervical carcinoma and mesenchymal tumors

Ancillary Studies
• Apply an immunohistochemical/in situ hybridization panel (Ki-67, p16, HPV (where available)) to distinguish high-grade squamous intraepithelial lesion and adenocarcinoma in situ from their benign mimics (eg, atrophy, reactive/metaplastic conditions)
• Recognize limitations of a small biopsy such as endocervical curettage in the evaluation of atypical glandular proliferations of the uterus (ie, endocervical adenocarcinoma versus endometrial hyperplasia/carcinoma)
• Utilize a panel of immunohistochemical stains to distinguish between primary endocervical and primary endometrial adenocarcinoma
• Interpret results of immunohistochemistry targeted at defects in mismatch repair genes (MLH1, MSH2, MSH6, PMS2) correctly

Clinical Implications
• Describe the significance of depth of invasion and horizontal spread measurements provided for LEEP/cone specimens and how these values determine the need for and type of surgical intervention
• Assess clinical impact of accurately dating the endometrium and of the assessment of hormonal disturbances and exogenous hormone effect
• Recognize the therapeutic implications of a diagnosis of less common types of carcinoma arising in the cervix (eg, neuroendocrine carcinoma) and endometrium (eg, serous, clear cell)
• Identify features of malignant mixed epithelial/stromal tumors and their benign counterparts that are associated with adverse prognosis (eg, sarcomatous overgrowth, presence of heterologous rhabdomyosarcoma)
Competency: Gynecologic/Obstetric Pathology
Sub-competency: Ovary, Fallopian Tube, Peritoneum

Sub-competency Definition:
Employs best practices in diagnosing and reporting diseases of the ovary and fallopian tube. These best practices apply to specimen handling, gross examination, tissue processing, interpretation of morphologic findings, and communication with other health care professionals. These practices include integration of morphologic findings with results of ancillary studies and, as appropriate, with available clinical and radiologic information; understanding the clinical implications of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary healthcare team.

Competency Areas
A. Disease Types
B. Ancillary Studies
C. Clinical Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Disease Types
- Recognize common non-neoplastic functional, hormonal, inflammatory, and pregnancy-related lesions of the ovary, fallopian tube, and pelvic peritoneum
- Distinguish non-neoplastic from neoplastic changes that may occur in endometriosis or in peritoneal mesothelium
- Diagnose the major histologic subtypes of surface epithelial ovarian tumors (serous, endometrioid, clear cell, and mucinous)
- Apply criteria to distinguish benign, borderline, and malignant surface epithelial ovarian tumors and apply grading criteria when applicable (eg, low- versus high-grade serous carcinoma)
- Distinguish non-invasive from invasive implants of serous borderline tumors
- Recognize the histologic features of benign and malignant germ cell tumors (eg, mature and immature teratoma, dysgerminoma, yolk sac tumor, embryonal carcinoma)
- Diagnose the most common types of ovarian sex cord tumors (fibroma/thecoma, adult and juvenile granulosa cell tumors, sex cord tumor with annular tubules, Sertoli-Leydig cell tumors, steroid cell tumors)
- Describe histologic features associated with adverse prognosis in ovarian sex cord neoplasms
- Apply gross, microscopic, and immunohistochemical criteria to distinguish primary ovarian epithelial tumors from metastatic adenocarcinomas of non-gynecologic origin
- Apply morphologic and immunohistochemical criteria to distinguish tubal carcinoma from benign mimics
- Recognize the histologic subtypes of ovarian and fallopian tube neoplasms that may be associated with a hereditary syndrome (eg, BRCA mutation, Lynch syndrome)
- Identify common and rare lesions arising in the paratubal and paraovarian soft tissue (eg, leiomyoma, endometriosis, ectopic adrenal tissue, female adnexal tumor of Wolffian origin)

Ancillary Studies
- Recognize the diagnostic scenarios in which immunohistochemistry and/or special stains (ie, reticulin) may be most useful, including distinguishing epithelial, sex cord, and germ cell tumors from each other, sub-classifying high-grade/poorly-differentiated tumors (ie, small cell carcinoma of hypercalcemic type, undifferentiated carcinoma, neuroendocrine carcinoma, endometrioid adenocarcinoma, FIGO grade 3), and excluding metastatic tumors to the female adnexa
- Recognize the histologic subtypes of ovarian epithelial tumors that are most likely to be associated with Lynch syndrome
- Interpret immunohistochemical stains for mismatch repair proteins in ovarian tumors

Clinical Implications
- Recognize the association between the histologic subtype and grade of ovarian malignancies and the prognosis, adjuvant treatment implications, and risk for specific hereditary syndromes
- Recognize the association between morphologic features in ovarian borderline tumors and risk for extra-ovarian involvement
Competency: Gynecologic/Obstetric Pathology
Sub-competency: Gestational Trophoblastic Disease

Sub-competency Definition:
Employs best practices in diagnosing and reporting gestational trophoblastic diseases. These best practices apply to specimen handling, gross examination, tissue processing, interpretation of morphologic findings, and communication with other health care professionals. These practices include integration of morphologic findings with results of ancillary studies and, as appropriate, with available clinical and radiologic information; understanding the clinical implications of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary healthcare team.

Competency Areas:
A. Disease Types
B. Ancillary Studies
C. Clinical Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Disease Types
- Apply histologic criteria in the diagnosis of partial and complete hydatidiform mole, choriocarcinoma, placental site trophoblastic tumors, and epithelioid trophoblastic tumors
- Differentiate between tumors that have syncytiotrophoblast giant cells and choriocarcinomas
- Correlate histologic findings with the imaging, laboratory, and clinical findings when a molar pregnancy is suspected
- Assess the need for obtaining expert consultation in challenging cases
- Accurately identify histologic findings which are diagnostic of an intrauterine pregnancy in a specimen collected to rule out an ectopic pregnancy
- Identify the clinical and histologic scenarios that could account for postpartum hemorrhage or retained products of conception

Ancillary Studies
- Identify the most appropriate ancillary study (eg, p57 immunohistochemistry, DNA ploidy analysis, or short tandem repeat genotype analysis) in diagnosing molar pregnancies depending on the differential diagnosis, amount of tissue available, and cost considerations
- Correctly interpret p57 immunohistochemical staining patterns in complete versus partial moles and non-molar pregnancies
- Utilize appropriate immunohistochemical stains to distinguish between trophoblastic tumors and uterine carcinomas or sarcomas

Clinical Implications
- Recognize the different follow-up regimens recommended for patients with complete moles, partial moles and hydropic/abnormal non-molar abortuses

Competency: Gynecologic/Obstetric Pathology
Sub-competency: General Practices

Sub-competency Definition:
Employs best practices in diagnosing and reporting diseases of the female genital tract with respect to specimen handling, gross examination, tissue processing, interpretation of morphologic findings, and communication with other health care professionals in a timely and effective manner.
Competency Areas
A. Specimen Handling
B. Reporting and Communication

Specimen Handling
- Ensure correct specimen identity by patient identification, specimen labeling, completion of requisition form, etc., according to local laboratory policy
- Recognize the limitations of biopsy specimens and determine when to recommend repeat sampling
- Advise clinicians on the appropriate use and limitations of frozen section and, when indicated, appropriately select tissue for frozen section
- Consider selecting tissue for special studies prior to formalin fixation and ensure that adequate sectioning and formalin are applied to avoid artifacts associated with poor fixation
- Incorporate clinical and radiologic information in specimen grossing
- Select appropriate tissue sections for histologic examination, including sufficient sampling of visible lesions (often one section per centimeter of tumor), maximum depth of invasion where applicable, relationship of lesion to closest margins or organ surfaces, and sampling of normal/uninvolved structures
- Given the clinical scenario and surgical procedure, consider when it is most appropriate to submit the entire fallopian tube and/or fimbriated end
- Consider when to request submission of additional tissue following initial histologic examination

Reporting and Communication
- Generate accurate, clear and complete reports that effectively communicate the diagnosis to the health care team, including using current WHO terminology and incorporating the results of ancillary studies completed before or after release of the final report
- Correlate the histopathologic findings with imaging and clinical findings in the report and verbal communication as appropriate
- Perform TNM staging of malignancies according to current AJCC/FIGO guidelines and utilize synoptic reporting (eg, CAP Cancer Protocols)
- Communicate significant and unexpected findings and document these preliminary communications in the final report
- Demonstrate willingness and ability to discuss results with the multidisciplinary health care team

Also relevant to this competency:
Pediatric Pathology \ Placental Pathology
Pediatric Pathology \ Perinatal Pathology

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Competency: Head and Neck Pathology

Competency Definition:
Employs best practices in performing and interpreting head and neck pathology testing and the diagnosis of disorders of the head and neck; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating the morphologic, immunophenotypic, cytogenetic, and genotypic findings with the patient’s clinical information; understands how specific diagnoses affect treatment; and how accurate reporting and communication ensure accurate and comprehensive diagnoses and optimal patient care.

Sub-competencies:
1. Craniofacial Bone Pathology
2. Ear and Temporal Pathology
3. Laryngeal and Hypopharangeal Pathology
4. Neck Soft Tissue Pathology
5. Odontogenic Pathology
6. Oral Pathology
7. Oropharynx and Nasopharynx Pathology
8. Salivary Gland Pathology
9. Sinonasal Tract Pathology

Sub-competency: Craniofacial Bone Pathology

Sub-competency Definition:
Applies best practices in procedures and clinical indications for jaw/craniofacial bone evaluation, integrating the morphologic interpretation of bone biopsies and resections with the clinical history, radiologic findings, laboratory values, and specialized ancillary testing results to diagnose reactive, neoplastic benign, and neoplastic malignant processes.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Reporting and Communication
F. Treatment Implications
G. Radiologic Pathologic Correlation

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
• Recognize key radiologic findings as applied to diagnosis of reactive bony and cartilaginous lesions
• Recognize specific clinical, radiologic, or chemical features that point to metabolic bone disease
• Distinguish infectious reactive bony lesions from true benign fibro-osseous lesions
• Recognize osseous and cartilaginous metaplasia (chondrometaplasia) at various head and neck sites
• Recognize the clinical scenarios and features associated with gnathic osteonecrosis
• Recognize unique clinical, radiologic, and histologic findings associated with dentition related reactive bone lesions
Competency Area: Neoplastic - Benign
- Recognize key radiologic findings as applied to diagnosis of benign bony and cartilaginous lesions
- Recognize unique clinical, radiologic, and histologic findings to classify benign fibro-osseous lesions and recognize specific subtypes within each category
- Recognize unique clinical and histologic findings in benign chondroid neoplasms of the jaw and craniofacial region

Competency Area: Neoplastic - Malignant
- Recognize key radiologic findings as applied to diagnosis of malignant bony and cartilaginous lesions
- Distinguish osteosarcoma from benign and reactive fibro-osseous proliferative processes
- Recognize osteosarcoma and chondrosarcoma variants commonly seen in the jaw and craniofacial region
- Differentiate chordoma from chondrosarcoma from other matrix producing mimics
- Recognize and assess therapy related change in osteosarcoma, chondrosarcoma, and rhabdomyosarcoma (cytodifferentiation)
- Distinguish true osteosarcoma and chondrosarcoma from sarcomatoid carcinoma/carcinosarcoma with matrix production arising from mucosa or salivary gland
- Differentiate between 'round blue cell' malignancies of the bone
- Recognize metastases and hematolymphoid neoplasms to the jaw or craniofacial bones

Competency Area: Ancillary Testing
- Utilize immunohistochemical stains to distinguish between chordoma, chondrosarcoma, and other histologic mimics
- Utilize immunohistochemical stains and molecular markers delineating 'round blue cell' malignancies of the bone

Competency Area: Reporting and Communication
- Employ published recommendations on reporting of bone and cartilaginous lesions
- Generate clear, concise, and accurate reports that effectively communicate jaw and craniofacial bone testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency Area: Treatment Implications
- Recognize the implications of intraoperative diagnosis in subsequent surgical management
- Recognize entities that may have a familial or genetic predisposition and may thus require further evaluation of both patient and family members
- Recognize the implications of diagnosis of bony and cartilaginous neoplasms that may require specific management approaches
- Convey the significance of a histologic variant of a bony or cartilaginous neoplasm that may require deviation from the standard clinical management of an entity
- Recognize the implications of specific immunohistochemical and molecular markers in targeted therapeutic approaches

Competency Area: Radiologic Pathologic Correlation
- Recognize the basic uses and limitations of various imaging modalities (ie, panoramic roentgenogram, computerized tomogram) in the diagnosis of craniofacial bone and cartilage lesions
- Recognize normal variations in jaw and craniofacial radiologic findings that may mimic a lesion
- Correlate histologic findings with radiologic features in jaw and craniofacial radiologic findings in benign and reactive processes
- Correlate radiologic lesional border and landmarks of involvement to assess malignant potential of a lesion
- Recognize varying radiologic patterns of lesional matrix deposition to arrive at a diagnosis
Competency: Head and Neck Pathology
Sub-competency: Ear and Temporal Pathology

Sub-competency Definition:
Incorporates best practices in evaluating and interpreting laboratory, imaging, and pathology testing into reporting the diagnosis of ear and temporal bone disorders; recognizes how specific diagnoses alter treatment and outcome; and how accurate reporting and communication ensure comprehensive diagnoses with optimal patient care of an up to date multidisciplinary approach.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Specimen Handling
F. Differential Diagnosis
G. Radiologic Pathologic Correlation
H. Reporting and Communication
I. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
- Diagnose commonly recognized reactive and proliferative ear and temporal bone lesions, with specific attention to mimics of malignancy; eg, accessory tragus, encephalocele, first branchial cleft anomaly, necrotizing otitis externa, otitis media, chondrodermatitis nodularis helicis, otic polyp, cystic chondromalacia, otosclerosis, gout, cholesteatoma, exostosis, keloid, Langerhans cell histiocytosis, malakoplakia, synovial chondromatosis
- Identify the specific anatomic parts of the ear and temporal bone which may be uniquely affected by these disorders
- Distinguish between infectious, inflammatory, and reactive changes which may affect ear and temporal sites
- Relate the specific features which are specific to dermatologic disorders, as well as ear/temporal bone manifestations of systemic disorders

Competency Area: Neoplastic - Benign
- Diagnose commonly recognized benign neoplasms of the ear and temporal bone, eg, ceruminous adenoma, middle ear adenoma, paraganglioma, schwannoma, meningioma, angiolymphoid hyperplasia with eosinophilia, and endolymphatic sac tumor
- Correlate the histopathologic findings with otoscopic, imaging, and specific anatomic site of involvement
- Advise on when biopsy is indicated and when additional studies may be required to confirm a diagnosis

Competency Area: Neoplastic - Malignant
- Diagnose commonly recognized malignant neoplasms of the ear and temporal bone, eg, skin based tumors (atypical fibroxanthoma, squamous cell carcinoma, basal cell carcinoma, Merkel cell carcinoma, melanoma, dermatofibrosarcoma protuberans), ceruminous adenocarcinoma, rhabdomyosarcoma, and metastatic tumors
- Distinguish mimics of malignant neoplasms, benign neoplasms, and reactive lesions
- Interpret artifacts unique to the anatomic site with the histologic findings
- Apply standard World Health Organization histologic criteria for the initial classification of neoplasms
- Analyze pertinent immunohistochemical and histochemical tests to support a specific diagnosis
- Describe the differences in immunohistochemical staining that may occur in primary versus metastatic tumors
Competency Area: Ancillary Testing
- Recognize the limitations of small biopsies in making a definitive diagnosis
- Correlate the histologic findings with imaging and otoscopic findings to determine if the lesion is adequately sampled

Competency Area: Specimen Handling
- Appropriately select tissue for frozen section or additional studies, especially in limited biopsy samples
- Incorporate the clinical and imaging findings in specimen handling
- Determine appropriate tissue submission for histologic examination
- Ensure there is sufficient material for ancillary tests or additional testing (culture, electron microscopy, immunohistochemistry, flow cytometry, molecular testing)
- Identify the pitfalls associated with crush artifact, especially when biopsies are small or limited

Competency Area: Differential Diagnosis
- Assess the lesion/tumor based on targeted and pertinent differential diagnosis
- Utilize imaging information to formulate differential diagnosis
- Demand the exact anatomic site be incorporated into the request or report to narrow the differential diagnosis
- Select pertinent ancillary tests to narrow a differential diagnosis down to the correct interpretation; limited material may force a triage of how to order ancillary testing
- Evaluate clinical and laboratory information in light of the histologic features
- Describe the limitations of subtyping or classification in small biopsy specimens
- Identify the range of morphologic patterns which may be seen in various ear/temporal bone neoplasms (middle ear adenoma, ceruminous adenoma specifically)

Competency Area: Radiologic Pathologic Correlation
- Explain the importance of communication between pathologist, radiologist, and surgeon in evaluating specimens obtained from targeted areas
- Recognize the importance of radiographic information in ensuring optimal pathology interpretation
- Correlate the histopathologic findings with imaging and clinical findings
- Recommend a specific course of action to resolve discrepancies between pathology and imaging

Competency Area: Reporting and Communication
- Follow published recommendations for ear and temporal bone reporting and appropriate staging (including skin based primaries)
- Demonstrate consistent use of terminology (World Health Organization) in reports
- Generate clear, accurate, and complete reports that effectively communicate results and treatment implications to the patient’s health care team
- Demonstrate willingness and ability to discuss current issues about ear and temporal bone tumors with clinicians and other members of the health care team
- Accurately integrate the results of all ancillary testing in the final diagnosis
- Clearly communicate critical values or diagnosis which may require immediate action; appropriately indicate when there is going to be a delay in diagnosis

Competency Area: Treatment Implications
- Explain the basic treatment alternatives for ear and temporal bone lesions and how pathology findings affect the choice
- Explain the pathologic factors that influence patient management and treatment options
- Demonstrate an understanding of how different treatment options will change outcome
- Define when to utilize pre-operative embolization or imaging to help guide ultimate management
Competency: Head and Neck Pathology
Sub-competency: Laryngeal and Hypopharangeal Pathology

Sub-competency Definition:
Employs best practices in evaluating and reporting larynx and hypopharynx specimens; integrates clinical, imaging, and pathologic information to establish a diagnosis that supports optimum patient management and outcome; incorporates up to date information to participate in multidisciplinary larynx lesion management.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Specimen Handling
F. Differential Diagnosis
G. Reporting and Communication
H. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
- Diagnose commonly recognized reactive and proliferative larynx/hypopharynx lesions, with specific attention to mimics of malignancy; eg, laryngocele, laryngeal cysts, laryngitis, vocal cord nodules and polyps, contact ulcer, tracheopathia osteoplastica, and reactive epithelial changes (keratosis, parakeratosis, hyperplasia, dyskeratosis)
- Recognize specific anatomic sites of predilection for each lesion
- Distinguish between the types of laryngeal cysts
- Recognize the spectrum of changes seen in reactive epithelial lesions, including keratosis, parakeratosis, hyperplasia, pseudoepitheliomatous hyperplasia, and radiation changes
- Identify specific features of unique infectious agents (virus, fungi, bacteria)

Competency Area: Neoplastic - Benign
- Diagnose commonly recognized benign neoplasms of the larynx/hypopharynx, with specific attention to mimics of malignancy; eg, squamous papilloma, granular cell tumor, amyloidoma, adult rhabdomyoma, paraganglioma, and salivary gland neoplasms
- Determine when to recommend a repeat biopsy due to processing or acquisition limitations
- Correlate the histopathologic findings with endoscopic or operative findings and patient symptoms

Competency Area: Neoplastic - Malignant
- Diagnose commonly recognized malignant neoplasms of the larynx/hypopharynx, eg, dysplasia (keratinizing and non-keratinizing), carcinoma in situ, squamous cell carcinoma and its variants (verrucous, spindle cell, basaloïd, exophytic, and adenosquamous), neuroendocrine carcinoma, chondrosarcoma, and metastases
- Distinguish between mimics of carcinoma and reactive lesions
- Interpret artifacts in processing, frozen section, and fixation as they apply to diagnostic limitations
- Utilize ancillary techniques in a judicious and targeted fashion, as samples are usually limited and may be difficult to re-acquire
- Correlate potential treatment alterations (such as radiation therapy) with histologic findings
- Describe basic treatments for laryngeal/hypopharyngeal malignancies in order to appropriately select patients for specific therapies
Competency Area: Ancillary Testing
- Assess accompanying samples (such as radical neck dissections) to assure appropriate evaluation of disease stage
- Describe when each special/additional study should be used and how it will influence the diagnosis
- Develop a course of action to resolve potential discrepancies or spurious results which may influence diagnosis or additional testing

Competency Area: Specimen Handling
- Appropriately select tissue for frozen section or additional studies, especially in limited biopsy samples
- Limit unnecessary frozen sections so that the sample integrity can be maintained and artifacts limited
- Incorporate the clinical and imaging findings in specimen handling
- Determine appropriate tissue submission for histologic examination based on anatomy, margins, and tumor location
- Specifically address margin status and detect when margins are positive or close
- Describe the effects on tissue subjected to decalcifying agents and fixatives
- Ensure there is sufficient material for ancillary tests or additional testing (culture, electron microscopy, immunohistochemistry, flow cytometry, molecular testing)

Competency Area: Differential Diagnosis
- Assess the lesion/tumor based on a pertinent differential diagnosis
- Select several diagnoses for the site and actively eliminate them
- Choose targeted ancillary tests to narrow a differential diagnosis down to the correct interpretation; limited material may force a specific order of incorporating special studies
- Evaluate clinical and laboratory information in light of the histologic features
- Determine exact anatomic site in all cases to specifically formulate a differential diagnosis

Competency Area: Reporting and Communication
- Follow published recommendations for larynx/hypopharynx reporting and appropriate staging
- Demonstrate consistent use of terminology (World Health Organization, etc) in reports
- Comply with standardized processing recommendations for laryngectomy specimen
- Generate clear, accurate, and complete reports that effectively communicate results and treatment implications to the patient’s health care team
- Discuss cases with treating physicians in pre-operative (preanalytic) stage to resolve potential conflicts or difficulties
- Demonstrate willingness and ability to discuss current issues about laryngeal/hypopharyngeal tumor with clinicians and other members of the health care team
- Accurately integrate the results of all ancillary testing in the final diagnosis
- Explain the impact of preanalytic variables on the final diagnosis and interpretation (ie, inappropriate frozen sections, insufficient tissue sampling, artifacts of tangential sectioning)
- Clearly communicate critical values or diagnosis which may require immediate action; appropriately indicate when there is going to be a delay in diagnosis

Competency Area: Treatment Implications
- Recognize the importance of margins and assessment of tumor
- Incorporate treatment effects into specimen evaluation and diagnosis
- Describe the basic treatment alternatives for laryngeal/hypopharyngeal tumors and how pathology factors affect the choices
- Explain the pathologic factors that influence patient management and treatment options
- Demonstrate an understanding of how different treatment options will change outcome
- Recognize the need for additional testing after therapy and be able to recommend biopsy timing or interpretation
Competency: Head and Neck Pathology
Sub-competency: Neck Soft Tissue Pathology

Sub-competency Definition:
Employs best practices for collecting, processing, and diagnosing neck and soft tissue lesions; apply organ and site-specific criteria for the microscopic evaluation of reactive and neoplastic lesions; select appropriate ancillary testing; integrate the morphologic findings with the clinical, imaging, and ancillary tests to report a diagnosis that supports optimum patient management and outcome.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Specimen Handling
F. Differential Diagnosis
G. Radiologic Pathologic Correlation
H. Reporting and Communication
I. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
• Diagnose commonly recognized reactive and proliferative neck and soft tissue lesions, with specific attention to mimics of malignancy; eg, branchial cleft cyst, cervical thymic cyst, bronchogenic cyst, infectious diseases (within lymph nodes, such as cat scratch disease, bacillary angiomatosis, mycobacterial spindle cell pseudotumor), sarcoïd, and nodular fasciitis
• Identify the specific anatomic compartments of the neck (lymph nodes, vessels and nerves, soft tissue) and which may be uniquely affected by these disorders
• Distinguish between infectious, inflammatory, and reactive changes which may affect these sites
• Incorporate the clinical findings and imaging results into determining the diagnosis
• Utilize fine needle aspiration, core biopsy, and open biopsy techniques in interpreting findings
• Describe the common pitfalls in diagnosis

Competency Area: Neoplastic - Benign
• Diagnose commonly recognized benign neoplasms of the neck and soft tissue lesions, with specific attention to mimics of malignancy; eg, paraganglioma, elastofibroma, perineurioma, lipoma (spindle cell and pleomorphic subtypes), lipoblastoma, hibernoma, nuchal-type fibroma, and lymphangioma
• Differentiate between various lipomatous tumors of the soft tissues of the neck
• Incorporate imaging findings and anatomic sites of involvement into the diagnosis
• Recognize key features to distinguish between benign and malignant tumors based on fine needle aspiration or core needle biopsies and excision/resection samples
• Utilize ancillary tests to assess the tumor

Competency Area: Neoplastic - Malignant
• Diagnose commonly recognized malignant neoplasms of neck and soft tissue, eg, metastatic tumors to lymph nodes (especially cystic squamous cell carcinoma), synovial sarcoma, chordoma, liposarcoma, fibrosarcoma, and angiosarcoma
• Distinguish between spindle cell carcinoma and mesenchymal primaries and how to separate them
• Utilize ancillary techniques to help narrow the differential diagnosis for metastatic disease, especially for cystic squamous cell carcinoma, among others
• Interpret artifacts in processing, frozen section, and fixation as they apply to diagnostic limitations
• Describe basic treatments for soft tissue malignancies in order to appropriately select patients for specific therapies
• Describe the significance of margin status as it applies to various malignancies in these sites
Competency Area: Ancillary Testing
- Assess accompanying samples to assure appropriate evaluation of disease stage
- Describe when each special/additional study should be used and how it will influence the diagnosis
- Develop a course of action to resolve potential discrepancies or spurious results which may influence diagnosis or additional testing

Competency Area: Specimen Handling
- Appropriately select tissue for culture, flow, or other ancillary studies, especially in limited biopsy samples (such as fine needle aspiration or core needle)
- Incorporate the clinical and imaging findings in specimen handling
- Determine appropriate tissue submission for histologic examination based on anatomy, margins, and tumor location, especially for radical neck lymph node dissections
- Obtain orientation and anatomic landmarks from the surgeon before processing radical neck samples

Competency Area: Differential Diagnosis
- Recognize the many anatomic compartments and different tissue types within the neck which can be used to narrow the focus of diagnosis
- Incorporate pertinent and selected ancillary testing into the diagnosis, especially in metastatic tumors or spindle cell lesions of the neck
- Utilize imaging, clinical, and laboratory information to formulate differential diagnosis
- Obtain the exact anatomic site to narrow the differential diagnosis
- Describe the limitations of subtyping or classification in small or limited biopsy specimens

Competency Area: Radiologic Pathologic Correlation
- Describe the importance of communication between pathologist, radiologist, and surgeon in evaluating specimens obtained from targeted areas
- Recognize the importance of radiographic information in ensuring optimal pathology interpretation
- Correlate the histopathologic findings with imaging and clinical findings
- Recommend a specific course of action to resolve discrepancies between pathology and imaging

Competency Area: Reporting and Communication
- Follow published recommendations for reporting and appropriate staging of specific tumor types of the neck
- Demonstrate consistent use of terminology (World Health Organization) in reports
- Generate clear, accurate, and complete reports that effectively communicate results and treatment implications to the patient’s health care team
- Accurately integrate the results of all ancillary testing in the final diagnosis
- Clearly communicate critical values or diagnosis which may require immediate action; appropriately indicate when there is going to be a delay in diagnosis

Competency Area: Treatment Implications
- Recognize the importance of ancillary testing and how it may apply to patient management and outcome
- Describe the effect neoadjuvant or adjuvant therapy may have on specimen evaluation
- Explain any pathologic factors which may influence patient therapy or outcome
- Define the basic treatment options for each disorder in the neck and know how to incorporate these factors into diagnosis
Competency: Head and Neck Pathology
Sub-competency: Odontogenic Pathology

Sub-competency Definition:
Employs best practices in evaluating and reporting odontogenic neoplasms of the jaws; integrates clinical, radiographic, and pathologic information to diagnose reactive, benign, and malignant processes. Recognizes the appropriate use and significance of ancillary and molecular studies for optimum patient care.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Reporting and Communication
F. Treatment Implications
G. Radiologic Pathologic Correlation

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
- Diagnose common inflammatory processes that occur in the jaws related to teeth, eg, radicular (periapical) cyst and periapical inflammation
- Distinguish between mimics of inflammatory cysts and inflamed developmental cysts

Competency Area: Neoplastic - Benign
- Diagnose commonly recognized benign odontogenic cysts and tumors, eg, dentigerous cyst keratocystic odontogenic tumor (odontogenic keratocyst), glandular odontogenic cyst, calcifying cystic odontogenic tumor, calcifying epithelial odontogenic tumor, squamous odontogenic tumor, and odontoma
- Diagnose commonly recognized non-ameloblastoma, benign tumors of odontogenic epithelium, eg, odontoma, adenomatoid odontogenic tumor, and calcifying epithelial odontogenic tumor
- Recognize the morphologic variants of ameloblastoma, eg, plexiform, follicular, unicystic, acanthomatous, and peripheral
- Distinguish hyperplastic dental follicle from odontogenic neoplasms, eg, odontogenic myxoma and odontogenic fibroma
- Correlate the pathologic findings to the clinical and radiographic findings
- Determine when to apply special stain and/or immunohistochemical stains for diagnosis
- Recommend a course of action when the pathologic findings do not correlate with the radiographic and/or clinical findings

Competency Area: Neoplastic - Malignant
- Recognize the histopathologic features of malignant odontogenic tumors, eg, ameloblastic carcinoma, ameloblastic fibrosarcoma, intraosseous mucoepidermoid carcinoma, and clear cell odontogenic carcinoma
- Define the difference between malignant ameloblastoma and ameloblastic carcinoma
- Distinguish metastases to the jaws, eg, renal cell carcinoma and prostate carcinoma
- Determine when to apply immunohistochemical and/or special stains for diagnosis

Competency Area: Ancillary Testing
- Recognize the limitations of special stains and immunohistochemical stains when evaluating odontogenic neoplasms
- Recognize the effects of decalcification of tissue morphology
Competency Area: Reporting and Communication
- Generate clear, accurate, and complete reports that effectively communicate results and treatment implications for the patient’s health care team
- Demonstrate willingness to discuss pathologic findings with the multidisciplinary health care team relating to rare odontogenic neoplasms
- Accurately integrate results of ancillary testing into the final diagnosis
- Report on radiographic correlation if applicable
- Employ consistent use of terminology (World Health Organization) in generating reports

Competency Area: Treatment Implications
- Explain the clinical significance of multiple keratocystic odontogenic tumors on patient management
- Communicate how different treatment options will affect patient outcome

Competency Area: Radiologic Pathologic Correlation
- Explain the importance of evaluating radiographs when diagnosing and differentiating odontogenic neoplasms
- Correlate the histopathologic features with the imaging and clinical findings
- Recommend a specific course of action to resolve discrepancies between pathology and imaging

Competency: Head and Neck Pathology
Sub-competency: Oral Pathology
Sub-competency Definition:
Employs best practices in evaluating and reporting oral cavity specimens; integrates clinical and pathologic information to diagnose reactive, benign, and malignant processes. Utilizes radiologic information as needed to correlate with pathologic findings. Recognizes the appropriate use and significance of ancillary and molecular studies for optimum patient care.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Reporting and Communication
F. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
- Diagnose common reactive processes that occur in the soft tissue of the oral cavity, eg, mucocele/ranula, chronic sialoadenitis, fibroma, pyogenic granuloma, benign migratory glossitis (geographic tongue), oral lymphoepithelial cyst, and pseudoepitheliomatous hyperplasia
- Diagnose the clinical presentation of necrotizing sialometaplasia and differentiate from mucoepidermoid carcinoma and/or squamous cell carcinoma
- Distinguish morphologic mimics of squamous cell carcinoma, eg, pseudoepitheliomatous hyperplasia associated with reactive or infectious (fungal) agent
- Distinguish morphologic mimics of hematopoietic malignancy, eg, traumatic ulcerative granuloma with stromal eosinophilia
Competency Area: Neoplastic - Benign

- Diagnose common benign growths of oral cavity mucosa including peripheral ossifying fibroma, peripheral giant cell granuloma, congenital epulis, granular cell tumor, verruform xanthoma, schwannoma, and neurofibroma
- Distinguish pigmented lesions such as melanotic macule and melanocanthoma from other clinically pigmented lesions including amalgam tattoo
- Distinguish morphologic mimics of squamous cell carcinoma, eg, pseudoepitheliomatous hyperplasia associated with a granular cell tumor, squamous metaplasia in sialadenitis
- Recognize general features of oral epithelial dysplasia and distinguish between mild, moderate, and severe dysplasia using World Health Organization guidelines
- Recognize oral immune-mediated vesiculobullous disorders including lichen planus, mucous membrane pemphigoid, and pemphigus vulgaris
- Recognize morphologic mimics of oral lichen planus such as lichenoid drug reactions and "lichenoid" dysplasia
- Recognize the morphologic pattern of atypical verrucous epithelial hyperplasia and understand the clinical setting and relevance of proliferative verrucous leukoplakia

Competency Area: Neoplastic - Malignant

- Differentiate squamous cell carcinoma from known mimics, eg, pseudoepitheliomatous hyperplasia, therapeutic changes, necrotizing sialometaplasia, and granulomatous diseases
- Recognize the limitations of small oral biopsies in diagnosis of malignancy
- Recognize the significance of invasive or in situ carcinoma at the margins within the context of a specific case
- Report the distance of invasive or in situ carcinoma from the tissue border
- Identify the variants of squamous cell carcinoma
- Recognize the morphologic findings of radiation therapy and/or chemotherapy on tissue specimens
- Recognize the need to correlate the histopathology and clinical features to diagnose verrucous carcinoma
- Distinguish Kaposi Sarcoma from morphologic mimics, eg, angiosarcoma and pyogenic granuloma
- Distinguish metastases to the oral mucosa from primary malignancies, eg, lung, renal, breast, and prostate cancer
- Determine when to apply immunohistochemical and/or staining for diagnosis
- Correlate the pathologic findings to the clinical and radiographic findings
- Recommend a course of action when the pathologic findings do not correlate with imaging studies

Competency Area: Ancillary Testing

- Describe when high risk HPV testing of oropharyngeal cancer is recommended
- Recognize the uses and limitations of ancillary testing
- Explain the role of direct and indirect immunofluorescence in vesiculobullous diseases
- Recognize the effects of decalcification on tissue specimens

Competency Area: Reporting and Communication

- Follow published recommended guidelines (AJCC) for oral squamous cell carcinoma for reporting and staging
- Accurately integrate results of ancillary testing (immunohistochemistry, in situ hybridization) into the final diagnosis
- Generate clear, accurate, and complete reports that effectively communicate results and treatment implications for the patient's health care team
- Demonstrate willingness to discuss pathologic findings with the multidisciplinary health care team relating to oral squamous cell carcinoma
- Apply the new AJCC staging classification for primary oral melanoma
- Recommend additional testing (immunofluorescence) in vesiculobullous diseases to ensure proper patient treatment
Competency Area: Treatment Implications
- Explain the pathologic factors that influence re-excision in oral dysplasia
- Correlate accurate staging with treatment options for surgery, chemotherapy, or radiation therapy

Competency: Head and Neck Pathology
Sub-competency: Oropharynx and Nasopharynx Pathology

Sub-competency Definition:
Applies best practices in procedures and clinical indications for oropharynx and nasopharynx evaluation, integrating the morphologic interpretation of oropharyngeal and nasopharyngeal fine needle aspirates, biopsies, and resections with the clinical history, laboratory values, and specialized ancillary testing results to diagnose reactive, neoplastic benign, and neoplastic malignant processes.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Reporting and Communication
F. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS
Competency Area: Reactive
- Interpret imaging modalities as applied to diagnosis of reactive oropharyngeal and nasopharyngeal lesions
- Recognize distinct infectious and inflammatory processes that can involve the oropharynx and nasopharynx
- Recognize various developmental cysts and abnormalities that can involve the oropharynx and nasopharynx

Competency Area: Neoplastic - Benign
- Interpret imaging modalities as applied to diagnosis of benign oropharyngeal and nasopharyngeal lesions
- Distinguish between benign and malignant papillary epithelial proliferations
- Recognize benign mesenchymal and salivary gland neoplasms that can involve the oropharynx and nasopharynx

Competency Area: Neoplastic - Malignant
- Interpret imaging modalities as applied to diagnosis and staging of malignant neoplasms of the oropharynx and nasopharynx
- Distinguish between keratinizing and non-keratinizing oropharyngeal squamous cell carcinomas
- Classify nasopharyngeal carcinoma according to World Health Organization 2005 subtypes
- Recognize the morphologic spectrum of nasopharyngeal carcinoma post treatment
- Distinguish hematolymphoid neoplasms from reactive lymphoid hyperplasia in the oropharynx and nasopharynx
- Recognize metastases to the oropharynx and nasopharynx
Competency Area: Ancillary Testing
- Utilize immunohistochemical stains to delineate mucosal derived oropharyngeal and nasopharyngeal carcinomas from salivary type, hematolymphoid, and neuroendocrine type malignancies
- Interpret immunohistochemical, in-situ hybridization, and PCR findings to define human papilloma virus driven oropharyngeal carcinomas
- Recognize pitfalls and limitations of various methodologies for the detection of human papilloma virus DNA or RNA
- Interpret immunohistochemical, in-situ hybridization, and PCR findings to define Epstein Barr virus driven nasopharyngeal carcinomas

Competency Area: Reporting and Communication
- Employ published recommendations on reporting of oropharyngeal and nasopharyngeal lesions
- Generate clear, concise, and accurate reports that effectively communicate oropharyngeal and nasopharyngeal testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency Area: Treatment Implications
- Recognize the implications of intraoperative diagnosis in subsequent surgical management
- Recognize the implications of distinguishing between human papilloma virus driven and non-human papilloma virus driven oropharyngeal carcinomas
- Recognize the implications of distinguishing between Epstein-Barr virus and non-Epstein-Barr virus driven nasopharyngeal carcinomas
- Recognize the implications of specific immunohistochemical and molecular markers in targeted therapeutic approaches

Competency: Head and Neck Pathology
Sub-competency: Salivary Gland Pathology

Sub-competency Definition:
Applies best practices in procedures and clinical indications for salivary gland evaluation, integrating the morphologic interpretation of salivary gland fine needle aspirates, biopsies, and resections with the clinical history, laboratory values, and specialized ancillary testing results to diagnose reactive, neoplastic benign, and neoplastic malignant processes.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Reporting and Communication
F. Treatment Implications
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
- Recognize key radiologic findings as applied to the diagnosis of reactive conditions of the salivary gland
- Recognize reactive findings on fine needle aspirates and other preparations
- Recognize characteristic morphologic features of infectious and autoimmune salivary gland lesions
- Distinguish post-therapy related reactive changes and pseudotumoral salivary gland lesions from true neoplasms
- Correlate histologic features with clinical, microbial, and/or serologic findings to further classify reactive salivary gland lesions
- Interpret lip biopsies for the diagnosis of Sjogren syndrome and other autoimmune conditions

Competency Area: Neoplastic - Benign
- Recognize key radiologic findings as applied to the diagnosis of benign conditions of the salivary gland
- Interpret findings on salivary gland core and incisional biopsies and recognize the limitations and contraindications of this technique
- Recognize cytologic features and pitfalls in the diagnosis of benign salivary gland neoplasms on fine needle aspirates and other preparations
- Classify benign salivary gland neoplasms based on distribution and morphologic features of tumor cell types and stromal characteristics
- Recognize common histologic variants or metaplastic changes in each benign salivary gland tumor category

Competency Area: Neoplastic - Malignant
- Recognize key radiologic findings as applied to the diagnosis and stage of malignant conditions of the salivary gland
- Interpret findings on salivary gland core and incisional biopsies and recognize the limitations and contraindications of this technique
- Recognize cytologic features and pitfalls in the diagnosis of malignant salivary gland neoplasms on fine needle aspirates and other preparations
- Classify malignant salivary gland neoplasms based on distribution and morphologic features of tumor cell types and stromal characteristics
- Recognize common histologic variants or metaplastic changes in each malignant salivary gland tumor category
- Apply grading schemes for malignant salivary gland tumors when appropriate
- Recognize co-existing benign precursor lesions in salivary gland malignancies
- Distinguish primary salivary gland malignancies from metastases

Competency Area: Ancillary Testing
- Apply histochemical tests to distinguish between different salivary gland lesions
- Utilize immunohistochemical stains to define tumor cell phenotype for the diagnosis of salivary gland tumors
- Utilize immunohistochemical biomarkers for treatment and prognosis of salivary gland tumors
- Interpret molecular studies for diagnostic translocations in salivary gland tumors
- Interpret molecular studies for biomarkers used in the treatment and prognosis of salivary gland tumors

Competency Area: Reporting and Communication
- Employ published recommendations on reporting of salivary gland lesions
- Generate clear, concise, and accurate reports that effectively communicate salivary gland testing results and treatment implications to the patient’s health care team
• Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
• Accurately integrate results of ancillary testing into the final diagnosis and generate clear, concise, and accurate ancillary testing documentation
• Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency Area: Treatment Implications
• Recognize the implications of intraoperative diagnosis in subsequent surgical management
• Recognize the implications of diagnosis of salivary gland neoplasms that may require specific management approaches
• Convey the significance of a histologic variant of a salivary gland neoplasm that may require deviation from the standard clinical management of an entity
• Recognize the implications of specific immunohistochemical and molecular markers in targeted therapeutic approaches

Competency: Head and Neck Pathology
Sub-competency: Sinonasal Tract Pathology

Sub-competency Definition:
Applies best practices in procedures and clinical indications for sinonasal tract evaluation, integrating the morphologic interpretation of sinonasal cytologic preparations, biopsies, and resections with the clinical history, laboratory values, and specialized ancillary testing results to diagnose reactive, neoplastic benign, and neoplastic malignant processes.

Competency Areas:
A. Reactive
B. Neoplastic - Benign
C. Neoplastic - Malignant
D. Ancillary Testing
E. Reporting and Communication
F. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Reactive
• Recognize key radiologic findings as applied to diagnosis of reactive sinonasal tract disease
• Classify various types of chronic rhinosinusitis
• Distinguish between non-invasive (allergic) and invasive fungal sinusitis and recognize that the later often constitutes a medical emergency
• Categorize the various midfacial (granulomatous) destructive diseases
• Recognize developmental and hamartomatous entities in the sinonasal tract

Competency Area: Neoplastic - Benign
• Interpret imaging modalities as applied to diagnosis of benign sinonasal tract neoplasms
• Categorize each type of Schneiderian type papilloma and delineate these from non-Schneiderian papillary epithelial neoplasms
• Recognize benign salivary and mesenchymal neoplasms involving the sinonasal tract
• Recognize ectopic benign central nervous system tumors that can arise in the sinonasal tract
Competency Area: Neoplastic - Malignant
- Interpret imaging modalities as applied to diagnosis and staging of malignant neoplasms of the sinonasal tract
- Delineate olfactory neuroblastoma from other ‘blue cell tumors’ and undifferentiated neoplasms of the sinonasal tract
- Apply Hyams grading scheme to olfactory neuroblastomas
- Classify primary sinonasal adenocarcinomas into intestinal and non-intestinal types
- Recognize the morphologic spectrum of primary mucosal melanomas
- Recognize metastases to the sinonasal tract

Competency Area: Ancillary Testing
- Incorporate histochemical, immunohistochemical, and serologic findings to classify midfacial destructive diseases
- Utilize immunohistochemical stains, in-situ hybridization, and PCR findings to delineate between ‘round blue cell’ and undifferentiated tumors of the sinonasal tract
- Utilize immunohistochemical stains to classify sinonasal adenocarcinomas into intestinal, non-intestinal, and salivary types

Competency Area: Reporting and Communication
- Employ published recommendations on reporting of sinonasal tract lesions
- Generate clear, concise, and accurate reports that effectively communicate salivary gland testing results and treatment implications to the patient’s health care team
- Clearly communicate critical/significant diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Accurately integrate results of ancillary testing into the final diagnosis and generate clear, concise, and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians and multidisciplinary health care teams

Competency Area: Treatment Implications
- Recognize the implications of intraoperative diagnosis in subsequent surgical management
- Recognize the implications of delineating non-infectious (allergic) fungal sinusitis from invasive fungal sinusitis
- Recognize the implications of distinguishing between the various midfacial destructive diseases
- Recognize the implications of distinguishing between the various ‘round blue cell’/undifferentiated tumors of the sinonasal tract
- Recognize the implications of specific immunohistochemical and molecular markers in targeted therapeutic approaches

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Competency: Hematology

**Competency Definition:**
Employs best practices in performing and interpreting clinical hematology testing and the diagnosis of hematolymphoid and non-neoplastic disorders; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating the laboratory findings with the patient’s clinical picture; additional testing recommendations; understanding how specific diagnoses affect treatment; and accurate reporting and communications to ensure accurate and comprehensive diagnoses and optimum patient care.

**Competency Areas:**
A. Instrumentation  
B. Peripheral Blood  
C. Cerebrospinal Fluid (CSF) and Body Fluid Specimens  
D. Special Hematology  
E. Treatment Implications  
F. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Instrumentation**
- Identify and apply age-appropriate and gender-specific reference intervals for peripheral blood parameters obtained from automated hematology analyzers for pediatric and adult specimens
- Understand the value of absolute reticulocyte counts when compared with reticulocyte percentages
- Interpret RBC indices to characterize anemias
- Recognize the limitations and uses of automated WBC differentials
- Identify spurious results with automated hematology instrumentation
- Perform a validation/verification of a new analyzer
- Establish reference ranges for a new assay

**Competency Area: Peripheral Blood**
- Recognize the laboratory and morphologic features associated with acute leukemia (lymphoid and myeloid), including acute promyelocytic leukemia
- Recognize the laboratory and morphologic features of the myelodysplastic and myeloproliferative neoplasms, and what features separate these from reactive conditions (ie, leukemoid reaction)
- Identify a leukoerythroblastic blood smear and explain its clinical significance
- Recognize features of lymphoproliferative diseases including chronic lymphocytic leukemia (and transformation), hairy cell leukemia and circulating lymphoma cells vs. reactive lymphocytosis (ie, as due to a viral infection)
- Recognize the laboratory and morphologic features of inherited RBC disorders including thalassemia, other hemoglobinopathies, RBC enzyme deficiencies, RBC membrane disorders and hereditary sideroblastic anemia; recommend further laboratory testing for confirmation of diagnoses
- Identify laboratory and morphologic findings of nutritional deficiencies (iron deficiency anemia, megaloblastic anemias - vitamin B12 or folate deficiency) and features distinguishing these anemias from anemia of chronic disease and hereditary RBC disorders
- Detect laboratory and morphologic features of some forms of hemolysis including microangiopathic hemolysis, hemolytic uremic syndrome, thrombotic thrombocytopenia purpura, maternal-fetal incompatibility and autoimmune hemolysis
- Distinguish morphologic features of hereditary leukocyte disorders including Chidiak-Higashi syndrome, May-Hegglin anomaly, Pelger-Hukt anomaly, and Alder-Reilly anomaly from reactive features including toxic granulation and Dohle bodies or myelodysplasia
- Recognize malaria and distinguish Plasmodium falciparum from Plasmodium non-falciparum species versus babesia or blood smear artifacts
- Recognize and resolve artifacts in peripheral blood smears
Competency Area: Cerebrospinal Fluid (CSF) and Body Fluid Specimens

- Apply age-appropriate reference intervals for CSF and body fluid leukocyte and red cell counts for pediatric and adult specimens
- Recognize the morphologic characteristics of blasts and lymphoma cells on cytocentrifuge preparations from body fluid specimens; recommend additional testing to confirm leukemia and lymphoma in these specimens, such as flow cytometry studies
- Distinguish hematopoietic neoplasms from non-hematopoietic neoplasms; recommend appropriate confirmatory tests
- Correlate CSF and body fluid morphologic findings with cytology/histology specimens
- Recognize the changes seen with CSF shunts, remote CSF hemorrhage, central nervous system tissue, and bone marrow contamination of CSF
- Differentiate malignant versus reactive tissue and mesothelial cells in serous fluids
- Recognize the morphologic and laboratory features of chylothorax
- Recognize the morphologic features of infection and common infectious organisms found in CSF and body fluids, including joint fluids
- Identify crystals on synovial fluid examination

Competency Area: Special Hematology

- Understand the application, interpretation, and testing limitations of enzymatic cytochemistries
- Understand testing algorithms to identify abnormal hemoglobins
- Interpret hemoglobin electrophoreses, high-performance liquid chromatography and sickle solubility test results; recommend further studies as appropriate
- Understand the performance and testing limitations of G6PD enzyme testing
- Interpret osmotic fragility tests
- Recognize and interpret Heinz body stain
- Understand the utilization of serum viscosity testing
- Comprehend testing for unstable hemoglobins by heat stability
- Understand the theory, interpretation, and clinical implications of testing for fetal maternal hemorrhage.

Competency Area: Treatment Implications

- Recognize critical hematology laboratory results necessitating immediate contact with clinicians (e.g., microangiopathic hemolysis, acute leukemia, especially acute promyelocytic leukemia, Burkitt lymphoma/leukemia, Plasmodium falciparum, and bacteria/yeast in CSF and peripheral blood)
- Recommend additional laboratory testing based on initial hematology laboratory results (e.g., molecular genetic results to confirm acute promyelocytic leukemia, coagulation testing for microangiopathic hemolysis, microbiologic cultures for bacteria/yeast in CSF, body fluids and peripheral blood, flow cytometry for new lymphomas/acute leukemias)

Competency Area: Reporting and Communication

- Generate clear, concise and accurate hematology testing reports with reference values that effectively communicate results and treatment implications
- Effectively communicate critical values and diagnoses requiring immediate action; communicate appropriately when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Demonstrate consistent use of terminology for malignant (WHO) and non-neoplastic conditions in reports
- Demonstrate willingness and ability to discuss current hematology testing and patient issues with clinicians and multidisciplinary health care teams
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Supporting Committee(s)

Hematology/Clinical Microscopy Resource Committee
Competency: Hematopathology

Competency Definition:
Employs best practices in performing and interpreting hematopathology testing and the diagnosis of hematolymphoid disorders; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating the morphologic, immunophenotypic, cytogenetic and genotypic findings with the patient’s clinical picture; understanding how specific diagnoses affect treatment; and accurate reporting and communications to ensure accurate and comprehensive diagnoses and optimal patient care.

Sub-competencies:
1. Bone Marrows
2. Hemopath Cytogentics
3. Immunophenotyping
4. Lymph Nodes/ Extranodal Tissues

Sub-competency: Bone Marrows

Sub-competency Definition:
Applies best practices in procedures and clinical indications for a bone marrow evaluation, integrating the morphologic interpretation of a bone marrow aspirate and biopsy with the clinical history, laboratory values and specialized ancillary testing results to diagnose benign conditions and hematolymphoid processes of the bone marrow.

Competency Areas:
A. Procedure, Handling and Interpretation
B. Reactive Conditions
C. Neoplastic Conditions
D. Molecular Testing for Bone Marrows
E. Treatment Implications
F. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Procedure, Handling & Interpretation

- Demonstrate skill in the technical aspects and performance of a bone marrow aspirate and biopsy including identification of appropriate sites and limitations of this procedure in adults and children
- Understand the significance of a `dry tap` and how to collect additional specimens for ancillary studies; appropriately handle specimens when collecting for microbiologic and viral cultures
- Recognize the preparation and handling involved for the analysis of a bone marrow biopsy and aspirate specimen, including the interpretation of routine Wright- Giemsa, hematoxylin and eosin and special stains (such as Prussian blue, reticulin, trichrome stains)
- Review clinical history, blood findings, radiologic studies and other pertinent laboratory testing and integrate this information with the morphologic assessment
- Demonstrate knowledge of hematopoiesis and distinguish the maturation stages of cells in each hematopoietic cell lineage for classification
- Understand the major hematopoietic regulatory factors/cytokines that influence hematopoiesis
- Assess bone marrow for adequacy, cellularity, the stromal compartment, the bony trabeculae and apply age appropriate reference ranges for cellularity and bone marrow lineage composition; calculate a myeloid/erythroid ratio
- Recognize morphologic features of normal myeloid, erythroid and megakaryocytic maturation, age appropriate components (eg, hematogones), and detect features of cellular dysplasia or malignancy
- Identify storage iron and assess adequacy of iron stores on a bone marrow aspirate or biopsy
Competency Area: Reactive Conditions

- Recognize the morphologic features associated with adult anemias due to chronic disease, nutrient deficiencies and other causes (e.g., parvovirus infection) including integration of associated laboratory values
- Recognize the morphologic features associated with pediatric anemias due to nutrient deficiencies, constitutional erythrocyte disorders and other causes (e.g., parvovirus infection, transient erythroblastopenia) including integration of associated laboratory values
- Identify the bone marrow manifestations of infectious diseases including viral (e.g., HIV), fungal, parasitic, and hereditary and acquired hemophagocytic syndromes; distinguish infectious disorders from hereditary storage disorders
- Distinguish the morphologic features and effects of non-infectious systemic diseases (e.g., alcoholism, collagen vascular disease, hyperparathyroidism, sarcoidosis, amyloidosis, renal disease and metastatic malignancy)
- Understand the pathophysiology, clinical findings, etiology and expected bone marrow morphology for bone marrow failure syndromes including aplastic anemia
- Distinguish reactive leukocytosis, secondary erythrocytosis and thrombocytosis from clonal disorders
- Differentiate transient myeloid proliferations (e.g., transient myeloproliferative disorder associated with Down syndrome), transient cytopenias and transient lymphocytosis (e.g., transient stress lymphocytosis, transient plasmacytosis) from clonal disorders
- Recognize the clinical and morphologic effects of common drugs including chemotherapy, mineral supplements (e.g., zinc) and growth factors on peripheral blood and hematopoiesis

Competency Area: Neoplastic Conditions

- Recognize the morphologic features of lymphoblastic leukemia/lymphoma and acute myeloid leukemia and related precursor neoplasms
- Recognize the morphologic features of acute leukemia of ambiguous lineage, infantile leukemias, and distinguish acute myeloid leukemia versus growth factor therapy effect
- Recognize the morphologic features of myelodysplastic syndromes and myeloproliferative neoplasms, including features distinguishing these from reactive leukocytosis, thrombocytosis, and erythrocytosis
- Recognize the morphologic features of myelodysplastic/myeloproliferative neoplasms, including the distinction from reactive monocytoses
- Recognize the features of myeloproliferative neoplasms with eosinophilia, specifically PDGFR and FGFR1 neoplasms and distinguish these from reactive eosinophilia
- Recognize the morphologic features of Hodgkin and non-Hodgkin lymphomas
- Distinguish between immunodeficiency associated lymphoproliferative disorders, including post-transplant lymphoproliferative disorders, and malignant lymphoma
- Identify the morphologic features of mast cell disease and distinguish from reactive mast cell hyperplasia
- Identify the bone marrow manifestations of histiocytic and dendritic cell neoplasms, including Langerhans cell histiocytosis
- Recognize neoplasms of undetermined lineage and stage of differentiation, including blastic plasmacytoid dendritic cell neoplasm
- Integrate ancillary studies, including flow cytometry, cytochemistry, and immunohistochemistry, to diagnose and classify myeloid and lymphoid neoplasms
- Employ cytogenetic and genotypic studies in the diagnosis and classification of acute leukemias, myelodysplastic and myeloproliferative disorders and lymphoid neoplasms
- Recognize the morphologic findings post-chemotherapy and post stem cell transplantation in the treatment of acute and chronic leukemias and lymphoma, including the temporal relationships to marrow regeneration post-therapy
- Identify bone marrow necrosis including that secondary to the presence of tumor, leukemia, lymphoma, chemotherapy or embolic events
Competency Area: Molecular Testing for Bone Marrows

- Perform polymerase chain reaction (PCR) analysis for B and T cell clonality and other hematolymphoid disorders, including sample requirements for fresh and formalin-fixed tissue, sample preparation and DNA quality, PCR inhibitors, PCR setup, and PCR product detection (gel or capillary electrophoresis) and correct interpretation
- Perform reverse transcription PCR analysis for BCR/ABL1 among other targets, including sample preparation, set up and PCR product detection
- Relate real-time PCR operating principles, interpretation of data, and use of standard curves
- Distinguish between PCR versus FISH when detecting certain translocations
- Identify the methods for mutation detection and the clinical relevance of mutations in hematopathology
- Incorporate molecular pathology results into final diagnoses of hematolymphoid neoplasms

Competency Area: Treatment Implications

- Recognize critical hematology laboratory results necessitating immediate contact with clinicians (e.g., hemophagocytic syndrome, acute leukemia, especially acute promyelocytic leukemia, Burkitt lymphoma/leukemia, malaria and new/unsuspected diagnosis)
- Recognize need for additional testing for acute leukemia prior to treatment (e.g., bone marrow specimen, immunophenotyping, cytogenetic/molecular genetic testing)
- Recognize the implications of diagnoses of myeloproliferative neoplasms such as chronic myelogenous leukemia and PDGFR-associated neoplasms that require specific small molecule inhibitor therapy

Competency Area: Reporting and Communication

- Generate clear, concise and accurate reports that effectively communicate bone marrow testing results and treatment implications to the patient’s health care team
- Clearly communicate critical values and diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Demonstrate consistent use of terminology for malignant (WHO) and non-neoplastic conditions in reports
- Accurately integrate results of ancillary testing (e.g., flow cytometry, cytogenetics, molecular genetic testing) into the final diagnosis, and generate clear, concise and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current hematopathology and patient issues with clinicians and multidisciplinary health care teams (e.g., residual disease versus regenerating bone marrow, difficulties in classification as in acute leukemias of ambiguous lineage, establishing a diagnosis of a specific type of low grade B-cell lymphoma in the bone marrow often requiring correlation with additional tissue biopsy)
Competency: Hematopathology
Sub-competency: Hemepath Cytogentics

Sub-competency Definition:
Apply best practices in cytogenetic procedures including standard karyotyping analysis, fluorescence in situ hybridization (FISH) and more specialized techniques (e.g., comparative genomic hybridization) as necessary, understanding the applications and limitations of these techniques, and recognizing the common cytogenetic findings in hematologic disorders.

Competency Areas:
A. Cytogenetic Methods, Procedures and Interpretation
B. Myeloid Neoplasms
C. Lymphoid Neoplasms
D. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Cytogenetic Methods, Procedures & Interpretation
- Understand which tissues/fluids are best sent for standard karyotyping and/or FISH analysis and under what conditions (fresh, fixed), including proper handling
- Evaluate when cytogenetic versus molecular testing is appropriate (i.e., considerations of turnaround time, specificity, sensitivity)
- Define the limitations of FISH vs. standard karyotyping and when each is useful
- Recognize limitations of cytogenetic testing for cryptic deletions and translocations
- Understand and use standard cytogenetic nomenclature and definition of a cytogenetic clone
- Incorporate cytogenetic results into bone marrow, lymph node and tissue pathology reports

Competency Area: Myeloid Neoplasms
- Identify acute myeloid and lymphoid leukemias and chronic leukemias defined by recurrent cytogenetic abnormalities
- Recognize cytogenetic abnormalities sufficient to diagnosis acute myeloid leukemia with myelodysplasia-related features when ≥ 20% blood or marrow blasts are present
- Identify cytogenetic abnormalities associated with therapy-related myeloid neoplasms
- Relate cytogenetic findings in myeloproliferative neoplasms and myelodysplastic syndromes, including findings indicative of disease acceleration
- Explain prognostically important cytogenetic findings in myeloid disorders

Competency Area: Lymphoid Neoplasms
- Identify the cytogenetic findings in the diagnosis of B and T cell lymphoproliferative disorders
- Relate the cytogenetic findings and prognostic impact in acute lymphoblastic leukemias/lymphomas and chronic lymphoid leukemias
- Identify the cytogenetic and FISH findings and their importance in plasma cell neoplasms

Competency Area: Reporting and Communication
- Generate clear, concise and accurate reports that effectively communicate cytogenetic testing results to the patient’s health care team
- Clearly communicate critical values and diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Demonstrate consistent use of terminology for malignant (WHO) and non-neoplastic conditions in reports
- Accurately integrate results of ancillary testing (e.g., flow cytometry, cytogenetics, molecular genetic testing) into the final diagnosis, and generate clear, concise and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current hematopathology and patient issues with clinicians and multidisciplinary health care teams
**Competency: Hematopathology**

**Sub-competency: Immunophenotyping**

**Sub-competency Definition:**
Apply best practices in interpretation of data, and the immunophenotypic patterns associated with hematologic disorders; manage the pitfalls of immunophenotyping when collecting, synthesizing, and using the immunophenotypic data in arriving at a diagnosis.

**Competency Areas:**
A. Immunophenotyping Techniques  
B. Lymphomas  
C. Acute Leukemias  
D. Fine Needle Aspiration (FNA) Specimens and Body Fluids  
E. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Immunophenotyping Techniques**
- Describe the applications and limitations of immunohistochemistry in evaluating tissue biopsies for hematolymphoid disorders  
- Describe the applications and limitations of immunohistochemistry in evaluating bone marrow clot sections and trephine biopsies for hematolymphoid disorders  
- Diagnose paroxysmal nocturnal hemoglobinuria (PNH) by flow cytometry immunophenotyping  
- Describe the applications, advantages, and disadvantages of flow cytometric immunophenotyping in evaluating tissue biopsies and bone marrow specimens for hematolymphoid disorders

**Competency Area: Lymphomas**
- Appropriately diagnose and subclassify non-Hodgkin lymphomas and Hodgkin lymphoma  
- Accurately distinguish reactive proliferations from lymphoma  
- Appropriately identify prognostic markers of chronic lymphocytic leukemia  
- Recognize immunophenotypic features distinguishing plasma cell neoplasms from B-cell lymphoma  
- Recognize the lack of surface immunoglobulin light chain expression seen by flow cytometry in some non-Hodgkin lymphomas and reactive follicular hyperplasia  
- Recognize characteristic immunophenotypic features of mature (peripheral) T-cell lymphomas/chronic leukemias and NK-cell lymphoproliferative disorders  
- Recognize immunophenotypic features differentiating lymphoma from a leukemic infiltrate or non-hematopoietic neoplasm  
- Recognize immunophenotypic features differentiating lymphoma from histiocytic and dendritic cell neoplasms

**Competency Area: Acute Leukemias**
- Distinguish acute myeloid leukemia from acute lymphoblastic leukemia  
- Recognize the immunophenotypic features of the various subtypes of acute myeloid leukemias  
- Recognize the immunophenotypic features of B-cell and T-cell lymphoblastic leukemia/lymphoma  
- Recognize the immunophenotypic features of acute leukemias of ambiguous lineage  
- Recognize the immunophenotypic features of B-cell lymphoblastic leukemia versus hematogones (normal immature B cell precursors)  
- Distinguish peripheralized circulating lymphoma from acute leukemia  
- Distinguish acute leukemia from blastic plasmacytoid dendritic cell neoplasm
Competency Area: Fine Needle Aspiration (FNA) Specimens & Body Fluids
- Identify the applications and limitations of flow cytometric immunophenotyping in evaluating FNA specimens for hematolymphoid disorders
- Recognize the applications of flow cytometric immunophenotyping in evaluating CSF and body fluid specimens for hematolymphoid disorders

Competency Area: Reporting and Communication
- Generate clear, concise and accurate reports that effectively communicate immunophenotyping testing results to the patient’s health care team
- Clearly communicate critical values and diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Demonstrate consistent use of terminology for malignant (WHO) and non-neoplastic conditions in reports
- Accurately integrate results of ancillary testing (e.g., flow cytometry, cytogenetics, molecular genetic testing) into the final diagnosis, and generate clear, concise and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current hematopathology and patient issues with clinicians and multidisciplinary health care teams

Competency: Hematopathology
Sub-competency: Lymph Nodes/Extranodal Tissues

Sub-competency Definition:
Accurately evaluate lymph nodes and extranodal tissues for reactive processes vs. a hematolymphoid disorder; classify the latter according to the 2008 WHO classification and incorporate ancillary diagnostic techniques as appropriate.

Competency Areas:
A. Specimen Handling for Ancillary Testing
B. Benign Lymphadenopathies
C. Lymphomas
D. Other Neoplasms
E. Spleen
F. Thymus
G. Cutaneous Hematolymphoid Disorders
H. Molecular Testing for Lymph Nodes/Extranodal Tissues
I. Treatment Implications
J. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling for Ancillary Testing
- Recognize the gross characteristics of lymphoma, hemorrhage, and necrosis (e.g., necessary for when sampling tissue for further studies)
- Properly handle fresh tissue biopsies submitted for intraoperative consultation with a previous history (or high suspicion) of malignant lymphoma
- Appropriately triage nodal and extranodal tissue specimens, including excisional biopsies, fine needle aspirations and biopsies, for touch preparations, fixation for histologic sectioning, flow cytometry, cytogenetic, and/or molecular genetic testing
Competency Area: Benign Lymphadenopathies
- Recognize normal lymph node histology and the histologic patterns associated with benign and reactive conditions
- Use the histologic patterns identified to generate a differential diagnosis
- Further refine the differential diagnosis based on histology allowing distinction of reactive lymphadenopathies from malignant lymphomas, indicating additional testing as appropriate
- Recognize the histopathologic features of lymphadenopathies associated with specific clinical syndromes (ie, Castleman lymphadenopathy, dermatopathic lymphadenopathy, hemophagocytic syndrome, Kikuchi-Fujimoto lymphadenopathy, Kimura lymphadenopathy, sinus histiocytosis with massive lymphadenopathy)
- Recognize the histopathologic features of lymphadenopathies associated with infection, medication/treatment effects, and autoimmune disorders; recommend appropriate testing as indicated
- Recognize the histopathologic features of vascular, myomatous and lipomatous lymphadenopathies and benign disorders of unclear etiology (ie, inflammatory pseudotumor)
- Recognize the histopathologic, diagnostic features of foreign body lymphadenopathies

Competency Area: Lymphomas
- Identify the histologic patterns associated with lymphomas and how these differ from normal histology and reactive patterns
- Use the histologic patterns identified to generate a differential diagnosis that is further refined by specific histologic features, immunophenotyping or other ancillary testing
- Recognize the histopathologic and diagnostic features of precursor lymphoid neoplasms of B- and T-cell types, including important cytogenetic and molecular genetic abnormalities and their prognostic associations
- Recognize the histopathologic and immunophenotypic features of Hodgkin lymphoma
- Recognize the histopathologic, immunophenotypic, and genetic features of mature B-cell neoplasms
- Recognize the histopathologic, immunophenotypic, and genetic features of mature T-cell and NK-cell neoplasms
- Recognize lymphoproliferative disorders associated with immune deficiency (ie, congenital immune deficiencies, post-transplantation, and acquired immunodeficiency)
- Distinguish myeloid neoplasms from lymphoma and non-hematopoietic neoplasms
- Explain clinical relevance of in situ lymphomas
- Be cognizant of gray zone lesions and the features defining lymphomas that fall within this category

Competency Area: Other Neoplasms
- Identify the histopathologic, immunophenotypic and genetic features of myeloid sarcoma
- Recognize the histopathologic, immunophenotypic and genetic features of histiocytic and dendritic cell neoplasms
- Recognize the histopathologic, immunophenotypic and genetic features of mastocytosis

Competency Area: Spleen
- Recognize the disorders associated with hypersplenism and hyposplenic states
- Recognize histopathologic and diagnostic features of neoplastic and non-neoplastic disorders of the white pulp and red pulp
- Recognize the histopathologic features of myeloproliferative neoplasms in the spleen
- Recognize the histopathologic and diagnostic features of non-neoplastic lesions in the spleen including splenic cysts, vascular lesions, nonhematopoietic tumors, and tumor-like lesions

Competency Area: Thymus
- Recognize the histopathologic and diagnostic features of Hodgkin lymphoma and non-Hodgkin lymphoma
- Distinguish thymoma from T-lymphoblastic lymphoma and thymic hyperplasia
- Interpret immunophenotyping and molecular studies in the diagnosis of thymic neoplasms
- Distinguish thymic carcinoma from thymoma
Competency Area: Cutaneous Hematolymphoid Disorders
- Recognize the histopathologic and diagnostic features of cutaneous B-cell and T-cell lymphomas
- Recognize the histopathologic and diagnostic features of plasmacytoid dendritic cell tumors
- Recognize secondary involvement of skin by non-Hodgkin lymphomas
- Distinguish cutaneous lymphoma from leukemia cutis, mast cell proliferations, and non-hematopoietic neoplasms
- Distinguish benign, reactive lymphoid proliferations from cutaneous lymphoma

Competency Area: Molecular Testing for Lymph Nodes/Extranodal Tissues
- Perform polymerase chain reaction (PCR) analysis for B and T cell clonality and other hematolymphoid disorders, including sample requirements for fresh and formalin-fixed tissue, sample preparation and DNA quality, PCR inhibitors, PCR setup, and PCR product detection (gel or capillary electrophoresis) and correct interpretation
- Perform reverse transcription PCR analysis for BCR/ABL1 among other targets, including sample preparation, set up and PCR product detection
- Relate real-time PCR operating principles, interpretation of data, use of standard curves
- Distinguish between PCR versus FISH when detecting certain translocations
- Identify the methods for mutation detection and the clinical relevance of mutations in hematopathology
- Incorporate molecular pathology results into final diagnoses of hematolymphoid neoplasms

Competency Area: Treatment Implications
- Recognize critical hematology laboratory results necessitating immediate contact with clinicians (eg, acute leukemia, Burkitt lymphoma/leukemia)
- Recognize treatment implications of Burkitt lymphoma from diffuse large B-cell lymphoma
- Understand treatment implications of classical Hodgkin lymphoma versus diffuse large B-cell lymphoma
- Convey treatment implications of classic hairy cell leukemia

Competency Area: Reporting and Communication
- Generate clear, concise and accurate reports that effectively communicate hematolymphoid testing results and treatment implications to the patient’s health care team
- Clearly communicate critical values and diagnoses requiring immediate action; appropriately indicate when there is going to be a delay in diagnosis and note these preliminary communications in the final report
- Demonstrate consistent use of terminology for malignant (WHO) and non-neoplastic conditions in reports
- Accurately integrate results of ancillary testing (eg, flow cytometry, cytogenetics, molecular genetic testing) into the final diagnosis, and generate clear, concise and accurate ancillary testing documentation
- Demonstrate willingness and ability to discuss current hematopathology and patient issues with clinicians and multidisciplinary health care teams (eg, B-cell lymphomas with features intermediate between diffuse large B-cell lymphoma and Burkitt lymphoma, B-cell lymphomas with features between diffuse large B-cell lymphoma and classical Hodgkin lymphoma, plasma cell neoplasms versus B-cell lymphomas with plasmacytic differentiation)
<table>
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| Supporting Committee(s) | Hematology/Clinical Microscopy Resource Committee |
Competency: Hemostasis Pathology

Competency Definition:
Employs best practices in routine and esoteric testing, diagnosis and treatment of disorders of hemostasis and thrombosis, remains knowledgeable of trends in monitoring of anticoagulant and anti-platelet therapies, and demonstrates the ability to integrate these modalities in practice to optimum patient care.

Competency Areas:
A. Hemostasis Physiology
B. Initial Hemostasis Tests
C. Inherited and Acquired Coagulation Disorders
D. Laboratory Evaluation of Thrombocytopenia
E. Qualitative Platelet Deficiencies & von Willebrand (VWB)
F. Laboratory Evaluation of Hypercoaguable States
G. Laboratory Assessment and Monitoring of Antithrombotic Therapies
H. Hemostasis Promoting Drugs and Concentrates
I. Hemostasis Point of Care Testing

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Hemostasis Physiology
• Explain the coagulation pathway including initiation, and amplification
• Describe the regulation of thrombin generation and fibrin clot formation/stabilization
• List the steps in platelet function including platelet adhesion, platelet activation and granule release, platelet aggregation and procoagulant activity
• Discuss the role of von Willebrand factor in platelet adhesion, platelet aggregation, and factor VIII transport
• Describe the constituents, pathway, and regulation of the fibrinolytic system

Competency Area: Initial Hemostasis Tests
• List pre-analytical variables, that can produce inaccurate coagulation test results
• Identify the indications, limitations, methods, and interpretation of initial tests of platelet function
• Explain the reagents and test methods for the Initial coagulation tests: activated partial thromboplastin time (aPTT), prothrombin time (PT), thrombin time (TT), and fibrinogen assay
• Employ algorithmic approaches to evaluate all combinations of normal and prolonged PT and aPTT
• Recommend the initial methods to evaluate for fibrinolysis activity: fibrinogen, fibrinogen degradation products (FDP), and D-dimer

Competency Area: Inherited and Acquired Coagulation Disorders
• Compare and contrast the clinical manifestations, epidemiology, laboratory diagnosis, genetics and principles of therapy of common inherited coagulation disorders including factor VIII deficiency (Hemophilia A), factor IX deficiency (Hemophilia B) and Factor XI deficiency
• Recommend the approved use of recombinant and plasma derived factor VIII and IX concentrates in the treatment of disorders of hemostasis
• Evaluate the clinical presentation, laboratory results, and treatment of patients with acquired coagulation factor inhibitors, including both alloantibodies and autoantibodies
• Identify the clinical conditions associated with disseminated intravascular coagulation (DIC), and the typical coagulation test patterns accompanying DIC
**Competency Area: Laboratory Evaluation of Thrombocytopenia**
- Summarize the most common mechanisms and employ an approach to the evaluation of thrombocytopenia
- Correlate the pathophysiology with clinical manifestations, laboratory testing, treatment and prevention of HIT (Heparin induced thrombocytopenia)
- Interpret laboratory testing for HIT in the context of pretest probability (eg, 4T score)
- Recognize the clinical and laboratory manifestations and principles of treatment of thrombotic thrombocytopenic purpura (TTP) and the utility of testing for ADAMTS13
- Discuss the laboratory diagnosis of congenital macro-thrombocytopenia syndromes, such as May-Hegglin Anomaly

**Competency Area: Qualitative Platelet Deficiencies & von Willebrand (vWD)**
- Integrate the genetics, epidemiology, and clinical presentations of vWD
- Apply laboratory methods to assess von Willebrand factor (vWF) function and antigen concentration used to identify quantitative (types 1 and 3) and qualitative (type 2) types of von Willebrand disease
- List the indications to perform von Willebrand factor multimer analysis and additional esoteric tests to differentiate type 2 vWD subtypes and platelet-type pseudo vWD
- Recommend appropriate treatment options for vWD including desmopressin (DDAVP) and plasma derived concentrates
- Distinguish between the platelet defects of rare inherited qualitative platelet disorders including Glanzmann thrombasthenia and Bernard-Soulier syndrome
- Discuss common causes of acquired qualitative platelet defects including uremia, medication induced, and hematologic disorders
- Recognize the limited indications for whole blood and platelet rich plasma aggregometry testing, and be familiar with their interpretation

**Competency Area: Laboratory Evaluation of Hypercoaguable States**
- Identify the indications for inherited and acquired thrombophilia testing
- Recognize the influence of preanalytic variables on interpretation and performance of these tests
- Interpret laboratory testing for inherited thrombophilia (Activated Protein C Resistance, Protein S deficiency, Protein C deficiency, Antithrombin deficiency, Factor V Leiden mutation, Prothrombin gene mutation, and dysfibrinogenemia) and correlate with thrombosis risk
- Correlate the pathogenesis of the antiphospholipid syndrome with clinical manifestations and treatment
- Recommend guidelines for performing and interpreting clotting (lupus anticoagulant) and serologic (cardiolipin and B2 glycoprotein 1 antibodies) to support a clinical suspicion for antiphospholipid syndrome
- Apply D-dimer testing in patients with suspected venous thrombosis (DVT and PE)

**Competency Area: Laboratory Assessment and Monitoring of Antithrombotic Therapies**
- Interpret functional and molecular tests to assess patients` responsiveness to antiplatelet drugs including aspirin, clopidogrel, and other thienopyridines, incorporating the limitations of their use in dosing
- Apply the pharmacology of warfarin inhibition of vitamin K dependent coagulation factor synthesis and be familiar with the evolving role of pharmacogenetic testing
- Derive INR from PT results using the ISI of a thromboplastin reagent and geometric mean of control plasmas, and describe the use and limitations of INR for monitoring warfarin anticoagulation therapy
- Summarize the pharmacology and clinical utility of unfractionated heparin and low molecular weight heparin, and the effects of these anticoagulants on coagulation tests, including aPTT, PT, TT and anti Xa assays
- Compare the aPTT and the heparin assay (anti Xa method) as means of monitoring of unfractionated heparins
- Integrate the pharmacology and clinical utility of intravenous and oral direct thrombin inhibitors and oral direct factor Xa inhibitor medications, and their effects on clot based coagulation tests
Competency Area: Hemostasis promoting Drugs and Concentrates

- Specify the appropriate use, dosing and side effects of recombinant factor VIIa
- Recommend appropriate usage of plasma derived concentrates including prothrombin complex concentrates (PCC), activated PCC, antithrombin and fibrinogen concentrates, and fibrin glue
- Review the appropriate use, dosing and side effects of pharmaceutical agents used for hemostasis such as tranexamic acid, aminocaproic acid, aprotinin and protamine

Competency Area: Hemostasis Point of Care Testing

- Direct the clinical laboratory’s role in coordinating point of care hemostasis testing with other healthcare providers including quality assurance, quality control, competency of non-laboratory staff performing POC tests, proficiency testing, and accreditation
- Apply the principles of operation and clinical applications of whole blood activated clotting times (eg, ACT) and thromboelastography instruments (eg, TEG, ROTEM)

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Supporting Committee(s)
Coagulation Resource Committee
Competency: Hepatopathology (To Be Developed)
Competency: Heritable Disease Pathology (To Be Developed)
Competency: Histocompatibility

Competency Definition:
Demonstrate knowledge of parameters for testing in the following situations: matching of donor and recipient for transplantation, donor selection to avoid or minimize graft vs. host disease, pre-transplant compatibility testing, post-transplant monitoring, and disease association testing. Demonstrate understanding of immunologic concepts, and the communication and reporting of results related to those tests.

Note: Federal regulations preclude pathologists and doctoral-level scientists from serving as “Specialty Lab Directors” or Technical Supervisors of laboratories performing histocompatibility testing if they do not meet the specific requirements listed in 42CFR493.1449(o).

Competency Areas:
A. Specimen Handling
B. Testing Methods
C. Analytic Concerns
D. Test Interpretation – Solid Organ Transplant Compatibility - General
E. Test Interpretation – Solid Organ Transplant Compatibility – ABO Typing
F. Test Interpretation – Solid Organ Transplant Compatibility – HLA Typing (Low Resolution)
G. Test Interpretation – Solid Organ Transplant Compatibility – HLA Typing (High Resolution)
H. Test Interpretation – Solid Organ Transplant Compatibility – Antibody Testing
I. Test Interpretation – Solid Organ Transplant Compatibility – Donor Selection
J. Test Interpretation – Solid Organ Transplant Compatibility – Post Transplant Monitoring and Donor Specific Antibodies
K. Test Interpretation – Stem Cell Transplant Compatibility - General
L. Test Interpretation – Stem Cell Transplant Compatibility – ABO Typing
M. Test Interpretation – Stem Cell Transplant Compatibility – HLA Typing (Low Resolution)
N. Test Interpretation – Stem Cell Transplant Compatibility – HLA Typing (High Resolution)
O. Test Interpretation – Stem Cell Transplant Compatibility – Antibody Testing and Donor Selection
P. Test Interpretation – Stem Cell Transplant Compatibility – KIR Testing
Q. Test Interpretation – Stem Cell Transplant Compatibility – Post Transplant Monitoring - Chimerism Studies – General
R. Test Interpretation - Inheritable Disease Associations with HLA Type
S. Test Interpretation - Drug Hypersensitivity Associations with HLA Type
T. Test Interpretation – Transfusion Support
U. Quality Assurance
V. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling
- Determine optimal, acceptable and unacceptable labeling requirements for specimens.
- Determine optimal, acceptable and unacceptable collection, transport and storage requirements for each specimen type and each testing method.
- Communicate to appropriate clinical services the specimen handling requirements for all specimen types including pre- and post-transfusion specimens.
- Establish a mechanism to ensure viability of the specimen in histocompatibility laboratories doing cell-based assays (eg, cytotoxicity and crossmatch).
Competency Area: Testing Methods
- Select appropriate instrumentation for the test menu provided and transplant services supported
- Recognize limitations of instrumentation utilized for each test performed
- Effectively communicate alternative methods/instruments for each test performed to transplant physicians and surgeons and administrators
- Determine optimal workstation and instrument placement to prevent contamination, optimize ergonomics and workflow in the laboratory
- Identify optimal, acceptable and unacceptable samples for each instrument platform/test provided.
- Determine the typing resolution necessary for each supported transplant service.
- Ensure typing databases are up to date and appropriate for the instrument, test and transplant service supported.
- Explain signal detection in flow cytometric fluorescent microparticle analyzers for antibody detection and oligonucleotide typing.
- Compare and contrast PCR-SSP, PCR-SSO, PCR-rSSO and Sanger sequence-based typing for histocompatibility.
- Compare and contrast complement dependent lymphocytotoxic crossmatch methods with flow cytometric methods
- Compare and contrast complement dependent lymphocytotoxic and solid phase antibody identification methods.

Competency Area: Analytic Concerns
- Select appropriate controls (positive and negative) and ensure they perform as expected for each test performed
- Evaluate test results for the presence of contamination and interfering substances and when applicable establish methods to overcome the presence of interfering substances
- Ensure appropriate validation for each test performed and each analysis software used
- Determine sensitivity, specificity and limits of detection, as appropriate, for each test performed
- Establish cutoffs for flow crossmatch and flow cytometry analysis for antibody detection and identification
- Ensure analysis is based upon current software version and/or IMGT/HLA database
- Correlate results obtained with different methodologies

Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – General
- Determine what type(s) of testing methods will be required to provide the level of support required by the clinical service(s)
- Validate and implement the testing methods within the lab section
- Communicate laboratory test capabilities and limitations to the transplant physicians and surgeons
- Establish a collaborative working relationship with the transplant team to identify and resolve clinical problems
- Determine when patients require retyping and/or additional typing
- Collect information regarding past sensitization history including donor HLA types of past transplants, whether allograft is still in situ, and patient’s current immunosuppression status.

Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – ABO Typing
- Determine what type(s) of testing methods will be required to provide the level of support required by the clinical service(s)
- Select appropriate cells, anti-sera and controls for typing
- Develop process to ensure appropriate number of typings on donor and recipient
- Validate and implement the testing methods and reagents within the lab section
- Communicate the laboratory test capabilities, limitations, and turn-around-time (e.g., significance of ABO titer in A2 to O to B solid organ transplants)
Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – HLA Typing (Low Resolution)
- Determine the appropriate sample and testing method as required by current regulations
- Select appropriate controls and ensure they perform as expected
- Understand the strengths and limitations of different methods such as serology, PCR, hybridization, etc.
- Validate and implement the testing methods and reagents
- Provide serological equivalent typing results when testing is performed by molecular method
- Provide results as per the current WHO nomenclature for HLA typing
- Develop a process to ensure timely typing of the donor and/or recipient based on clinical and regulatory requirements
- Ensure analysis is based upon current software version and/or IMGT/HLA database

Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – HLA Typing (High Resolution)
- Determine what level of testing is necessary to meet the clinical service needs
- Validate the testing methods and implement them into lab operations
- Develop quality monitors to ensure that the service needs are being met
- Communicate with the transplant physicians to ensure that they understand the capabilities and limitations of the test systems

Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – Antibody Testing
- Define appropriate pre-transplant and post-transplant frequency of antibody testing
- Understand how to establish cutoff/threshold for reporting the presence of antibodies
- Correlate antibody testing results with crossmatch results
- Communicate criteria for determination of unacceptable antigens for solid organ transplant recipients
- Determine the need for additional testing if antibody test results are not conclusive
- Define post-transplant antibody testing algorithms and clinical significance for diagnosis of antibody mediated rejection

Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – Donor Selection
- Define role of virtual crossmatching in donor selection
- Determine that crossmatch control results are appropriate and within established ranges
- Examine crossmatch event numbers, peak architecture and gates to determine if test results are valid
- Correlate crossmatch results with antibody identification results to determine if results are consistent
- Communicate with transplant team regarding test interpretation (eg, does patient have clinically significant donor specific antibody?)
- Determine need for additional testing if crossmatch results are not consistent

Competency Area: Test Interpretation – Solid Organ Transplant Compatibility – Post Transplant Monitoring and Donor Specific Antibodies
- Recommend frequency of testing to transplant team
- Define threshold for reporting the presence of a new donor specific antibody
- Determine methodologies to assess the strength of the donor specific antibody
- Correlate donor specific antibody results with clinical treatment

Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – General
- Determine what type(s) of testing methods will be required
- Validate and implement the appropriate testing methods within the lab section
- Determine which alleles are problematic and will require additional testing to discriminate
- Ensure that typing systems remain up-to-date and can discriminate all clinically significant alleles
- Inform the transplant physicians and transplant team concerning the laboratory test capabilities limitations, and ambiguities which cannot be discriminated
Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – ABO Typing
- Determine what type(s) of testing methods will be required to provide the level of support required by the clinical service(s)
- Select appropriate typing reagents
- Validate and implement the testing methods and reagents within the lab section
- Communicate the laboratory test capabilities, limitations, and turn-around time
- Generate a report that communicates the test results and their clinical significance to the patient’s physician or healthcare provider

Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – HLA Typing (Low Resolution)
- Determine the appropriate sample and testing method as required by current regulations
- Select appropriate cells and controls for typing
- Understand the strengths and limitations of different methods such as serology, PCR, hybridization, etc.
- Validate and implement the testing methods and reagents
- Understand the utility of low resolution typing for related and unrelated donor selection. Develop a process to ensure timely typing of the donor and/or recipient based on clinical and regulatory requirements
- Ensure analysis is based upon current software version and/or IMGT/HLA database

Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – HLA Typing (High Resolution)
- Determine what level of testing is necessary to meet the clinical service needs
- Validate the testing methods and implement them into lab operations
- Develop quality monitors to ensure that the service needs are being met
- Communicate with the transplant physicians to ensure that they understand the capabilities and limitations of the test systems
- Participate with clinicians in donor selection process to ensure that Histocompatibility issues have been adequately addressed
- Understand the role of KIR typing in a stem cell transplantation

Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – Antibody Testing and Donor Selection
- Determine when it is appropriate to perform antibody testing on a patient who will be receiving a stem cell transplant.
- Understand how to establish cutoff/threshold for reporting the presence of a donor specific antibody.
- Recommend donor selection based upon antibody test results
- Determine whether the level of mismatching is acceptable for the type of transplant, type of stem cell transplant

Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – KIR Testing
- Determine the appropriate sample and testing method as required by current regulations
- Select appropriate controls and ensure they perform as expected
- Understand the strengths and limitations of different methods such as PCR, sequencing, etc.
- Validate and implement the testing methods and reagents
- Understand the current nomenclature and determine appropriate testing method
- Generate a report that communicates the nomenclature used and its utility for the clinical condition it is used for
Competency Area: Test Interpretation – Stem Cell Transplant Compatibility – Post Transplant Monitoring - Chimerism Studies – General

- Understand the strengths and weaknesses of different detection methods, such as capillary electrophoresis, real time PCR, slab gel, and others
- Chose appropriate samples and, if needed, cell types for evaluation
- Select the appropriate formula for calculating the percent patient or donor cells, based on the phenotype pattern observed
- Understand the limitations of using various phenotype patterns seen in the post transplant sample for calculations of percent patient or donor cells
- Report longitudinal studies as required to assist in patient care

Competency Area: Test Interpretation - Inheritable Disease Associations with HLA Type

- Determine what diseases have significant inheritable HLA disease associations
- Determine the loci and degree of resolution to be tested for each indication
- Determine what type(s) of testing methods will be required to provide the necessary level(s) of resolution
- Explain the relative risk associated with the presence of disease-associated HLA alleles for commonly tested markers for ankylosing spondylitis, drug-associated epidermal lysis, narcolepsy and celiac disease.

Competency Area: Test Interpretation - Drug Hypersensitivity Associations with HLA Type

- Determine what drugs have significant HLA-associated adverse reactions
- Determine the loci and degree of resolution to be tested for each indication

Competency Area: Test Interpretation – Transfusion Support

- Review HLA antibody testing results in highly allo-immunized patients and identify those of greatest concerns
- Identify compatible platelet donors for platelet refractory patients
- Recognize those HLA types that are in the same cross-reactive groups
- Understand the differences, advantages, and disadvantages of selecting compatible platelet donors by HLA matching vs. avoidance of antibody specificities vs. crossmatching

Competency Area: Quality Assurance

- Understand the application of quality assurance principles to unregulated analytes such as HLA antigen typing and molecular allele identification.
- Develop appropriate monitoring needed for each testing process in your laboratory to identify errors or potential problems that could result in errors
- Develop appropriate corrective actions to address errors or potential problems that could result in errors
- Evaluate corrective actions taken and ensure their effectiveness and prevention of recurrence
- Define process(es) for identifying needs to meet client expectations which includes equipment, supplies, space, etc.
- Define and maintain a plan for equipment validation, monitoring, maintenance and repair
- Identify the parameters and processes for validation of reagent and equipment suppliers

Competency Area: Reporting and Communication

- Determine relevant components to incorporate into final report
- Effectively communicate results to clinical services in appropriate medical record system
- Explain complex results to clinical team and identify potential clinical implications for results
- Develop a reporting format that clearly communicates the testing results to the transplant team
- Generate a report that communicates the test results and their clinical significance to the patient’s physician or healthcare provider
- Communicate regarding test result interpretation and impact on compatibility to appropriate clinical team members
- Establish a collaborative working relationship with the transplant team to identify and resolve clinical problems
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Supporting Committee(s)
Histocompatibility/Identity Testing Committee
Competency: Identity and Relationship Testing

Competency Definition:
Ability to interpret a report or oversee the laboratory operation for relationship and/or identity testing, including specimen handling, testing methods, analytic concerns, test interpretation, quality assurance and reporting and communication, to ensure credible and accurate determinations of identity and biologic kinship analysis for patients, families and courts.

Competency Areas:
A. Specimen Handling
B. Testing Methods
C. Analytic Concerns
D. Test Interpretation
E. Quality Assurance
F. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling
- Specify the appropriate methods for detection of investigatory and probative evidentiary specimens of interest
- Understand how the quality of a sample may alter methods used and the interpretation and reporting of results
- Establish the appropriate procedures for initial evidence screening, prioritization, and evaluation of DNA and non-DNA forensic specimens
- Recommend choice of tissue sampling from routine, decomposing, skeletonized, and fragmented human remains for DNA testing
- Select the most informative of the available references for relationship testing or unidentified remains testing
- Specify procedures for ensuring authenticity of reference specimen donors
- Describe informed consent form elements for voluntary genetic testing to clients and reference donors
- Ensure employment of appropriate methods of collection, documentation, preservation, and packaging of evidentiary specimens, with minimal risk of contamination and with maintenance of chain-of-custody

Competency Area: Testing Methods
- Select appropriate method of DNA extraction based on the nature and quality of the sample
- Determine the need for and methods of DNA quantification
- Describe PCR amplification to clients and stakeholders, including courts, recognizing appropriate PCR thermal cycling parameters, polymerase selection criteria, and considerations for primer design
- Explain analytic methods to clients and stakeholders, including courts, STR, SNP, Y-chromosome, and mitochondrial DNA analysis

Competency Area: Analytic Concerns
- Recognize sources of PCR inhibition and recommend methods to address it
- Review electropherogram for overall quality, dye blobs, balance, and for STR stutter, drop-in, drop-out phenomena for consideration of further testing
- Evaluate and recognize sequencing artifacts (eg, c-stretch region of MtDNA)
**Competency Area: Test Interpretation**
- Explain to clients and stakeholders, including courts, the appropriate statistical interpretation of the forensic DNA identity test results, including match probability or likelihood ratio.
- Explain to clients and stakeholders, including courts, the various relationship measures, including the likelihood ratio (paternity index), combined likelihood ratio (combined paternity index), and random man not excluded (RMNE), as well as the application of Bayes' Theorem to relationship testing, including the prior probability and the posterior probability (probability of the relationship).
- Select the appropriate population database before calculating the statistics.
- Incorporate considerations for mutational events or heteroplasmy.
- Evaluate the results for detection of mixtures, such as possible contamination, blood transfusion, hematopoetic progenitor cells transplantation and chimerism, and determine an approach for deconvolution of any mixtures.

**Competency Area: Quality Assurance**
- Understand the requirements for compliance with the AABB Standards for relationship testing
- Understand the requirements for compliance with the FBI Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories
- Understand the NRC II and ISFG statistical recommendations.
- Understand the requirements for compliance with the ISO/IEC 17025 standards
- Understand the requirements for compliance with the CAP Molecular Testing standards

**Competency Area: Reporting and Communication**
- Identify the applicable legal context and framework for testimony.
- Understand the ethical and policy implications of a revealed unannounced family relationship and medical genetic findings.
- Maintain appropriate communication privacy and confidentiality.
- Incorporate all applicable elements into reports.
- Provide testimony to jurors about scientific methods, results, and interpretations.

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**Supporting Committee(s)**
Histocompatibility/Identity Testing Committee
Competency: Immunohistochemistry

Competency Definition:
Employs best practices in the use and interpretation of immunohistochemical testing in patient care; follows appropriate laboratory practices in ensuring optimal test accuracy; understands the impact of preanalytic, analytic and postanalytic variables on test results; recognizes the appropriate use of antibody panels in tumor diagnosis.

Competency Areas:
A. Quality Management
B. Specimen Handling
C. IHC Techniques
D. Interpretation
E. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Quality Management
- Implement external proficiency testing when required
- Employ appropriate methods for pathologist competency assessment
- Apply controls appropriately (eg, internal, external, reagent, and tissue)
- Distinguish between batch and on-slide controls
- Ensure that controls react as expected before issuing reports on patient specimens
- Differentiate between antibodies designated for research use only, analyte specific reagents, and reagents designated for in vitro diagnostic (IVD) use
- Comply with statutory limitations on use of reagents (including frozen aliquots)
- Maintain proper equipment operation and documentation

Competency Area: Specimen Handling
- Establish procedures to minimize cold ischemia time
- Identify the impacts of inadequate and prolonged fixation on test results
- Establish procedures to ensure appropriate fixation
- Recognize potential limitations of alternative fixatives and decalcification on IHC test results
- Recognize the potential impact of improper handling of unstained tissue sections on IHC test results
- Determine specimen adequacy for IHC testing of cytology samples
- Recognize how differences in fixation and processing methods between laboratories may affect test results

Competency Area: IHC Techniques
- Explain the basic principles of immunohistochemistry
- Recognize differences between primary antibody types (ie, mouse vs. rabbit; monoclonal vs. polyclonal)
- Recognize the utility of antigen retrieval, including heat-induced epitope retrieval or protease treatment
- Recognize differences in antigen detection systems, chromogenic reporter molecules, and potential need for blocking steps (eg, biotin-based)
- Differentiate between initial assay validation/verification and ongoing assay assessment
- Identify conditions requiring assay revalidation
- Implement a new immunohistochemistry test in your laboratory including selection of primary antibody, determination of initial antibody titer and test characteristics (eg, antigen retrieval, antibody dilution, incubation time and temperature), assay validation/verification, and ongoing monitoring of performance
- Differentiate between diagnostic and predictive immunohistochemistry tests and their clinical implications
- Recognize the importance of positive and negative internal controls when selecting blocks for analysis
Competency Area: Interpretation

- Interpret lineage marker results in the context of histologic and clinical evaluation
- Identify appropriate antibody panels that are effective in distinguishing cell types (e.g., adenocarcinoma vs mesothelioma; squamous carcinoma vs adenocarcinoma; carcinoma of unknown origin)
- Determine the significance of immunolocalization (nuclear, cytoplasmic, or membranous staining) when interpreting IHC stains
- Recognize common artifacts including endogenous pigment (hemosiderin, melanin, biotin), edge effect, necrosis, etc.
- Use appropriate scoring criteria for predictive markers
- Determine when to reject or repeat a test
- Identify common technical causes of staining problems, such as high background, uneven/weak staining, unexpected negative, failure of positive controls, or unexpected (false) positive staining
- Explain the potential role of quantitative image analysis in improving interpretation consistency

Competency Area: Reporting and Communication

- Generate clear and complete reports that effectively communicate test results and diagnostic implications
- Integrate IHC test results with the overall diagnostic assessment and other ancillary studies as appropriate
- Ensure that reports clearly communicate the clinical significance of IHC staining results when lack of (or negative reactivity) denotes an abnormal result
- Include all required information in predictive factor test reports
- Recognize when to incorporate the analyte specific reagents (ASR) disclaimer in reports

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Supporting Committee(s) N/A
Competency: Immunology (To Be Developed)
Competency: Infectious Disease Pathology

Competency Definition:
Employs best practices in performing and interpreting infectious disease testing and the diagnosis of infectious disorders; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating the morphologic and ancillary testing findings with the patient’s clinical picture; understanding how specific diagnoses affect treatment; and accurate reporting and communications to ensure accurate and comprehensive diagnoses and optimal patient care.

Sub-competencies:
1. Bacterial Infection
2. Fungal Infection
3. General Approach to Diagnosis
4. Mycobacterial Infection
5. Parasitic Infection
6. Viral Infection

Sub-competency: Bacterial Infection

Sub-competency Definition:
Applies best practices in procedures and clinical indications for diagnosis of bacterial infection by biopsy or cytology, integrating the morphologic interpretation of a specimen with the clinical history, laboratory values and specialized ancillary testing results.

Competency Areas:
A. Disease Types
B. Pathologic Features
C. Ancillary Studies
D. Reporting & Communication
E. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Interpret the clinical significance of bacterial infections in specific anatomic sites
- Address the limitations of histology and cytology in diagnosis of bacterial infection under certain clinical circumstances
- Identify inflammatory changes associated with bacterial infections
- Recognize non-infectious reactive and inflammatory conditions that resemble bacterial infection
- Distinguish between normal bacterial flora and bacterial infection

Competency Area: Pathologic Features
- Recommend appropriate collection and handling of additional specimens for further studies such as molecular testing and aerobic and anaerobic bacterial cultures
- Recognize what special histochemical stains are possible or available and select the correct stain for screening tissue sections (e.g., tissue Gram stain, Gomori methenamine silver for filamentous bacteria, other silver stains such as Steiner and warthin-starry, Fite stain for Rhodococcus)
- Interpret findings on special histochemical stains including bacterial that are morphologically altered by treatment or immune response
- Assess positive control slides accurately
Competency Area: Ancillary Studies
- Recognize when immunohistochemical stains and ancillary studies are indicated
- Identify reference laboratory and public health resources available for testing beyond local laboratory capacity

Competency Area: Reporting and Communication
- Identify mycobacterial infection reporting requirements for public health agencies and hospital infection control as appropriate
- Review clinical history (such as immune status and exposure history) and pertinent laboratory testing (such as serology and cultures), and integrate this information with the morphologic assessment
- Report critical bacterial infections promptly, especially if not clinically suspected
- Communicate with clinicians the implications of the findings

Competency Area: Treatment Implications
- Distinguish between colonization, normal flora and infection
- Address the limitations of bacterial culture methods
- Ensure that clinicians receive adequate information for treatment decisions

**Competency: Infectious Disease Pathology**
**Sub-competency: Fungal Infection**

**Sub-competency Definition:**
Sub- Applies best practices and procedures for diagnosis of fungal infection by histopathology or cytopathology, integrating morphologic interpretation with clinical history and ancillary test results.

**Competency Areas:**
A. Disease Types
B. Pathologic Features
C. Ancillary Studies
D. Reporting & Communication
E. Treatment Implications

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Disease Types**
- List common and uncommon etiologic agents of fungal infection that may be found in different anatomic locations and specimen types
- Correlate list of potential fungal agents with patient exposure history, immune status and clinical symptoms
- Address the limitations of histology and cytology in diagnosis of fungal infection under certain clinical circumstances

**Competency Area: Pathologic Features**
- Identify the best specimen type for diagnosis of specific fungal infections
- Recognize inflammatory changes associated with specific fungal infections
- Recognize diagnostic features of fungal elements (eg, hyphae, pseudohyphae, yeasts) on routine histology and cytology preparations
- Distinguish fungal mimics such as foreign bodies and natural phenomenon (eg, Hamazaki-Wesenberg bodies) from true fungal forms
- Recognize when special histochemical stains are indicated, which should be performed (eg, Gomori methenamine silver, Warthin Starry, mucicarmine, alcian blue, congo red) and how to use them to screen tissue sections
- Interpret histochemical stains in the context of positive and negative controls
- Identify fungal morphologic changes associated with treatment or immune response


**Competency Area: Ancillary Studies**
- Recognize when immunohistochemical stains, culture, in situ hybridization, and/or other molecular studies are indicated
- Recommend appropriate collection and handling of additional specimens for ancillary studies such as molecular testing and fungal culture
- Interpret results of ancillary studies including positive and negative controls in context of the pathologic features
- Identify reference laboratory and public health resources for diagnosis of fungal infections when required tests are not performed in-house

**Competency Area: Reporting and Communication**
- Review medical records for relevant clinical history (e.g., immune status and exposure history) and laboratory testing (e.g., serologic testing), and integrate this information with the morphologic assessment
- List fungal infections which may be immediately life threatening (e.g., mucormycosis) and report results promptly to the clinical team
- Identify reporting requirements for reporting fungal infections to public health agencies

**Competency Area: Treatment Implications**
- Distinguish between latent and active fungal infection
- Recognize the limitations of laboratory tests for diagnosis of fungal infections
- Provide clinicians with adequate information for making treatment decisions

**Competency: Infectious Disease Pathology**

**Sub-competency: General Approach to Diagnosis**

**Sub-competency Definition:**
Applies best practices and procedures to prepare fresh tissue and body fluids (cytopathology) in order to optimize the histopathologic interpretation and diagnosis of infectious diseases including bacterial, viral, fungal, mycobacterial and parasites in frozen sections, permanent sections and cytologic preparations. Integrates the use of basic and ancillary tissue studies, tissue stains, clinical history, results of cultures, serology and molecular testing, if available and, if not, facilitates obtaining the clinical material necessary to obtain such results through consultation with clinical healthcare providers. Communicates diagnoses and recommends further actions (such as local health department reporting, treatment or referral to Infectious Disease specialist). Provides written reports to treating clinicians and public health department when requested.

**Competency Areas:**
A. Gross Specimen Handling
B. Microscopic Appearance
C. Stains for Microorganisms
D. Non-Infectious Artifacts
E. Ancillary Studies
F. Reporting and Communication
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Gross Specimen Handling

- When frozen sections are requested, obtain patient history and include infection in differential diagnosis, if suspected
- Develop a standard operating procedure (SOP) for specimen submission requirements and for maintaining sterility of tissue and fluids
- When infection is suspected, adhere to specimen handling SOPs to maintain sterility of tissue and fluids
- Identify adequate facilities to maintain a sterile environment in the grossing room to allow for sterile collection of tissue
- Recognize gross pathologic changes suggestive of infection in tissue and fluids
- Indicate how much tissue and/or fluid is required to make an accurate diagnosis of infectious disease
- Provide assistance to grossing room staff in selection and submission of appropriate and adequate portions of tissue and fluid specimens for analysis
- Recognize when to consult with clinical physician and other health care providers and what recommendations to make for types of cultures and/or ancillary studies such as special stains and NAAT molecular tests based on clinical history, signs and symptoms presented to you by clinician caring for the patient
- Develop a personal protective equipment (PPE) SOP for all grossing room, autopsy and histology staff covering where, when and how to employ appropriate biosafety precautions based on type of infectious disease suspected
- Direct grossing room staff to use appropriate PPE when indicated by risk assessment based on clinical history, type of specimen and procedure to be performed (eg, Autopsy, frozen section, gross examination etc.)

Competency Area: Microscopic Appearance

- Recognize when infectious disease may be in the differential diagnosis and obtain appropriate stains and ancillary studies to establish the diagnosis
- Select the most appropriate stains and staining methods available based on patient history and most likely diagnosis, availability, sensitivity and specificity
- Recognize non-infectious artifacts of tissues, fixation and staining
- Select the most appropriate use of tissue controls for staining
- Choose the appropriate magnifications to examine histologic preparations based on knowledge of etiologic agent suspected, stain employed and morphologic background

Competency Area: Stains for Microorganisms

- Choose basic histologic stains as appropriate for initial diagnosis
- Understand function of and use special stains specific for organisms suspected in the context of morphologic appearance and pattern
- Recognize differences in sensitivity and specificity for different stains and apply that knowledge to accurately determine in order to accurately identify number of sections and/or fields to examine, and at what powers of magnification to use, and whether the need for additional or different stains are needed
- Interpret histologic stains in the context of adequate and appropriate positive and negative control stains
- Review positive and negative control slides and be able to recognize and solve problems with "out of control" stains such as "false positive" negative control slides due to contamination with bacteria or mycobacteria in tap water or other problems
- Demonstrate knowledge of the wide variety of special stains available for the different organisms, understand the "pros and cons" of each stain and the context in which to use it
Competency Area: Non-Infectious Artifacts
- Recognize the morphologic appearance of bacterial, mycobacterial and fungal contamination of tissue sections, stains or fluids
- Identify and distinguish between foreign material/bodies (e.g., Liesegang rings, Hamazaki-Wesenberg bodies, Makalils Guttman-Michaelis Gutmann bodies) and true infectious agents
- Distinguish between the presence of normal bacterial or fungal colonization and true infection

Competency Area: Ancillary Studies
- Recognize the differences between immunohistochemical stains, culture, in situ hybridization, and other molecular studies and when such tests are indicated for identifying different classes (e.g., virus, bacterial, fungal, parasite) of infectious organisms
- Recommend appropriate specimen collection requirements and handling techniques of additional specimens for ancillary studies
- Interpret results of ancillary studies including positive and negative controls within the context of the pathologic features
- Identify reference laboratory and public health resources available for tests not performed in the laboratory of specimen origin

Competency Area: Reporting and Communication
- Define critical findings for reporting the results of infectious disease pathology
- Recognize when additional patient history is needed to supplement diagnosis
- Know when to notify hospital infection prevention team, local and state departments of health of a diagnosis or suspected diagnosis of infectious disease in your state or country
- Recommend additional testing to the clinician as necessary to support and/or confirm histologic diagnosis

Competency: Infectious Disease Pathology
Sub-competency: Mycobacterial Infection

Sub-competency Definition:
Applies best practices and procedures for diagnosis of mycobacterial infection by histopathology and/or cytopathology. Integrates morphologic interpretation with the clinical history and ancillary test results in a written laboratory report. Provides clinical consultation as needed to ensure optimal treatment for the patient.

Competency Areas:
A. Disease Types
B. Pathologic Features
C. Ancillary Studies
D. Reporting & Communication
E. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- List the varied clinical presentations of different types of mycobacterial infections (e.g., M. leprae, M. tuberculosis, rapidly growing mycobacteria and others) and how this affects the histologic patterns seen in tissue
- Understand the limitations of histology and cytology in the diagnosis of mycobacterial infection
- Recognize the gross pathologic features suspicious for mycobacterial infection in the surgical pathology/autopsy suite ensure appropriate protective biosafety measures are implemented
Competency Area: Pathologic Features
- Recognize the different histologic patterns of infection associated with mycobacterial infection
- Identify gross pathologic features associated with mycobacterial infection
- Select the appropriate specimen types for optimal tissue diagnosis of mycobacterial infection
- Select best portions of tissue specimens for histopathology, stains and culture in order to optimize diagnostic sensitivity
- Recognize which special histochemical stains are indicated (e.g., fluorescent, Fite’s stain, Ziehl-Neelsen acid fast stain) and how to use them to screen tissue sections
- Interpret histochemical stains in the context of positive and negative controls

Competency Area: Ancillary Studies
- Recognize when additional stains, culture, in situ hybridization, or other molecular studies and other ancillary studies are indicated
- Recommend appropriate collection and handling of additional specimens for ancillary studies such as molecular testing and culture based on type of mycobacterial infections suspected
- Identify reference and public health laboratory resources available for testing beyond local laboratory capacity for diagnostic testing when needed

Competency Area: Reporting and Communication
- Review medical records for relevant clinical history, discuss case with clinicians caring for the patient and integrate this information with the morphologic assessment and ancillary studies
- Report legally required mycobacterial infections to public health agencies and to hospital infection control as appropriate

Competency Area: Treatment Implications
- Distinguish between latent and active mycobacterial infections
- Recognize limitations of laboratory tests for diagnosis of mycobacterial diseases
- Communicate adequate information for treatment decisions

Competency: Infectious Disease Pathology
Sub-competency: Parasitic Infection

Sub-competency Definition:
Applies best practices and procedures for diagnosis of parasitic infection by histopathology or cytopathology, integrating morphologic interpretation with clinical history and ancillary test results.

Competency Areas:
A. Disease Types
B. Pathologic Features
C. Ancillary Studies
D. Reporting & Communication
E. Treatment Implications

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- List common and uncommon etiologic agents of parasitic infection that may be found in different anatomic locations and specimen types
- Correlate list of potential parasitic agents with patient exposure history, immune status and clinical symptoms
- Address the limitations of histology and cytology in diagnosis of parasitic infection under certain clinical circumstances
Competency Area: Pathologic Features

- Identify the best specimen type for diagnosis of specific parasitic infections
- Recognize inflammatory changes associated with parasitic infections
- Recognize diagnostic features of adult and larval parasites and parasite ova on routine histology and cytology preparations
- Distinguish parasite mimics such as foreign bodies and natural phenomenon (e.g., Liesegang rings) from true parasites
- Recognize when special histochemical stains are indicated, which should be performed (e.g., Periodic acid-Schiff and acid fast stains for microsporidia) and how to use them to screen tissue sections
- Interpret histochemical stains in the context of positive and negative controls
- Identify parasite morphologic changes associated with treatment or immune response

Competency Area: Ancillary Studies

- Recognize when immunohistochemical stains, culture, molecular studies such as in situ hybridization, or other ancillary studies are indicated
- Recommend appropriate collection and handling of additional specimens for ancillary studies such as molecular testing and culture (e.g., Leishmania spp., free-living amebae) and molecular testing
- Interpret results of ancillary studies including positive and negative controls in context of the pathologic features
- Identify reference laboratory and public health resources available for testing beyond local laboratory capacity for diagnosis of parasitic infections

Competency Area: Reporting and Communication

- Review medical records for relevant clinical history (e.g., immune status and exposure history) and laboratory testing (e.g., serologic testing), and integrate this information with the morphologic assessment
- List parasitic infections which may be immediately life threatening (e.g., disseminated strongyloidiasis, amebic encephalitis, falciparum malaria) and report results promptly to the clinical team
- Identify reporting requirements for reporting required parasitic infections to public health agencies

Competency Area: Treatment Implications

- Distinguish between latent and active parasitic infection
- Recognize the limitations of laboratory tests for diagnosis of parasitic diseases
- Provide clinicians with adequate information for making treatment decisions

Competency: Infectious Disease Pathology
Sub-competency: Viral Infection

Sub-competency Definition:
Applies best practices in procedures and clinical indications for diagnosis of viral infection by biopsy or cytology, integrating the morphologic interpretation of a specimen with the clinical history, laboratory values and specialized ancillary testing results.

Competency Areas:
A. Disease Types
B. Pathologic Features
C. Ancillary Studies
D. Reporting & Communication
E. Treatment Implications
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Disease Types
- Identify inflammatory changes associated with viral infections
- Detect diagnostic viral cytopathic changes in tissue sections stained with hematoxylin and eosin-stained cytology preparations
- Recognize reactive and neoplastic cytologic changes that resemble viral infection
- Specify viral infections that are associated with, or predispose to, neoplastic disease
- Address the limitations of histology and cytology in diagnosis of viral infection under certain clinical circumstances

Competency Area: Pathologic Features
- Choose the best specimen type for diagnosis of particular viral infections
- Recommend appropriate collection and handling of additional specimens for further studies such as molecular testing and viral cultures

Competency Area: Ancillary Studies
- Recognize when immunohistochemical stains, in situ hybridization or other ancillary studies are indicated
- Identify reference laboratory and public health resources available for testing beyond local laboratory capacity

Competency Area: Reporting and Communication
- Review clinical history (such as immune status and exposure and travel history) and pertinent laboratory testing (such as serology and cultures)
- Integrate clinical history and laboratory test results with the morphologic assessment
- Report critical viral infections findings promptly, especially if not clinically suspected
- Communicate with clinicians the implications of the findings
- Recommend further testing when necessary
- Report viral infections associated with, or predisposing to, neoplastic disease
- Identify reporting requirements for reporting viral infections to public health agencies

Competency Area: Treatment Implications
- Provide adequate information to clinicians for making treatment decisions
- Address the limitations of viral culture methods

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Supporting Committee(s) N/A
Competency: Laboratory Medical Direction

Competency Definition:
Ensuring successful accreditation, regulatory compliance, quality management, and implementation of tests and equipment in the laboratory; effectively managing the laboratory’s resources, operations and research activities, and planning, leading, and controlling the laboratory to provide integrated patient information and consultation to laboratory stakeholders (eg, ordering providers, patients, hospital administrators, etc.). NOTE: Please see the Leadership competency and the Practice Finance competency for additional knowledge and skills related to Laboratory Medical Direction.

Competency Areas:
A. Inspection and Accreditation Process
B. Compliance and Regulatory Process
C. Implementation of Laboratory Tests and Equipment
D. Quality Management
E. Laboratory Risk Management
F. Laboratory Operations and Resourcing
G. Information Management and Consultation
H. Personnel Management
I. Financial Administration and Management
J. Research and Development

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Inspection and Accreditation Process
- Ensure the laboratory is compliant with CLIA Lab Requirements
- Lead the process of obtaining and maintaining laboratory accreditation
- Train and prepare staff for hosting and conducting successful laboratory inspections
- Use the inspection and accreditation process for continuous improvement in patient care

Competency Area: Compliance and Regulatory Oversight
- Identify federal and state compliance and regulatory issues that impact the lab
- Establish and maintain a laboratory compliance program as specified by the Office of Inspector General
- Ensure consistent and correct CPT coding in the laboratory and recognize implications of incorrect coding
- Establish and document policies and procedures for communicating lab results in accordance with existing regulations, including untoward events and critical values
- Develop and document the delegation of responsibilities to qualified personnel and monitor their performance

Competency Area: Implementation of Laboratory Tests and Equipment
- Identify and evaluate clinical need for new laboratory tests and equipment
- Evaluate and select optimal tests and equipment for the laboratory’s patient care environment (eg, financially viable, in alignment with staff competencies, consistent with turn-around-time requirements, etc.)
- Assess the precision and performance of new laboratory equipment and tests
- Establish policies and procedures for implementing (eg, validating, verifying, etc.) new tests in compliance with applicable regulations in the context of quality patient care
- Understand regulations applying to laboratory developed tests and how to implement laboratory developed tests
- Develop and utilize a working manual (SOPs) that accurately reflects practices in the laboratory
Competency Area: Quality Management
- Develop, implement, and maintain an effective quality management program that continuously improves patient care
- Determine the root cause(s) of a quality problem or issue
- Establish quality control parameters for the laboratory
- Ensure proficiency testing specimens are handled appropriately
- Act on proficiency survey results
- Work effectively with institutional partners (eg, Quality Personnel, Legal Department, Risk Management) on quality initiatives
- Establish a standard and culture of quality in the lab through leading by example

Competency Area: Laboratory Risk Management
- Identify types of risks and risk factors faced by the laboratory (eg, patient safety, employee safety, PT referral)
- Conduct a risk assessment, in conjunction with facility administration, for areas of your responsibility including risks that may affect or be affected by others outside of the laboratory (eg, external clients, organizations, facilities, community)
- Monitor areas of the lab that may be prone to high risk situations
- Design and implement risk mitigation strategies for high risk areas
- Create a safe laboratory environment that is regulatory and legally compliant (eg, OSHA, chemical hazards, MSDS, radiation safety, biological hazards)
- Report and effectively manage an incident (eg, performance improvement events, lab mistakes, deviant results etc.) in accordance with regulatory and legal requirements
- Know the laboratory and institution(s) disaster plan and your role in the plan, including planning for downtime (eg, instrument, electrical, technology) and temporary fluctuations in patient volume

Competency Area: Laboratory Operations and Resourcing
- Understand how productivity and efficiency are measured (eg, ongoing activities, reports, communications) in the lab
- Understand clinical integration, implications of turn-around-times and outcome measurement
- Plan for a sufficient number of qualified laboratory staff members with the right training and experience to be available for proper functioning of the laboratory (eg, staffing models)
- Define criteria for choosing an appropriate venue (point of care, main laboratory, reference laboratory) of testing to meet a specific need based on patient requirements and cost
- Understand how to evaluate, select, and periodically review reference laboratories
- Manage direct laboratory and medical expenses (eg, send out test costs, blood products)
- Optimize testing system logistics for quality patient care (eg, pre-analytic, analytic and post-analytic components)
- Implement a document control system and use it to ensure that manuals reflect current practices and are utilized in the laboratory

Competency Area: Information Management and Consultation
- Describe the basic information flow (manual and electronic) for the initiation and receipt of test orders
- Recognize important elements in the distribution and presentation of test results (formatting, readability, context information, and how results present in end-user reports)
- Provide clinically useful information to key stakeholders (eg, ordering providers, patients, hospital administrators) regarding assay performance, applicability, relevance, and technology
- Create a system for objectively evaluating the clinical utility of test requests
- Communicate and consult on the medical significance of laboratory data
Competency Area: Personnel Management

- Develop superior staff through the creation of effective hiring, compensation, benefits, evaluation, and succession planning practices
- Understand how to participate in the hiring process in accordance with current legal statutes (e.g., what can/cannot be asked in an interview)
- Remediate poor performance by lab personnel using appropriate HR procedures (e.g., proper escalation and documentation)
- Understand CLIA, state, The Joint Commission and local regulations and licensing as they apply to assessing qualifications of personnel
- Evaluate the competency of staff, plan for staff education/training, and create related documentation
- Apply current policies associated with HIPAA, ADA, FMLA, CMS, HITECH, Workers Compensation, OSHA, EPA and other relevant regulatory and standards organizations to the development of employee policies
- Communicate and exhibit behaviors that support organizational and legal policies (e.g., sexual harassment issues) and discourage egregious behaviors
- Obtain and maintain medical staff privileges (FPPE/OPPE documentation)
- Describe the credentialing process and how it applies to the laboratory and pathologists

Competency Area: Financial Administration and Management

- Describe the cost structure of laboratory operation (e.g., fixed and variable costs, overhead concepts etc.)
- Establish and monitor financial dashboard metrics (e.g., revenue per requisition and FTE, revenue-expense margin)
- Evaluate resource allocation versus patient outcome

Competency Area: Research and Development

- Define the lab’s interest in and capability of participating in research and development
- Identify opportunities for research and development
- Plan and implement research and development activities in the lab
- Obtain proper approval for clinical research studies (e.g., IRB, CITI)
- Comply with regulations for conducting research (consent forms etc.)
- Work with other departments on research and development activities
Competency: Microbiology (To Be Developed)
Competency: Molecular Genetics

Competency Definition:
Employing best practices in the selection and utilization of molecular genetics assays and the appropriate interpretation and reporting of assay results in the context of optimized patient care.

Sub-competency:
1. Molecular Genetics-Techniques for Extracted Materials Like DNA

Sub-competency: Molecular Genetics-Techniques for Extracted Materials Like DNA

Sub-competency Definition:
Understanding the principles underlying analytical techniques utilized in molecular genetics assays; maintaining an up-to-date knowledge of specimen requirements, specific assay limitations, and the impact of these factors on the interpretation of assay results.

Competency Areas:
A. Nucleic Acid Hybridization
B. Amplification of Nucleic Acids Using the Polymerase Chain Reaction
C. Mutation Detection Technologies
D. Interpretation of Sequence Variants
E. Real Time PCR
F. Reverse Transcription PCR (RT-PCR)
G. Array CGH (aCGH)

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Nucleic Acid Hybridization
- Discuss the roles of base pairing and hydrophobic base shielding in the formation of a duplex (double stranded) molecule from two single stranded nucleic acid molecules
- Explain the role of complementary base pair association in determining the specificity of nucleic acid hybridizations
- Understand the concept of melting temperature as it applies to nucleic acid hybridizations
- Identify environmental conditions which can affect the strength and specificity of nucleic acid hybridizations as well as the melting temperature of the hybridized product

Competency Area: Amplification of Nucleic Acids Using the Polymerase Chain Reaction
- Describe the three basic steps involved in a typical nucleic acid amplification carried out using the polymerase chain reaction
- List the basic components (reagents) used in a polymerase chain reaction and identify those which have a significant effect on the target specificity of the amplification
- Compare and contrast the appropriateness and potential limitations of each of the following sample types for analysis by polymerase chain reaction: 1) blood specimen with EDTA anticoagulant, 2) heparinized blood specimen, 3) fresh or frozen tissue sample, 4) formalin fixed paraffin embedded tissue sample.
- Identify the most common inhibitors of the polymerase chain reaction encountered in a clinical laboratory setting
- Explain the purpose of physically separating pre-amplification and post-amplification areas of laboratories which perform testing using the polymerase chain reaction
- Understand the fundamental difference between target amplification (e.g., the polymerase chain reaction) and signal amplification techniques for nucleic acid analyses
Competency Area: Mutation Detection Technologies

- Describe the technique of allele specific polymerase chain reaction and explain the difference between this and a standard, non-allele specific polymerase chain reaction
- Understand the basic biochemical processes underlying the Sanger method of DNA sequencing
- Describe the limitations of Sanger sequencing for the detection of whole exon deletions and duplications
- Describe the process of pyrosequencing and contrast this with the Sanger sequencing method in terms of the length of DNA sequence read in a single assay and the analytical detection limit for mutations or polymorphisms
- Explain why there may be a different analytical level of detection required for the evaluation of somatic mutations in tumor tissue identified in a biopsy specimen versus mutations in the germline sequence of an individual

Competency Area: Interpretation of Sequence Variants

- Distinguish between the terms mutation, polymorphism and sequence variant, both in terms of definitions and colloquial use
- Describe each of the following types of mutations which may occur within a gene: 1) single nucleotide substitution, 2) nucleotide deletion, and 3) nucleotide insertion
- Explain the functional effects of the following types of mutations on the protein product of a gene: 1) nonsense mutations, 2) missense mutations, and 3) frameshift mutations
- Understand the possible effects on the protein product of splice site mutations

Competency Area: Real Time PCR

- Understand the different chemistries utilized (DNA binding dyes vs. target specific probes) and the fluorescence detection technology used in real-time PCR
- Understand the distinction between the exponential and plateau phases of PCR amplification and the concept of CT (threshold cycle)
- Compare the advantages of real-time PCR over end-point PCR, especially in terms of dynamic range and precision of quantification
- Explain the importance of appropriate selection of internal controls for sample normalization
- Recognize the different applications of real-time PCR in molecular diagnostics

Competency Area: Reverse Transcription PCR (RT-PCR)

- Explain that the template used in RT-PCR (RNA) requires special handling to avoid degradation
- Describe how genomic DNA contamination of template RNA poses special problems and the means of rectifying that
- Describe the basic steps in RT-PCR (including reagents used, choice of primers and amplicon size) and understand the meaning of cDNA
- Recognize that RT-PCR is often combined with real-time quantification in molecular diagnostics

Competency Area: Array CGH (aCGH)

- Describe the basic principles of aCGH including differential labeling of normal and reference DNA and co-hybridization to the array
- Identify the relation between array resolution and the twin parameters of target clone size and clone density
- Recognize the applications of aCGH in detection of copy-number variations and loss of heterozygosity
- Understand the concept of copy number polymorphisms
- Recognize the chromosomal aberrations in which aCGH is not applicable (balanced translocations, inversions)
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Supporting Committee(s) CAP/ACMG Biochemical and Molecular Genetics Resource Committee
Competency: Molecular Oncology

Competency Definition:
Employ best practices in the selection and utilization of molecular (nucleic acid-based) tests for the optimal diagnosis and classification of malignant tumors, and for determining potential therapeutic options for specific tumors in patients.

Competency Areas:
A. Specimen Handling  
B. Patient Selection  
C. Analytic Concerns  
D. Test Prioritization  
E. Test Interpretation  
F. Reporting  
G. Quality Assurance  
H. Patient Management

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling
- Ensure effective communication between the medical or surgical oncologist, surgical pathologist and molecular pathologist to facilitate appropriate specimen collection including the types, quantities, and specimen handling requirements of samples that are needed at the time of diagnosis
- Determine the most appropriate samples for chromosomal and molecular testing
- Assess if the specimen is collected appropriately
- Ensure that the specimen is adequate in quantity and quality for the necessary histologic and molecular testing, triaging the specimen as needed to achieve those goals
- Ensure that the specimen is appropriately preserved for the anticipated testing, with appropriate documentation of specimen handling conditions
- Establish policies and procedures to ensure specimens are of sufficient quantity and appropriately fixed to permit ancillary testing

Competency Area: Patient Selection
- Identify which neoplasms can be better classified with ancillary molecular testing
- Assess the utility of molecular testing for determining treatment options for various neoplasms
- Identify additional tests to narrow the differential diagnosis or assess prognosis
- Determine whether the primary or metastatic tumor should be submitted for molecular testing
- Recognize the indications for molecular testing so that patients who can potentially benefit from them will be treated appropriately

Competency Area: Analytic Concerns
- Recognize sources of analytical error for various molecular tests
- Take steps to reduce the risk of analytical error
- Ensure that the specimen contains lesional tissue when submitting snap frozen tissue for RT-PCR analysis or fresh tissue for conventional cytogenetic analysis
- Ensure that lesional tissue is present
- Identify the lesional tissue of interest on a corresponding H & E stained slide that is adjacent to the unstained slides submitted for in situ hybridization (ISH) molecular analysis so that the appropriate area may be dissected and the appropriate cells are scored for in situ assays
- Consider the clinical and imaging studies when establishing the diagnosis for any bone or soft tissue tumor
Competency Area: Test Prioritization
- Determine the need to allocate limited tissue appropriately for immunohistochemical and molecular testing to ensure optimal specimen utilization
- Recognize the advantages and limitations of molecular testing as an adjunct to cytopathologic evaluation of cellular specimens
- Recognize the advantages and limitations of molecular approaches commonly used in the assessment of mesenchymal neoplasms i. New cytogenetic and molecular variants continue to be discovered ii. Cytogenetic variant translocations occur as the result of rearrangement of one consistent gene with differing chromosomal translocation partners
- Recognize that assays are frequently complementary and one approach may reveal the underlying abnormality when another approach has failed
- Use clinicohistopathologic impression to determine what tests should be performed
- Identify the three common genetic approaches used to identify tumor-specific abnormalities: (1) conventional cytogenetic; (2) molecular cytogenetic (in situ hybridization (ISH); (3) sequencing, and, (4) reverse transcription-polymerase chain reaction (RT-PCR) analyses

Competency Area: Test Interpretation
- Interpret all molecular diagnostic test results together with available clinical and histopathological data
- Interpret appropriate molecular test results in terms of the specific therapeutic options available for specific tumors (eg, KRAS and BRAF in colon cancer; KRAS and EGFR in NSCLC; BRAF in melanoma, etc.)
- Assess the in situ hybridization (ISH) molecular findings in light of other clinical and histopathologic features
- Recognize that molecular and cytogenetic variants may be such that designed primer sets will not be able to amplify the gene product resulting in a false-negative
- Integrate the molecular results into the anatomic pathology report

Competency Area: Reporting
- When integrating molecular results into an anatomic pathologic report, include the recommended reporting elements
- When referencing a freestanding molecular pathology report, ensure it is available to the oncologist
- Utilize the standardized mutation nomenclature and standardized gene nomenclature (HUGO) when reporting molecular results

Competency Area: Quality Assurance
- Ensure that all molecular tests have undergone adequate analytical validation
- Ensure that all molecular tests are supported by appropriate clinical validation studies and that clinical utility is defined
- Ensure that appropriate proficiency testing is in place for all molecular tests and that performance is being adequately monitored
- Establish departmental (and interdisciplinary) protocols for the utilization of molecular tests for specific tumors and patient populations
- Devise appropriate quality assurance monitors to demonstrate that protocols are being uniformly and consistently adhered to
- Communicate with the clinicians and other pathologists (eg, submitting pathologist, and molecular pathologist)
- Review report for proper use of conventions and formatting issues that are unique to molecular reports, including proper gene nomenclature
- Maintain open lines of communication with the clinicians to discuss test results and interpretation as they become available
Competency Area: Patient Management

- Recommend appropriate ancillary molecular and cytogenetic studies
- Communicate information about corresponding therapies when using molecular oncology testing as a companion diagnostic test (i.e., EGFR for erlotinib)
- Recognize the clinical utility of monitoring minimal residual disease by molecular methods

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Supporting Committee(s)

Molecular Oncology Committee
Competency: Neuropathology (To Be Developed)
Competency: Ophthalmic Pathology (To Be Developed)
Competency: Orthopedic Pathology

**Competency Definition:**
Employs best practices in performing and interpreting orthopedic pathology and the diagnosis of bone and joint disorders; these best practices include: specimen collection, handling, preparation, processing, and interpretation; integrating the morphologic, radiographic, immunophenotypic, genetic and molecular findings with the patients clinical picture; understanding how specific diagnoses affect treatment; and accurate reporting and communication to ensure accurate and comprehensive diagnoses and optimal patient care.

**Sub-competency:**
1. Metabolic Bone Diseases
2. Non-Neoplastic/Neoplastic Diseases

**Sub-competency: Metabolic Bone Diseases**

**Sub-competency Definition:**
Employs best practices and procedures to prepare bone biopsy tissue to optimize the histomorphologic interpretation and bone histomorphometry analysis for accurate diagnosis of metabolic bone disease; these best practices include: specimen collection, handling, preparation, and processing; integration of morphologic, histomorphometric, radiographic findings with the patient’s clinical picture; understanding how specific diagnoses affect treatment; and accurate communication with treating physicians to ensure optimal patient care.

**Competency Areas:**
A. Specimen Handling/Procedures
B. Testing Methods/Ancillary Studies
C. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Specimen Handling/Procedures**
- Recognize the ideal sample for evaluating metabolic bone disease: a horizontal transiliac crest core biopsy at least 5 mm in diameter, to which both cortices must be attached intact
- Recognize such biopsies require extensive processing time prior to analysis and interpretation
- Ensure that bone biopsies performed for metabolic bone disease are processed without prior decalcification
- Ensure that bone biopsies for metabolic bone disease are placed in an aqueous ethanol solution of 70% or greater if nontoxic fluorochromes are orally administered to patients prior to bone biopsy
- Recognize that the undecalcified bone biopsies require embedding in substance of similar specific hardness to bone for uniform sectioning, and should not be processed as paraffin-embedded tissues

**Competency Area: Testing Methods/Ancillary Studies**
- Recognize that bone histomorphometry is the gold standard in the evaluation and diagnosis of metabolic bone diseases
- Recognize that the first phase in the interpretation of an undecalcified bone biopsy evaluates the relationships of bone and unmineralized osteoid to one another and to the bone volume, as well as the total resorption surfaces and osteoclast number
- Recognize that the second phase is the evaluation of mineralization dynamics in order to calculate the bone formation rate and mineralization lag time
- Recognize the sensitivity and specificity of bone histomorphometry parameters are variable in diagnosing different types of metabolic bone disease
**Competency Area: Reporting and Communication**

- Utilize the standardized nomenclature, symbols, and units for bone histomorphometry analysis when writing metabolic bone disease pathology reports, as published by the American Society for Bone and Mineral Research Histomorphometry Nomenclature Committee (1987)
- Recognize the importance of clinico-radiologic-pathologic correlation in orthopedic pathology, and that the definitive diagnosis for each individual patient is to be based on morphological, clinical and metabolic parameters
- Recognize the treatment implications of the common metabolic bone diseases (eg, osteoporosis, renal osteodystrophy, primary hyperparathyroidism, osteomalacia)
- Generate reports that effectively communicate the interpretation of bone biopsy results accurately to the patient’s health care team
- Demonstrate ability to discuss the pathologic findings and patient issues with treating physicians and, if needed, expert consultants

**Competency: Orthopedic Pathology**

*Sub-competency: Non-Neoplastic/Neoplastic Diseases*

**Sub-competency Definition:**
Employs best practices in evaluating and reporting benign and malignant bone tumors, and tumor-like non-neoplastic conditions; integrates clinical, imaging, and pathologic information to establish a diagnosis that supports optimum patient management and outcome; provides up-to-date diagnostic information in multidisciplinary bone tumors management and treatment planning.

**Competency Areas:**
A. Specimen Handling/Procedures
B. Testing Methods
C. Ancillary Studies
D. Treatment Implications
E. Reporting and Communication

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Specimen Handling/Procedures**

- Integrate clinical history, laboratory findings and radiographic findings with the morphologic assessment
- Demonstrate skill in handling bone specimens for intraoperative evaluation including cytologic smears and frozen sections
- Recognize the techniques for processing and interpreting arthroplasty revision specimens including suspected septic loosening, hypersensitivity reaction and metal corrosion products
- Recognize the limitations of morphologic interpretation of bone specimens without radiographic and clinical findings especially during intraoperative evaluation
- Demonstrate skill in the techniques of proper fixation and decalcification (eg, acid or chelating agent [EDTA]) of routine bone specimens
- Recognize the morphologic artifacts induced by excess decalcification, inadequate fixation or biopsy technique of bone tissue
- Apply proper handling and sampling technique of post-chemotherapy osteosarcoma and Ewing sarcoma resection specimens
- Apply proper techniques required to handle specimens for suspected crystal-induced joint disease including direct wet-examination of synovial fluid, air dried smears, non-aqueous fixation and processing
- Recognize the indication for each type of bone procedure: CT-guided biopsy, incisional biopsy, curettage, extra-lesional excision, limb-sparing excision, amputation
Competency Area: Testing Methods
- Apply routine histochemical tests for diagnosis, prognostic and therapeutic indicators
- Apply appropriate immunohistochemistry tests for diagnosis, prognosis and targeted therapy (collect part of tumor before decalcification)
- Recognize the requirements for electron microscopic evaluation of bone tumors
- Recognize the role of the polymerase chain reaction (PCR), fluorescence in-situ hybridization (FISH) and cytogenetics to test for specific genetic aberrations in bone

Competency Area: Ancillary Studies
- Correlate the histologic findings with imaging findings to determine size and local behavior of the bone tumor
- Recognize the limitations of ancillary studies on small biopsies
- Recognize the effects of decalcification of tissue on ancillary studies
- Recognize the limitations of special histochemical stains and immunohistochemical stains when evaluating bone tumors
- Choose appropriate ancillary studies (histochemistry, immunohistochemistry, molecular genetics, chromosomal analysis, electron microscopy) for the differential diagnosis
- Describe the molecular genetics of distinct bone tumors and familial bone syndromes
- Incorporate molecular pathology results into final diagnoses of bone neoplasms

Competency Area: Treatment Implications
- Recognize the implications of intraoperative diagnosis on medical and surgical management
- Communicate adequate information for treatment decisions in bone and joint disease
- Identify critical pathology results necessitating immediate contact with the clinicians (eg, unexpected malignancy, fungal or acid-fast organisms) and document such contact
- Explain the major treatment options for bone and joint tumors (curettage, en-bloc resection, amputation) and how pathologic factors affect treatment decisions
- Recognize the diagnostic entities that are routinely treated with neoadjuvant chemotherapy
- Recognize the significance of treatment effect (eg, prior surgery, chemotherapy) in tumors
- Explain the significance of tumor grade and stage on prognosis, and on medical or surgical treatment
- Recognize the role for molecular or genetic testing of tumors that affect treatment (eg, for enrolment in clinical trials)
- Recognize the treatment implications of the common skeletal syndromes (eg, Ollier disease, Maffucci syndrome, multiple osteochondroma syndrome)
- Recognize the implication of infected orthopedic hardware on patient management and outcome
- Explain the importance of margin status on subsequent treatment
- Recognize the importance of radiographic-pathologic correlation in orthopedic pathology and the implications on diagnosis and treatment when correlation is not possible

Competency Area: Reporting and Communication
- Communicate critical pathology results necessitating immediate contact with the clinicians (eg, unexpected malignancy, fungal or acid fast organisms)
- Ensure that intraoperative pathology results are communicated to the surgeon accurately
- Generate clear, concise and accurate reports that effectively communicate pathology results to the patient’s health care team
- Use consistent terminology for neoplastic (WHO) and non-neoplastic conditions in pathology reports
- Employ CAP synoptic guidelines for malignancies
- Employ standard grading schemes for malignant neoplasms
- Use standard staging procedures (AJCC and Musculoskeletal Tumor Society) for skeletal tumors
- Demonstrate willingness and ability to discuss results and patient issues with clinicians, radiologists, multidisciplinary health care teams and, if needed, expert consultants and patients
- Communicate to clinical team if a delay in diagnosis is expected and document the communication
Competency: Pediatric Pathology

Competency Definition:
Employs best practices integrating anatomic and clinical pathology as applied to diseases and injuries of children, neonates, fetuses and the placenta; these best practices include appropriate specimen collection and handling, accurate gross and microscopic interpretation of findings, precise reporting of results with correlation to appropriate reference databases and communication with clinical colleagues in pediatrics, neonatology, maternal-fetal medicine and genetics. Knowledge of common developmental abnormalities and the unique aspects of pediatric/perinatal diseases help maximize quality patient care.

Sub-competency:
1. Perinatal Pathology
2. Placental Pathology
3. Gastrointestinal
4. Liver Pathology
5. Pulmonary Pathology

Sub-competency: Perinatal Pathology

Sub-competency Definition:
Correlates obstetric clinical history with findings on therapeutic, spontaneous, and missed abortion specimens and ectopic pregnancy specimens. Utilizes knowledge of normal placental and fetal development in each of the three trimesters and specific disease entities that disrupt normal development throughout pregnancy. Understands the causes of fetal demise in utero to allow for appropriate targeted studies at the time of perinatal autopsy. Recognizes the pathology in a newborn infant that occurs during birth, consequent to physiologic immaturity of major organ systems or as complication of antenatal care. Identifies molar pregnancies, ectopic pregnancies, and the presence of an intrauterine pregnancy given minimal tissue. Communicates with clinicians about abnormal results if needed for appropriate clinical follow-up.

Competency Areas:
A. Specimen Handling (include stillbirths)
B. Ancillary Studies (include skeletal dysplasias, metabolic disease, stillbirths)
C. Reporting and Communication
D. Complications of Prematurity (include NEC, BPD, and IVH)
E. Chromosomal Abnormalities (include common aneuploidies)
F. Infectious and Inflammatory Conditions (include stillbirths)
G. Developmental Defects (include multiples, stillbirths)

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling (include stillbirths)
- Confirm identity of the infant utilizing autopsy consent form and body identification tags/bands
- Determine autopsy consent restrictions as recorded on the consent form and adhere to those restrictions or if the scope of the permission is uncertain obtain clarification from the responsible clinician
- Review appropriate clinical charts prior to performing an autopsy
- Perform routine specimen radiographs as clinically appropriate
- Photograph autopsy specimens adequately to document the external, internal and radiographic findings
- Perform internal examination utilizing standard dissection techniques and a systematic format
- Record relevant weights and measurements using a standard reference table of normal ranges
- Examine the brain, meninges and pituitary if included in autopsy consent
- Fix brain prior to cutting and sampling if allowed by autopsy consent
- Select appropriate tissue samples from major organs for microscopy and stock storage
Competency Area: Ancillary Studies (include skeletal dysplasias, metabolic disease, stillbirths)

- Specify optimal sampling sites and tissue handling requirements for cytogenetic testing
- Describe the importance of autopsy radiologic evaluation of fetuses and neonates with known or suspected skeletal dysplasias, growth anomalies or congenital anomalies
- Determine when to request a Kleihauer-Betke test or equivalent to look for fetal maternal hemorrhage in cases of stillbirth or unexplained neonatal death with neonatal anemia
- Communicate to clinicians the importance of thorough placental examination in cases of unexplained stillbirth or perinatal death
- Determine when it is appropriate to perform a metabolic autopsy including the timing and handling of required tissue samples
- Determine ancillary tissue sampling appropriate for autopsy investigation of neonatal hydrops fetalis
- Select appropriate samples for microbiologic studies for evaluation of possible intrauterine or perinatal infection

Competency Area: Reporting and Communication

- Prepare a well organized, thorough provisional autopsy report within 2 working days including at least principal findings
- Perform appropriate literature searches to support pathologic findings with citation of references in the autopsy report as appropriate
- Communicate results to clinicians and quality assurance committees and families, as appropriate
- Communicate discrepancies between prenatal/premortem diagnoses and autopsy findings to relevant clinicians
- Generate a clear, concise final autopsy report that integrates clinical history, gross and microscopic findings, placental review, ancillary testing and clinicopathologic correlations

Competency Area: Complications of Prematurity (include NEC, BPD, and IVH)

- Identify the major organ systems that are affected by prematurity
- Identify the gross and histologic features of the bowel in necrotizing enterocolitis
- Identify the gross and histologic features of bronchopulmonary dysplasia
- Distinguish the phases of lung development in order to evaluate for pulmonary hypoplasia
- Diagnose diffuse lung disease in children following current classifications where applicable
- Classify the severity of intraventricular hemorrhage and correlate with the clinical history and imaging findings

Competency Area: Chromosomal Abnormalities (include common aneuploidies)

- Select the samples in a fetal or perinatal autopsy that are most likely to promote growth in culture for a successful cytogenetic analysis
- Recognize the pertinent phenotypic features associated with the three commonest autosomal trisomies seen at autopsy (the "surviving" trisomies, 21, 18, and 13)
- Identify the pertinent phenotypic features associated with monosomy X/Turner syndrome
- Outline the major clinical and pathologic features of selected syndromes associated with partial aneuploidy
- Summarize the cytogenetics, molecular genetics, and clinical features of chromosomal instability syndromes
- Identify the pertinent clinical features, major congenital malformations and methodologies to diagnose velocardiofacial/DiGeorge syndrome and other microscopic chromosomal anomalies
- Identify the pertinent phenotypic features in the most common pediatric imprinting disorders, namely, Beckwith-Wiedemann, Prader-Willi, and Angelman syndromes
Competency Area: Infectious and Inflammatory Conditions (include stillbirths)

- Identify the major congenital immunodeficiencies that are associated with an increased risk of sepsis and their characteristic associated infectious agents to guide the microbiology diagnostic workup
- Recognize the spectrum of adverse fetal outcomes that can complicate intrauterine infections with TORCH agents according to the particular organism and the timing of the insult
- Recognize particular clinical scenarios that should initiate an infectious disease workup in a perinatal or infant autopsy
- Outline a procedure for the autopsy evaluation of stillborn fetuses, neonates, or infants with suspected infectious causes of death, incorporating appropriate ancillary studies
- Identify the major etiologic microbial agents responsible for early- and late-onset neonatal sepsis
- Identify the potential fetal and newborn complications associated with maternal Group B Streptococcus colonization/infection
- Outline the major clinical, gross pathologic, and diagnostic laboratory features in fetal and neonatal syphilis
- Define the criteria for HIV infection in infants and children

Competency Area: Developmental Defects (include multiples, stillbirths)

- Specify the process (steps) involved in the diagnostic workup of a hydropic fetus (immune and nonimmune hydrops fetalis)
- Distinguish between syndrome, sequence, malformation, deformation, using particular examples likely to be encountered in a perinatal autopsy (eg, Potter/oligohydramnios sequence vs. Meckel syndrome)
- Identify the salient features of the major teratogenic disruptions, namely, embryopathies induced by thalidomide, folic acid antagonists and derivatives, valproic acid, warfarin, isoretinoin, alcohol (fetal alcohol syndrome), and diphenylhydantoin
- Identify the major fetal anomalies associated with maternal diabetes
- Identify the spectrum of fetal defects associated with the amnion rupture disruption sequence (ADAM complex)
- Recognition of postmortem/in utero changes and distinguish them from true pathologic alterations

Competency: Pediatric Pathology
Sub-competency: Placental Pathology

Sub-competency Definition:
Incorporates obstetrical clinical history into gross and histologic examination of the placenta and early products of conception in order to optimize patient care. Examines the placental disc, umbilical cord and membranes to diagnose ascending intrauterine infection, chronic inflammatory lesions, maternal and fetal vascular lesions, defects in maturation and placentation, placental signs of intrauterine fetal distress, and effects of fetal demise in utero. Performs appropriate evaluation of products of conception after abortion, utilizing ancillary testing where appropriate, to exclude molar pregnancy, ectopic pregnancy or confirm the presence of gestation in questionable cases.

Competency Areas:
A. Specimen Handling
B. Ancillary Studies
C. Reporting and Communication
D. Disorders of Placental Development (include tumors)
E. Infectious and Inflammatory Conditions
F. Circulatory Disorders of Maternal and Fetal Vasculature
G. Multiples
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling
- Utilize a systematic approach in the gross examination of the placenta
- Identify lesions on the fetal and maternal surfaces and within the parenchyma
- Identify defects in membranous insertion
- Demonstrate how to examine an umbilical cord and its salient features including the site of insertion, number of vessels, length, etc
- Demonstrate appropriate sectioning techniques and tissue to submit for microscopic examination of both singleton and multiple gestation placentas
- Photograph specimens adequately to document the gross appearance and lesions of the placenta

Competency Area: Ancillary Studies
- Identify the particular indications that warrant the use of ancillary testing in the differential diagnosis of complete and partial hydatidiform moles and hydropic abortuses, in particular, ploidy analysis and immunohistochemistry analysis for p57KIP2
- Identify when and how to obtain samples for cytogenetic (chromosomal) analysis from the placenta
- Perform the procedure for obtaining samples for microbial culture from the placenta in cases of suspected amniotic fluid infection or infectious villitis
- Recognize the rationale for obtaining both embryonic (fetal) and placental tissue for cytogenetic analysis in cases of suspected confined placental mosaicism (CPM)
- Utilize appropriate immunohistochemical profiles in the differential diagnosis of diseases of extravillous trophoblast, namely, placental site nodule, exaggerated placental site, placental site trophoblastic tumor, and epithelioid trophoblastic tumor
- Identify the pathologic findings within the placenta that would lead the pathologist to suggest a thrombophilia workup to the clinician

Competency Area: Reporting and Communication
- Communicate critical pathology results in a timely fashion (eg, placentas from babies in NICU, cases of acute chorioamnionitis, infectious villitis)
- Develop a mechanism to communicate clear, accurate and complete placental pathology results and clinical implications to the newborn’s and mother’s clinical team
- Demonstrate willingness and ability to discuss current results and patient issues with clinicians, ultrasonographers, multidisciplinary health care teams and, if needed, expert consultants and patients
- Utilize a standardized placental pathology reporting format derived from published sources

Competency Area: Disorders of placental development (include tumors)
- Distinguish between circumvallate and circummarginate membrane insertion
- Recognize abnormalities of the umbilical cord including umbilical cord length, coiling index, insertion site, true and false knots, and umbilical vessel number
- Diagnose disorders of placental implantation such as placenta accreta/increta/percreta, superficial implantation and exaggerated placentation
- Diagnose abnormal villous development including distal villous hypoplasia and villous immaturity
- Identify disorders of fetal vascular development including chorangiosis, chorangioma, and chorangiomatosis
- Recognize placental changes seen in metabolic storage disease, chromosomal abnormalities, and mesenchymal dysplasia
- Diagnose placental metastases from maternal malignancies
- Recognize postmortem in utero changes in the placenta and distinguish them from true pathologic alterations
- Classify benign tumors in the placenta, including chorangioma, leiomyoma, heterotopic liver, and heterotopic adrenal
- Recognize morphologic changes in the placenta that could be associated with later development of cerebral palsy
- Distinguish between placentas with accessory lobes, multilobation and monochorionic multiple gestation
Competency Area: Infectious and Inflammatory Conditions
- Grade and stage acute chorioamnionitis
- Identify the patterns of fetal acute inflammatory response (e.g., acute funisitis and chorionic vasculitis)
- Identify the patterns of villitis caused by organisms such as Listeria, E. coli, and TORCH organisms
- Diagnose non-infectious inflammatory lesions including villitis of unknown etiology, chronic histiocytic intervillitis, lymphoplasmacytic deciduitis, and eosinophilic/T-cell chorionic vasculitis
- Inform the appropriate public health authority of placental infections due to reportable microorganisms

Competency Area: Circulatory Disorders of Maternal and Fetal Vasculature
- Specify compartments of the placenta that contain maternal versus fetal blood
- Identify histologic features of maternal decidual vasculopathy
- Identify histologic features of fetal thrombotic vasculopathy
- Correlate clinical history with signs of abnormal maternal and fetal blood flow in the placenta
- Identify gross and histologic features that correlate with clinical abruption and retained placenta
- Correlate the presence of intravillous circulating fetal normoblasts during the first, second and third trimesters with clinical relevance

Competency Area: Multiples
- Determine placentation type (chorionicity) of a multiple placenta
- Identify abnormal cord insertions
- Examine all monochorionic twin placentas for vascular anastomoses by performing a gross examination and including injection technique for demonstrating artery-to-vein (A-V) anastomoses when appropriate
- Recognize the placental changes seen in twin-twin transfusion syndrome
- Detect the placental changes seen in twin-reversed arterial perfusion (TRAP) sequence
- Identify fetal remnants in cases of intragestational loss or selective fetal reduction
- Recognize sites of prenatal laser ablation therapy

Competency: Pediatric Pathology
Sub-competency: Gastrointestinal

Sub-competency Definition:
Applies best practices in analyzing gastrointestinal specimens, integrating the gross and microscopic findings with the clinical history, laboratory values and specialized ancillary testing results to diagnose disease processes, including systemic disorders, involving the gastrointestinal tract.

Competency Areas:
A. Specimen Handling/Ancillary Studies
B. Reporting and Communication
C. Developmental Anatomy and Anomalies
D. Esophageal Disorders
E. Gastropathies
F. Enteropathies Associated with Diarrhea and Malabsorption
G. Immunodeficiencies
H. Enterocolitis/Colitis
I. Intestinal Motor Disorders
J. Polyps and Tumors
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling/Ancillary Studies

- Ensure correct specimen identity by secure patient identification, specimen labeling, completion of requisition form, etc, according to local laboratory practice
- Review clinical and radiologic information before specimen grossing for large and/or complex specimens, when appropriate
- Take photographs of non-biopsy resection specimens, when appropriate
- Evaluate adequacy and proper orientation of the histologic sections of GI specimens
- Ensure appropriate collection and handling of specimens for additional studies as needed
- Recognize the utility of frozen sections performed during surgical procedures for Hirschsprung Disease
- Utilize appropriate histochemical and immunohistochemical stains

Competency Area: Reporting and Communication

- Generate accurate, clear, and concise reports (including synoptic reports, when appropriate) that effectively communicate results and therapeutic implications to the patient’s health care team
- Integrate results of ancillary testing into the final diagnosis
- Communicate significant and unexpected findings and anticipated delays in diagnosis, and document these preliminary communications (with date, time, and the name of the person to whom findings were reported) in the final report
- Demonstrate willingness and ability to discuss results with the multidisciplinary health care team

Competency Area: Developmental Anatomy and Anomalies

- Review the major anatomic aspects of embryologic development of the gastrointestinal tract and clinically relevant molecular details involved in the pathogenesis of common congenital anomalies
- Recognize the disorders more commonly associated with specific gastrointestinal malformations (eg, stenoses, atresias)
- Recognize cystic and tubular duplications
- Describe the spectrum of omphalomesenteric remnants, including Meckel’s diverticulum
- Recognize abnormalities of gastrointestinal rotation and fixation
- Recognize common heterotopias of the GI tract
- Recognize the histopathologic features and clinical presentation of intussusception

Competency Area: Esophageal Disorders

- Recognize the clinical features and histopathologic changes in gastroesophageal reflux in children
- Relate the endoscopic and histopathologic features and the role of special stains in making the diagnosis of Barrett esophagus in children
- Identify the pathologic changes, clinical features, and commonly associated conditions of eosinophilic (allergic) esophagitis
- Specify the elements to include in a pathologic report when evaluating a case for eosinophilic esophagitis
- Contrast the pathologic changes of eosinophilic esophagitis with the changes of reflux esophagitis and recognize the challenges in discriminating the two conditions
- Distinguish between the common types of infectious esophagitis in children and relate the pathologic features and ancillary stains helpful in diagnosing them
- Recognize the most common pathologic findings in systemic diseases involving the esophagus, including inflammatory bowel disease, connective tissue diseases, and immunodeficiency

Competency Area: Gastropathies

- Recognize the endoscopic and morphologic features of Helicobacter gastritis in children and relate the most common ancillary tests for diagnosis, the post-therapy pathologic changes, and the potential complications
- Recognize the etiologies and pathologic changes of reactive and chemical gastropathies in children
- Contrast the etiologic agents, pathologic changes, and clinical outcome of Menetrier disease in children and adults
- Recognize the most common pathologic findings in systemic diseases involving the stomach in children, including inflammatory bowel disease, eosinophilic disorders, and autoimmune disorders

**Competency Area: Enteropathies Associated with Diarrhea and Malabsorption**

- Recognize the value and limitations of the intestinal biopsy in the evaluation of diarrhea and malabsorption in the pediatric age group
- Recognize the major histologic features in intestinal biopsies of disorders of epithelial differentiation such as microvillous inclusion disease, enteroendocrine cell deficiency, and tufting enteropathy
- Review the clinicopathologic features of celiac disease, including serologic diagnosis, immunologic workup, associated disorders, and differential diagnosis
- Recognize the major categories of eosinophilic GI disorders and their differential diagnoses
- Identify the characteristic histologic features of the major primary immunodeficiency disorders in intestinal biopsies
- Recognize the primary and secondary causes of intestinal lymphangiectasia
- Recognize the histologic features of common small and large bowel infectious causes of diarrhea such as giardiasis and amebiasis

**Competency Area: Immunodeficiencies**

- Review the clinicopathologic features of autoimmune enteropathy, including serologic diagnosis, immunology workup, associated systemic conditions, and histologic and immunohistochemical features
- Identify the primary immunodeficiency disorders with prominent gastrointestinal manifestations
- Recognize the clinicopathologic features of gastrointestinal manifestations of primary B-lymphocytes disorders, including X-linked agammaglobulinemia, common variable immunodeficiency, and IgA deficiency
- Recognize the clinicopathologic features of gastrointestinal manifestations of primary T-lymphocyte defects, including DiGeorge syndrome, ataxia telangiectasia, Wiskott-Aldrich syndrome, and X-linked hyper-IgM syndrome
- Review the clinicopathologic features of gastrointestinal manifestations of severe combined immunodeficiency and its variants
- Review the clinicopathologic features of gastrointestinal manifestations of chronic granulomatous disease, leukocyte adhesion deficiency, and autoimmune polyglandular syndrome
- Review the clinicopathologic features of HIV enteropathy
- Recognize the histology, ultrastructural features, microbiologic diagnosis, and molecular diagnosis of gastrointestinal infections common in immunocompromised patients, including bacteria (Mycobacterium avium complex, Mycobacterium tuberculosis, Spirochetosis), parasitic (Cryptosporidium, Isospora belli, Microsporidium, Toxoplasma), fungal, and viral infections

**Competency Area: Enterocolitis/Colitis**

- Recognize artifacts produced by bowel preparations and biopsy procedures and distinguish them from disease
- Recognize the histologic features and complications of acute appendicitis and the changes in interval appendectomy specimens
- Recognize the histologic features of infectious (self-limited) colitis and distinguish them from chronic inflammatory bowel disease
- Outline the differential diagnosis of granulomatous colitis in the pediatric age group
- Recognize the histologic features of pouchitis and diversion colitis
- Recognize the histologic features of medication-induced abnormalities
- Recognize the histologic features of vasculitides affecting the colon such as HSP (Henoch–Schönlein purpura) and HUS (hemolytic uremic syndrome)
- Recognize the histopathologic features and clinical presentation of NEC (necrotizing enterocolitis) and solitary intestinal perforation of prematurity
Competency Area: Intestinal Motor Disorders

- Define the diagnostic criteria for Hirschsprung Disease, including histopathologic criteria for biopsy adequacy
- Recognize the utility of calretinin and acetylcholinesterase stains in the diagnosis of Hirschsprung Disease
- Recognize the features of the transition zone between aganglionic and normal bowel segments and how to identify them in intraoperative frozen sections
- Recognize the histologic changes, including cellular inclusions, which are seen in cytologic enteric neuropathies
- Recognize the primary and secondary enteric myopathies that may present with intestinal pseudo-obstruction

Competency Area: Polyps and Tumors

- Recognize the clinical, gross and microscopic features of a juvenile polyp, including when and how to diagnose a juvenile polyposis syndrome
- Relate the clinical, morphologic, and genetic characteristics of major hamartomatous polyposis syndromes in children, including Peutz-Jeghers, Cowden, Bannayan-Riley-Ruvalcaba, and Proteus
- Recognize the pathologic features and significance of adenomatous polyps in the gastrointestinal tract of children
- Relate the clinical, genetic, and pathologic findings of familial adenomatous polyposis and its variants (Gardner and Turcot syndromes)
- Relate the clinical and pathologic features of inflammatory, hyperplastic, and lymphoid polyps in children
- Identify the subtypes of colorectal carcinoma seen in children and genetic syndromes associated with them
- Discriminate between the most common types of stromal tumors of the gastrointestinal tract, including their morphologic features and immunohistochemical profiles
- Recognize the histopathologic features of ganglioneuromatous polyps and associated syndromes
- Recognize the types, clinical presentation, and pathologic findings of lymphoproliferative disorders seen in the gastrointestinal tract of children
- Recognize gastrointestinal neuroendocrine tumors and their management implications in children
- Recognize common benign masses such as lymphatic malformations and vascular tumors

Competency: Pediatric Pathology

Sub-competency: Liver Pathology

Sub-competency Definition:
Employs best practices in diagnosing and reporting diseases of the pediatric liver, gallbladder, and biliary tree. These best practices apply to specimen collection, grossing, tissue processing, interpretation, and communication including: integration of morphologic findings and the results of ancillary studies, as appropriate, with available clinical and radiologic information; appreciation of the prognostic and therapeutic import of specific diagnoses; and reporting in an accurate, timely, and effective manner as a key member of the patient’s multidisciplinary health care team..

Competency Areas:
A. Specimen Handling/Ancillary Studies
B. Reporting and Communication
C. Developmental Anatomy, Histology, and Congenital Anomalies of the Liver, Gallbladder, and Extrahepatic Biliary Tree
D. Diseases of the Biliary Tree
E. Familial Hepatocellular Cholestatic Diseases
F. Hepatitis and Liver Failure
G. Metabolic Disorders
COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Specimen Handling/Ancillary Studies

- Review clinical history, family history, clinical diagnoses, results of laboratory testing and any other information provided by the clinicians to formulate a differential diagnosis
- Use the clinicopathologic differential diagnosis to guide processing of the sample and the selection of ancillary tests that will need to be performed
- Define broad diagnostic categories (cholestasis, syndromic and nonsyndromic paucity, familial cholestatic syndromes, neonatal/infantile hepatitis, acute liver failure, chronic hepatitis, metabolic disorders) and establish a diagnostic algorithm using ancillary testing (light microscopy, electron microscopy, enzyme testing, molecular testing, other) to rule in/rule out given entities
- Choose appropriate processing conditions (fixative, storage medium, storage temperature) to triage samples according to the testing algorithm suggested by the clinical presentation
- Define major patterns of injury and their findings on light microscopy, electron microscopy, enzyme testing, and molecular testing
- Formulate criteria for the selection of reference laboratories for the performance of ancillary testing of liver biopsy samples

Competency Area: Reporting and Communication

- Integrate the clinical information, histology, ultrastructure, and biochemical and molecular findings to suggest a differential diagnosis or to formulate a specific diagnosis
- Describe the clinicopathologic and ultrastructural features of entities leading to neonatal cholestasis
- Review the different grading schemes for the activity and stage of chronic hepatitis and select the appropriate scheme to report in a given clinical situation
- Use the components of NAFLD Activity Score (NAS) and Fibrosis Staging to report on the activity and stage of nonalcoholic steatohepatitis
- Integrate the clinical and epidemiologic information with the histologic and ultrastructural features, and include the results of the ancillary tests (including genetic testing) and suggestions for further testing in your reports on metabolic disorders of the liver
- Integrate the clinicopathologic features of acute liver failure and include a differential diagnosis, prognosis and recommendation for further testing of the patient and/or family (if appropriate) in your reports

Competency Area: Developmental Anatomy, Histology, and Congenital Anomalies of the Liver, Gallbladder, and Extrahepatic Biliary Tree

- Review the embryologic development of the liver and biliary tree
- Review the developmental structural anomalies of the liver, including situs anomalies
- Recognize the histopathologic changes in the liver during fetal development and neonatal life
- Review the developmental structural anomalies of the gallbladder and extrahepatic biliary tree
- Recognize the histopathologic features of the liver in the various ciliopathies
- Recognize the disorders associated with ductal plate malformation

Competency Area: Diseases of the Biliary Tree

- Identify the major differential diagnosis of cholestasis in infancy and its clinical and laboratory evaluation
- Recognize the histologic features of obstructive cholestasis in a liver biopsy and outline its differential diagnosis
- Be familiar with the various clinical types of biliary atresia
- Outline the causes of sclerosing cholangitis in childhood
- Recognize the criteria for bile duct paucity in a liver biopsy and its differential diagnosis
Competency Area: Familial Hepatocellular Cholestatic Diseases
- Recognize the differential diagnosis of high and low GGT-associated liver disease
- Be familiar with the genetic basis of bile acid synthetic disorders and the different types of progressive familial intrahepatic cholestatic disorders
- Be familiar with the use and pitfalls of immunohistochemistry in the investigation of cholestasis in a liver biopsy
- Outline the differential diagnosis of unconjugated hyperbilirubinemia

Competency Area: Hepatitis and Liver Failure
- Recognize the clinicopathologic features of congenital and neonatal hepatitis and define the histologic features that distinguish neonatal hepatitis from extrahepatic biliary obstruction
- Identify the possible etiologies of congenital and neonatal hepatitis and the histologic and ultrastructural features that help to narrow down the differential diagnosis
- Employ ancillary testing to rule in/out infectious, autoimmune, metabolic, and/or toxic etiologies
- Identify the clinicopathologic features of chronic hepatitis and define histologic features that favor an infectious, autoimmune, drug-induced, metabolic, or other etiology
- Formulate a differential diagnosis of the etiology of chronic hepatitis and rule them in/out by integrating the clinical, epidemiological, histological, ultrastructural features and the results of ancillary testing
- Review the different grading/staging schemes for chronic hepatitis, and recognize the most appropriate to the clinical situation and clinician need/preference
- Recognize the clinicopathologic features of acute liver failure, including the Pediatric ALF study group diagnostic criteria of acute liver failure
- Identify possible etiologies of acute liver failure, according to the patient’s age and clinical history, and how to rule them in/out by integrating clinical, histologic, ultrastructural, biochemical, and genetic information

Competency Area: Metabolic Disorders
- Recognize the histologic patterns of liver involvement by metabolic disorders in childhood
- Identify the clinical, histologic, ultrastructural, biochemical, and molecular and genetic features of alpha-1 antitrypsin deficiency
- Define the clinical, histologic, ultrastructural, biochemical, and molecular and genetic features of Wilson’s disease
- Review the clinical, histologic, ultrastructural, biochemical, and molecular and genetic features of familial intrahepatic cholestasis, Alagille’s syndrome, bile acid synthesis defects, and other causes of neonatal cholestasis
- Recognize the clinical, histologic, ultrastructural, biochemical, molecular and genetic features of the most common storage diseases affecting the liver in children: mucopolysaccharidoses, glycogen storage diseases, Niemann-Pick (type A, B, C), and sphingolipidoses (Gaucher), and Wolman disease/cholesterol ester storage disease
- Define the clinical, histologic, ultrastructural, biochemical, molecular and genetic features of the most common etiologies of liver steatosis in children: steatohepatitis of childhood, mitochondrial disorders including defects of beta oxidation, fructose intolerance, galactosemia, and urea cycle disorders
- Recognize the risk of regenerative nodules, adenomas and hepatocellular carcinoma in metabolic diseases affecting the liver in children
**Competency: Pediatric Pathology**

**Sub-competency: Pulmonary Pathology**

**Sub-competency Definition:**
Employs best practices in evaluating and reporting disorders of the pediatric lung. These best practices apply to specimen handling, application of appropriate ancillary studies, interpretation of the pathologic findings and communication including integration of clinical, pathologic, and radiologic information, and appreciation of the prognostic and therapeutic importance of specific diagnoses.

**Competency Areas:**
- A. Specimen Handling/Ancillary Studies
- B. Developmental Anatomy and Histology
- C. Pulmonary Vascular Disease
- D. Congenital Anomalies and Cystic Lung Disorders
- E. Genetic Disorders
- F. Diffuse Lung Disease
- G. Disorders of Surfactant Metabolism
- H. Tumors

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Specimen Handling/Ancillary Studies**
- Evaluate clinical records, chest imaging studies, and communications with pediatric pulmonologists, neonatologists, and other treating physicians prior to handling and interpreting lung biopsy and lobectomy specimens
- Triage wedge lung biopsies to maximize the diagnostic yield, including tissue collection for morphologic and ancillary studies (microbiology cultures, molecular testing, electron microscopy, and immunofluorescence study)
- Recognize the potential indications for electron microscopy on pediatric lung biopsy specimens
- Apply special specimen handling techniques to distinguish bronchial atresia from other congenital pulmonary airway malformations
- Compare measured values to expected values for lung weight, lung/body weight ratio, and lung volume to evaluate for pulmonary hypoplasia and pulmonary hyperplasia during postmortem examination
- Inflame wedge lung biopsy, lobectomy, pneumonectomy, and autopsy lung specimens for fixation prior to sectioning
- Select tissue sections from pediatric lobar or explant lung specimens to optimize diagnosis of neoplastic and non-neoplastic disease and to allow staging of neoplasms
- Select appropriate special stains in the diagnostic evaluation of diffuse lung disease in children, for example, PAS, trichrome/pentachrome, iron, oil red O (Bronchoalveolar Lavage (BAL) specimens), and bombesin

**Competency Area: Developmental Anatomy and Histology**
- Apply the embryologic development of the respiratory tract to major malformations of the upper respiratory tract and lungs such as tracheoesophageal fistula and pulmonary agenesis
- Correlate the histologic lung developmental stage with gestational age
- Specify the relevant major molecular events of lung development
- Correlate disorders associated with specific lower respiratory malformations (eg, agenesis, abnormal lobation, fistulas, and atresias) with major clinical syndromes and disorders
- Evaluate lung histopathology of prematurity
Competency Area: Pulmonary Vascular Disease
- Recognize the histopathology and molecular indicators of fetal and postnatal pulmonary vascular development
- Identify the histologic and hemodynamic changes of pulmonary vascular tree at the transition period from intrauterine life to air-breathing
- Specify the clinicopathologic features of neonatal lung disorders associated with pulmonary hypertension
- Recognize disorders leading to pediatric pulmonary hypertension in childhood, including congenital heart disease
- Review the genetics of familial pulmonary hypertension
- Identify pulmonary vascular changes and lung findings associated with congenital heart disease

Competency Area: Congenital Anomalies and Cystic Lung Disorders
- Relate the spectrum of pulmonary hyperplasia in the fetus/neonate to the level of fetal airway obstruction, including laryngeal atresia, solid or adenomatoid cystic adenomatoid malformation (Stocker type 3), and polyvalveolar lobe
- Identify the spectrum of gross and histologic features seen in bronchial atresia
- Distinguish the pathologic features of the following bronchopulmonary abnormalities: eg, large cyst type congenital pulmonary airway malformation (CPAM), small cyst type CPAM, intralobar sequestration, extralobar sequestration, bronchogenic cyst, and congenital lobar overinflation
- Recognize both the primary (eg, acinar dysplasia) and secondary causes (eg, congenital diaphragmatic hernia) of lung hypoplasia in the fetus/neonate
- Identify the gross and histologic features of pulmonary hypoplasia, and recognize the clinical significance of these findings

Competency Area: Genetic Disorders
- List the differential diagnosis of developmental and acquired lung diseases associated with Down syndrome (trisomy 21)
- Identify the typical pulmonary manifestations of cystic fibrosis
- Recognize normal ciliary movement, normal ciliary ultrastructure, and the pathologic features associated with primary ciliary dyskinesia
- Distinguish the microscopic features of alveolar capillary dysplasia from other forms of neonatal pulmonary hypertension and developmental disorders of the lung
- Recognize the clinical and microscopic phenotypes associated with TTF1 (NKX2-1) deficiency
- List the genetic abnormalities associated with emphysema and lung cysts in children and young adults
- Recommend appropriate molecular testing for known genetic disorders of the pediatric respiratory tract based on integration of clinical and pathologic findings

Competency Area: Diffuse Lung Disease
- Diagnose diffuse lung disease in infants and young children utilizing the children’s interstitial lung disease (chILD) classification when applicable
- Recognize the different phases of lung development in order to identify potential abnormalities in lung development (acinar dysplasia) and lung growth (pulmonary hypoplasia, chronic neonatal lung disease of prematurity)
- Recognize alveolar simplification reflective of a lung growth abnormality and the common clinical settings in which it occurs
- Recognize the characteristic histologic and ultrastructural features of pulmonary interstitial glycogenosis and evaluate for common comorbidities
- Identify the criteria for diagnosing neuroendocrine cell hyperplasia of infancy including biopsy adequacy, bombesin immunohistochemical staining for assessing neuroendocrine cells, and correlation with the clinical history and radiographic appearance
Competency Area: Disorders of Surfactant Metabolism
- Identify etiologies of primary and secondary pulmonary alveolar proteinosis
- Recognize the histologic patterns associated with disorders of surfactant metabolism
- Communicate a differential diagnosis of inherited disorders of surfactant metabolism based on the histopathologic findings and clinical history
- Recognize the value and limitations of electron microscopy in evaluating for inherited disorders of surfactant metabolism

Competency Area: Tumors
- Identify the gross and histologic features of pleuropulmonary blastoma (PPB), including types IR, I, II, and III.
- Recognize the genetic implications (e.g. DICER-1) of a PPB diagnosis.
- Differentiate low-grade cystic (Type I) PPB from non-neoplastic cystic lung lesions of the pediatric population, particularly blebs, bullae, and CPAMs.
- Recognize the importance of adequate sampling in the diagnosis of Type I PPB
- Recognize the spectrum of pathologic lesions associated with DICER-1 predisposition syndrome.
- List the differential diagnosis of endobronchial tumors seen in children.

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Supporting Committee(s) N/A
**Competency: Pharmacogenomics**

**Competency Definition:**
Understand how variations in the human genome influence the response to drug therapy; demonstrate the ability to provide medical direction for pharmacogenomic testing and communicate its benefits for therapy selection and dosing.

**Competency Areas:**
A. Basic Genetic Principles  
B. Pharmacologic Principles  
C. Testing Methods  
D. Pharmacogenomic Applications  
E. Reporting and Communication  
F. Patient Management  
G. Regulatory Compliance  
H. Quality Assurance

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Basic Genetic Principles**
- Understand basic human genetic terminology
- Describe the extent of genetic diversity in human populations relevant to health and disease
- Recognize the types of inherited and acquired genetic variations such as point mutations, insertions, inversions, and deletions that are linked to alterations in drug responses
- Describe how specific genetic variants can lead to alterations in protein function that cause drug response differences
- Understand how allele frequencies at a locus relate to genotype frequencies in a population by being familiar with the Hardy-Weinberg Law
- Calculate allele frequencies for relevant loci in local populations
- Compare allele frequencies for relevant loci in local populations to allele frequencies cited in the literature
- Use Information systems to build statistics on the frequency of genetic polymorphisms in a specific geographic area
- Describe the segregation of alleles in families
- Calculate the risk that an allele will be transmitted to a related individual
- Describe how the double stranded, complementary structure of DNA provides a basis for techniques to detect genetic variation important in pharmacogenomics

**Competency Area: Pharmacologic Principles**
- Describe the clinical difference between oral dose vs. intravenous dose in attaining steady state levels related to drug absorption and bioavailability
- Explain the clinical significance of one compartment vs. multi-compartment drug distribution models
- Define key pharmacokinetic principles such as Volume of distribution, Elimination rate constant, Half-life (including variations in half-life due to differences in metabolism of drug), and Clearance
- Understand the pharmacodynamic effects on drugs whose activity is influenced by genetic variation
- Describe the key information and parameters that can be derived from an Area Under the Curve plot, such as a drug plasma concentration versus time curve with reference to pharmacogenomic drugs
- Interpret plasma drug concentrations taking into account drug absorption, bioavailability of drug, and compartment drug distribution models
Competency Area: Testing Methods
- Describe the methods for isolating genomic DNA from patient samples for pharmacogenomic testing
- Understand the use of the polymerase chain reaction to amplify genomic regions for pharmacogenomic analysis
- Delineate steps in designing a DNA hybridization assay to detect genetic variation in amplicons prepared from genomic DNA
- Understand the techniques, technology, and instrumentation useful for pharmacogenomic tests including DNA sequencing, high resolution melting assays, quantitative PCR, reverse oligonucleotide hybridization assays, cleavage
- Use the results of clinical validations to determine if results are verifying method performance specifications
- Identify sources of control cell lines and the methods of evaluating their quality
- Explain specimen types and their limitations for pharmacogenomic testing
- Understand how analytical sensitivity, specificity, accuracy, and precision are determined for pharmacogenomic tests

Competency Area: Pharmacogenomic Applications
- Understand the normal function of the protein encoded by the relevant gene
- Describe the mechanism of action of the relevant drug, its major pharmacokinetic and pharmacodynamic properties, and its clinical utility
- Describe the nature of variations in the relevant gene that are linked to clinically important alterations in the linked therapeutic drug’s action and adverse effects
- Describe how alterations in the gene’s encoded protein or alterations in the gene’s expression level affect the drug’s activity
- Delineate potential adverse events associated with the drug’s altered activity linked to variants of the gene
- Discuss the major elements of a molecular diagnostic assay(s) to detect clinically important variation in the gene
- Discuss how to interpret the presence of various alleles of the gene with respect to recommendations for drug use and dosage and risk of adverse effects
- Evaluate the impact of pharmacogenomic results in clinical practice in terms of drug selection and dosage choices and the frequency of adverse drug events

Competency Area: Reporting and Communication
- Confidently and accurately discuss pharmacogenomic issues with clinicians and patients
- Communicate pharmacogenomic test results clearly, integrating results with other available clinical and laboratory data to provide an interpretation
- Adapt communications to the needs of the audience by considering the recipient’s point of view
- Objectively discuss potentially difficult topics such as inherited genetic variation with health care providers and patients with sensitivity for the patient’s perspective
- Prepare an integrated report that is clinically informative and applicable for choice of drug dosage for pathologists and treating physicians
- Comply with guidelines regarding reporting criteria and ensure appropriate information is included in reports

Competency Area: Patient Management
- Explain the impact of Pharmacogenomic testing on the cost of patient care decisions
- Understand how the field of pharmacogenomics is relevant to clinical laboratory services and to patient care
- Identify databases and Internet resources to obtain genetic, pharmacologic, and regulatory information
- Understand the indications and limitations of pharmacogenomic testing relevant to specific clinical findings (eg, hematologic disorders, neoplastic diseases)
- Manage the ethical, legal, and social issues that may arise when genotyping results for a patient have implications for related family members
- Understand how pharmacogenomic tests may drive other costs in patient care via their influence on drug selection and use, and the incidence of adverse events
Competency Area: Regulatory Compliance

- Demonstrate familiarity with FDA regulations related to locally developed and FDA-cleared pharmacogenomic tests
- Demonstrate familiarity with regulatory and accreditation requirements (e.g., CAP Molecular Pathology Checklist)
- Describe elements contributing to pharmacogenomic test costs, how these tests are coded for billing, and how they are reimbursed
- Understand Genetic Information Nondiscrimination Act (GINA) legislation and the process of conducting informed consents for genetic testing

Competency Area: Quality Assurance

- Ensure that appropriate proficiency testing is in place for all molecular tests and that performance is being adequately monitored
- Establish departmental (and Interdisciplinary) protocols for the utilization of molecular tests for specific tumors and patient populations
- Devise appropriate quality assurance monitors to demonstrate that protocols are being uniformly and consistently adhered to
- Understand how to ensure quality of pharmacogenomic testing results and the appropriate clinical interpretation of these results

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N/A
**Competency: Pulmonary Pathology**

**Competency Definition:**
Utilizing best practices in diagnosing neoplastic and non-neoplastic pulmonary disease; applying a multidisciplinary approach to diagnosis and treatment; understanding the limitations of various biopsy types; recognizing the appropriate use and significance of ancillary and molecular studies for optimum patient care.

**Sub-competency:**
1. Neoplastic

**Sub-competency: Neoplastic**

**Sub-competency Definition:**
Employing best practices in diagnosing, reporting and staging of lung cancer specimens; recognition of the importance and significance of subtyping non-small cell carcinomas and their separation from small cell carcinoma and other neuroendocrine carcinomas; recognition and application of the updated classification of adenocarcinoma and the significance in regard to patient prognosis, selection of ancillary/molecular studies, management and treatment selection.

**Competency Areas:**
A. Staging of Lung Cancer
B. Subclassification of non-small cell carcinoma
C. Diagnosis of sarcomatoid carcinoma and its subtypes
D. Classification of Adeno
E. Assessment of Invasion
F. Immunostains
G. Interpretation of small biopsies of the lung (e.g., core needle biopsies, trans/endobronchial, bronchial biopsy, etc)
H. Small Cell and Differential

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Staging of Lung Cancer**

- Describe how size of tumor affects staging and recognize the impact of fixation, fibrosis, and adjacent airspace organization on tumor size
- Identify pleural invasion using current published criteria, utilize elastic tissue staining when appropriate, and understand how pleural invasion affects staging
- Differentiate intrapulmonary metastases from synchronous primaries using various methodologies (e.g., Martini-Melamed, comprehensive histologic assessment)
- Recognize importance of pleural and pericardial effusion in tumor staging and appraise need for histochemical or immunohistochemical testing as indicated
- Differentiate tumor staging based on invasion of important landmark structures (e.g., chest wall, large vessels, mainstem bronchus, adjacent lobe)
- Define how the extent of postobstructive pneumonia impacts staging
- Interpret how accurate staging guides treatment options for surgery, chemotherapy, or radiotherapy
Competency Area: Subclassification of non-small cell carcinoma
- Describe how classification may determine treatment options (e.g., chemotherapy regimen)
- Recognize subclasses which may benefit from molecular testing
- Apply standard WHO histologic criteria for initial classification of neoplasms
- Analyze pertinent immunohistochemical and histochemical tests to support a specific phenotype when histologic criteria are incomplete
- State the limitations of immunohistochemical staining in classification
- Diagnose large cell carcinoma when appropriate

Competency Area: Diagnosis of sarcomatoid carcinoma and its subtypes
- Define pleomorphic (sarcomatoid) carcinoma using current WHO criteria
- Recognize spindle and giant cell carcinomas
- Define and recognize carcinosarcoma (sarcomatoid carcinoma with heterologous differentiation)
- Recognize the utility and limitations of keratin staining in this subset of tumors

Competency Area: Classification of Adenocarcinoma
- Describe and apply the new IASLC/ATS/ERS classification of lung adenocarcinomas
- Define lepidic growth and understand the definition of adenocarcinoma in situ
- Contrast lepidic growth with various patterns of invasive growth (see also assessment of invasion section)
- Identify histologic features which distinguish lepidic growth from papillary and micropapillary growth
- Describe the significance of micropapillary growth as it relates to tumor prognosis
- Explain the updated definition of mucinous adenocarcinoma of the lung and how it relates to the former classification of mucinous bronchioalveolar carcinoma
- Describe the definitions and criteria for mucinous carcinoma, colloid carcinoma and enteric adenocarcinoma
- Explain the significance of histologic subtypes of adenocarcinoma in regard to the potential presence of molecular abnormalities (i.e., patterns which tend to have EGFR mutations, patterns which tend to have KRAS mutations, patterns which tend to have EML4-ALK mutations)
- Describe the importance of molecular abnormalities in regard to selection of chemotherapeutic agents

Competency Area: Assessment of Invasion
- Discuss radiographic features which correlate with invasive versus non-invasive disease
- Recognize the typical appearances of vascular and lymphatic invasion and apply characteristic histochemical and immunohistochemical stains to support findings when indicated
- Recognize the typical appearances of visceral pleural invasion and apply elastic stains when indicated
- Recognize the typical appearances of parietal pleura, chest wall invasion and elastic stains to support findings when indicated
- Describe the likely progression of many adenocarcinomas from in situ to collapse to invasion
- Summarize the importance of size of invasive focus in minimally invasive adenocarcinomas
- Recognize patterns of growth which indicate an invasive tumor (e.g., solid, papillary)
- Differentiate desmoplastic reaction as an indicator of invasion

Competency Area: Immunostains
- Explain the role and limitations of immunostains in distinguishing between adenocarcinoma and squamous cell carcinoma of the lung
- Explain the role and limitations of immunostains most commonly used to support a primary pulmonary origin for an adenocarcinoma (TTF-1, Napsin-A)
- Describe the differences in immunohistochemical staining that may occur in primary pulmonary mucinous adenocarcinomas in comparison to pulmonary tumors with non-mucinous morphology
• Identify the pitfalls associated with cdx-2 in regard to pulmonary mucinous adenocarcinomas and the concept of pulmonary carcinoma with "enteric" differentiation
• Identify the range of primary pulmonary neoplasms which may show positive staining for neuroendocrine markers (chromogranin, synaptophysin, CD56)
• Identify known mimics of pulmonary non-small cell carcinoma, including common metastatic lesions and interpret appropriate immunohistochemical panels for evaluating primary versus metastatic tumors in the lung

Competency Area: Interpretation of small biopsies of the lung (eg, core needle biopsies, trans/endobronchial, bronchial biopsy, etc)
• Identify the common methods of obtaining biopsies and the use of each (eg, transbronchial biopsy, endobronchial biopsy, percutaneous CT guided biopsy, endobronchial ultrasound-guided biopsy, electromagnetic navigation)
• Recognize the limitations of small lung biopsies in diagnosis of malignancy
• Determine the inability to rule out invasion in small biopsies showing BAC/AIS
• Differentiate carcinoma from known mimics (eg, sclerosing hemangioma, acute lung injury, carcinoid tumor, granulomatous disease)
• Evaluate small biopsies for triage for molecular studies and immunohistochemical staining
• Correlate histologic findings with radiographic imaging to determine if lesion is adequately sampled

Competency Area: Small Cell and Differential
• Define the major categories of pulmonary neuroendocrine carcinomas (typical carcinoid atypical carcinoid, large cell neuroendocrine carcinoma, small cell carcinoma) using WHO criteria
• Differentiate typical carcinoid (TC) from atypical carcinoid (AC)
• Differentiate TC and AC from the high grade neuroendocrine carcinomas
• Explain the concepts of carcinoid tumorlets, multiple carcinoid tumorlets and diffuse neuroendocrine cell hyperplasia (DIPNECH) and their clinical significance
• Identify the pitfalls associated with crush artifact, especially in small biopsy specimens
• Explain the utility and limitations of proliferation markers in the role of classifying pulmonary neuroendocrine carcinomas
• Describe the limitations of subtyping carcinoid tumors in small biopsy specimens
• Identify the range of morphologic patterns which may be encountered in carcinoid tumors
• Discriminate carcinoid tumors from other histologic mimics (adenoid cystic carcinoma, sclerosing hemangioma)
• Describe the significance of TTF-1 staining in carcinoid tumors in contrast to small cell carcinoma
• Identify the histologic features which distinguish small cell carcinoma from large cell neuroendocrine carcinoma
• Describe the limitations of diagnosing LCNEC on a small biopsy
• Discriminate the high grade neuroendocrine carcinomas from other histologic mimics (poorly differentiated and/or basaloid squamous carcinoma, basaloid carcinoma, PNET, lymphoma)

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Competency: Renal Pathology (To Be Developed)
Competency: Soft Tissue Pathology (To Be Developed)
Competency: Toxicology/TDM

Competency Definition:
Effectively utilizes analytical, clinical, pharmacologic and pathologic information to interpret the results of analyses of drugs and toxins in body fluids.

Competency Areas:
A. Pharmacologic Principles
B. Instrumentation
C. Procedures
D. Emergency Toxicology
E. Therapeutic Monitoring
F. Drugs of Abuse

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Pharmacologic Principles
- Define: volume of distribution (Vd), plasma half-life (t1/2), steady state levels, peak and trough levels, area under the curve (AUC), clearance, one and two compartment pharmacokinetic models, elimination rate constant
- Differentiate first and zero order kinetics with respect to expected concentrations of drugs and alcohols
- Recognize the potential significance of pharmacodynamic effects of drugs and toxins
- Relate observed blood and urine concentrations of drugs or toxins to the pharmacokinetics or toxicokinetics of their distribution/metabolism/excretion
- Recognize induction or inhibition of drug metabolism and Interpret results in patients on multiple medications
- Identify indications for the determination of free vs. total drug levels when available

Competency Area: Instrumentation
- Distinguish principles of operation of modern clinical laboratory instrumentation including immunoassay, spectrophotometry, chromatography (TLC, LC, GC, HPLC, etc.), and mass spectrometry and recognize advantages and disadvantages of each
- Address sources of analytical false positives and false negatives in immunoassay results
- Perform detailed test validation on all instrumentation available in the laboratory with particular attention to accreditation requirements such as those noted in the CAP checklist
- Evaluate pros and cons of immunoassay, chromatography and mass spectrometry (GC/MS, LC/MS-MS) in method selection

Competency Area: Procedures
- Distinguish between the need for screening vs. confirmation testing for drugs of abuse
- Evaluate testing for drugs of abuse adulteration
- Select appropriate TDM/Toxicology proficiency testing surveys for use in the clinical laboratory
- Review chromatographic and mass spectrometric assay validation and controls* (*only for specialized laboratories)
- Ensure appropriate therapeutic ranges for TDM are implemented which may be dependent upon the patient population
- Define preanalytical procedures such as specimen requirements that ensure accurate test results
- Establish procedures for rejection of specimens or reporting of unsatisfactory results (eg, high absorbance flag on IA, interfering peak on LC/MS)
- Incorporate a policy for reporting screening test results that indicate the limitations and/or that confirmatory testing is needed for definitive results
- Address validation requirements of Laboratory Developed Tests (LDTs)
Competency Area: Emergency Toxicology
- Utilize clinical signs and symptoms (i.e., toxidrome) to determine presumptive drug or toxin exposure
- Apply calculations of anion gap and osmolar gap in the workup of cases of suspected poisoning or drug overdose and demonstrate how anion gap and osmolar gap can be utilized in the absence of testing for the suspected drug
- Utilize laboratory parameters that are correlated with environmental toxic exposures (CO, Pb, etc.) in interpretation of cases
- Identify local industrial/environmental hazards and chemical terrorism agents and the role of the laboratory in public health emergency response to hazardous chemical and toxin exposures
- Review the principles of treatment of poisoning in particular those drugs for which an antidote can be administered
- Identify resources for toxicologic and poisoning related information
- Determine an appropriate test panel based on your patient population
- Recommend most appropriate body fluid to assess toxicity

Competency Area: Therapeutic Monitoring
- Assess menu of drugs monitored by TDM assays and methodology utilized
- Utilize: volume of distribution (Vd), plasma half-life (t1/2), sample collection for steady state, peak and trough levels, area under the curve (AUC), clearance to interpret drug concentrations
- Be familiar with the following theoretical concepts: one and two compartment pharmacokinetic models, elimination rate constant, first and zero order kinetics
- Assess genetic polymorphisms that influence drug response
- Determine appropriate drugs for which low and high critical results should be implemented
- Recognize difference in IA vs. confirmatory results (e.g., are active and/or inactive metabolites detected) and impact on patient and reference ranges

Competency Area: Drugs of Abuse
- Evaluate Point-of-Care testing methods for Urine Drugs of Abuse testing and understand advantages and disadvantages
- Relate the clinical signs and symptoms of intoxication and overdose to the class of agent represented by different drugs of abuse: stimulants, depressants, narcotic analgesics, hallucinogens
- Identify resources for maintaining current awareness of newly emerging street drugs and street drug contaminants
- Recognize the different non-clinical indications and regulatory requirements for workplace and forensic drugs-of-abuse testing, and the role of the Medical Review Officer (MRO) in the former
- Identify resources for maintaining current awareness of newly emerging street drugs and street drug contaminants
- Recognize the different clinical needs from drugs-of-abuse test results: toxicity for a suspected drug overdose or exposure, abstinence or compliance in drug abuse treatment, and compliance in pain management
- Determine appropriate cutoff for urine drug testing based on the patient population
- Demonstrate the utility of creatinine testing in urine specimens and calculate creatinine adjusted drug levels

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Supporting Committee(s)
Toxicology Resource Committee
Competency: Transfusion Medicine/Blood Banking (To Be Developed)
Competency: Transplant Pathology (Solid Organ)

Competency Definition:
Utilizes knowledge of current immunologic concepts and treatment options for transplanted patients to evaluate and report pathologic findings in solid organ transplant tissue samples to support optimum patient care; participates in multidisciplinary management conferences, actively sharing pathologic and immunobiologic concepts with others.

Competency Areas:
A. Transplantation Immunology
B. Testing Methods
C. Clinical Considerations
D. Specimen Handling
E. Ancillary studies
F. Monitoring Strategies
G. Pathologic Criteria for Rejection
H. Pathologic Criteria for Chronic Rejection and Allograft Vasculopathy (AV)
I. Differential Diagnosis for Rejection
J. Infections in Transplanted Organs
K. Malignancies in Solid Organ Transplant Patients
L. Graft vs Host Disease and other Hematologic Complications
M. Treatment Implications
N. Reporting and Communication

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Transplantation Immunology
- Explain the immunobiologic concepts that distinguish cellular and antibody mediated rejection types and describe how these relate to specific pathologic findings in transplant biopsies
- Define the various antigen systems, including the major histocompatibility complex (MHC) and blood group antigen systems that may trigger transplant rejection, and define laboratory methods of detection and monitoring
- Relate concepts of antigen presentation, immune cell signaling pathways, and effector mechanisms to the pathologic features found in acute and chronic rejection types
- Identify and define pathologic features of ischemia and inflammation that distinguish them from transplant rejection
- Relate emerging molecular diagnostic features of transplant rejection to established diagnostic test types and define their role in guiding management of transplant patients
- Compare and contrast the pathologic features and clinical challenges relating to xenotransplantation of various organ types

Competency Area: Testing Methods
- Define the role of the HLA laboratory and its testing methods in monitoring of pre and post solid organ transplant patients
- Define the role of the microbiologic serology laboratory and its testing methods in monitoring patients` pre and post solid organ transplantation
- Define the role of the blood bank in monitoring and/or providing blood products before, during and after solid organ transplantation, including strategies to avoid or prevent further sensitization
Competency Area: Clinical Considerations
- Enumerate the clinical, imaging and laboratory parameters of solid organ transplant patients that must be known in order to evaluate biopsies effectively in transplanted patients
- Identify clinical, imaging, and/or laboratory test thresholds that should prompt allograft biopsy
- Identify the appropriate elements of a clinical workup of a solid organ transplant recipient prior to transplantation
- Define the role of the transplant team in selecting appropriate patients for solid organ transplantation

Competency Area: Specimen Handling
- Summarize the pre-analytical variables involved in optimal handling and monitoring of peripheral blood testing in transplant patients
- Define the optimal pre-fixation ischemic time and fixation parameters for transplant tissue biopsies
- Compare and contrast the use of frozen versus formalin fixed paraffin embedded tissue in routine histology, immunohistochemistry and molecular methods
- Describe the appropriate use of electron microscopy in the pre and post transplant evaluation of solid organ transplant recipients
- Devise and implement procedures for appropriate procurement, preservation, and transportation of transplant biopsy specimens from the hospital to the laboratory

Competency Area: Ancillary Studies
- Define the optimal rationale for use of immunohistochemistry including frozen tissue immunofluorescence in solid organ transplant biopsy interpretation, taking into account evidence based published recommendations
- List available assays for cytokine, chemokine and ligand expression and leukocyte surface marker detection and discuss the possible role of each in evaluation of transplant biopsies for suspected rejection
- Describe the utility of viral markers in differentiating transplant rejection from infection or polyclonal post transplant lymphoproliferative disorder, especially the polymorphic type
- Describe the role of markers of vascular injury or coagulopathy in predicting severity or chronicity of transplant rejection
- Explain the role of diagnostic electron microscopy in the diagnosis of acute/chronic transplant rejection of the kidney and define its potential utility in transplants of other solid organs

Competency Area: Monitoring Strategies
- Describe the optimum monitoring methods for each class of drugs including monitoring test type, frequency, and therapeutic ranges
- Identify the optimal elements of a surveillance strategy for solid organ transplant patients, including clinical features, imaging studies and laboratory testing methods
- Compare and contrast the benefits and risks of scheduled `protocol` biopsies versus biopsies done in response to a clinical or laboratory trigger (for cause) during the surveillance of solid organ transplant patients

Competency Area: Pathologic Criteria for Rejection
- Apply the most current and accepted classification scheme for grading rejection in biopsy specimens, including acute cellular rejection, chronic rejection and antibody mediated rejection and their peak time of onset
- Explain the diagnostic criteria for each optimal grading system (eg, Banff Grading system, ISHLT grading system)
- Recognize the primary differential diagnoses in solid organ transplantation biopsies: recurrent and de novo disease, acute and chronic rejection, antibody mediated rejection, infections, post transplant lymphoproliferative disorder (PTLD), malignancies, surgical complications and vascular compromise
Competency Area: Pathologic Criteria for Chronic Rejection and Allograft Vasculopathy (AV)

- Define the biopsy criteria for allograft vasculopathy and chronic rejection according to the most current and widely accepted schema
- Recognize risk factors for the development of chronic rejection
- Describe the histopathologic findings and differential diagnoses including recurrent disease staging (for liver, biliary tract obstruction) and atherosclerosis

Competency Area: Differential Diagnosis for Rejection

- Define the features of recurrent disease in transplant biopsies (e.g., glomerulopathy in kidney, giant cell myocarditis in heart, primary biliary cirrhosis or Hepatitis C in liver, Langerhans cell histiocytosis in lung, etc.)
- Define the optimal evaluation of infiltrates in biopsies of solid organ transplant recipients that are suspected as post transplant lymphoproliferative disorder (PTLD)
- Define adverse effects found in solid organ biopsies that are related to different treatment agents (e.g., calcineurin inhibitor vascular changes in kidney) and distinguish these from chronic rejection
- Differentiate artifacts such as reperfusion injury, ischemia, viral infection, and post transplant lymphoproliferative disease from rejection in heart transplant biopsies
- Differentiate reperfusion injury and bacterial or viral infection from rejection in lung transplant biopsies
- Differentiate reperfusion/preservation injury, lipopeliosis, small-for-size-syndrome, biliary sludge syndrome and hepatic artery thrombosis from rejection in liver transplant biopsies
- Differentiate infection, ischemia and immunosuppressive drug toxicity from rejection in pancreatic transplant biopsies
- Differentiate reperfusion injury, inflammatory bowel disease, graft versus host disease, autoimmune disease and food allergies from rejection in small bowel biopsies

Competency Area: Infections in Transplanted Organs

- Differentiate the most common forms of bacterial, viral, fungal, rickettsial, and parasitic infections particular to each solid organ transplant (e.g., HCV in the liver, BK virus in the kidney, etc)
- Describe the clinical findings, radiologic imaging studies, laboratory testing methods, and diagnostic strategies to be used in work-up of infections
- Relate the immunobiologic contribution of infectious diseases to rejection of various transplanted organs such as cytomegalovirus and Hepatitis C
- Describe the histologic and serologic features of chromosomally integrated HHV-6 which may result in inappropriate antiviral therapy
- Define the role of Epstein-Barr virus (EBV) infection in the development of post-transplant lymphoproliferative disorder (PTLD)

Competency Area: Malignancies in Solid Organ Transplant Patients

- Define the presentation, diagnostic testing strategies, and pathologic criteria for common malignancies that can occur in patients with solid organ transplants
- Define the optimal surveillance for and treatment of common malignancies that can occur in patients with solid organ transplants
- Correlate the incidence of malignancies in patients with solid organ transplants to transplanted organ type, immunosuppressive regimen, and environmental factors

Competency Area: Graft vs Host Disease and other Hematologic Complications

- Define the sites and diagnostic features of acute and chronic graft versus host disease (GVHD) that can occur in solid organ transplant recipients, especially small bowel transplant recipients
- Outline strategies for monitoring and recognition of clinical and pathologic findings for diagnosis of GVHD
- Define the role of donor specific micro chimerism in predicting transplant recipient outcomes
- Distinguish between the types of hematologic diseases that can occur in solid organ transplant recipients including passenger lymphocyte syndrome, transplant-related thrombotic microangiopathy, hemophagocytic syndrome, hemolytic anemia, and pancytopenia of infection
Competency Area: Treatment Implications

- Compare and contrast the immunosuppressive mechanisms underlying treatment with new classes of immunosuppressive drugs including immunophilin binding agents, mTOR inhibitors, antiproliferative reagents, corticosteroids, and antibodies directed against immune reactants important in transplant rejection.
- Compare and contrast the optimal use of each drug class to its role in either induction, baseline immunosuppression or in acute transplant rejection therapy.
- Define the features found in solid organ biopsies that are related to treatment effects (e.g., calcineurin inhibitor vascular changes in kidney).
- Identify the types of complications to be expected in transplant patients from treatment with various immunosuppressive drug classes and how patients should be monitored to recognize and treat these complications.
- Describe the role of viral treatment prophylaxis in preventing viral infection in solid organ transplant recipients.

Competency Area: Reporting and Communication

- Summarize important diagnostic features that must be included in the biopsy report.
- Create a reporting format that will readily convey understanding of results to clinicians.
- Describe the types of collegial interactions that are needed to practice transplant pathology effectively.
- Define the role of previous biopsy findings, both native organ and transplant, in current transplant biopsy reports and how to optimally present this information.
- Describe the transplant team interaction documentation that should occur after transplant biopsy interpretation and reporting.
- Define the role of previous biopsy findings, both native organ and transplant, in current transplant biopsy reports and how to optimally present this information.

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Supporting Committee(s) N/A
MOC Category: Practice-Based Learning & Improvement

Demonstrate ability to investigate and evaluate diagnostic and laboratory practices in your own lab, appraise and assimilate scientific evidence, and improve laboratory practices and patient care.

Competencies
Click a competency name to access the competency page.

Assimilation of External Evidence
Practice Analysis
Process and Outcome Improvement
Competency: Assimilation of External Evidence

Competency Definition:
Identifying and utilizing relevant external information and resources to help improve your practice.

Competency Areas:
A. Collection of Informational Resources
B. Use of Evidence-Based Data

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Collection of Informational Resources
- Conduct clear, concise and systematic searches of literature (eg, Cochrane Collaboration Systematic Reviews)
- Locate and research appropriate benchmarks set by external groups/organizations
- Locate and research regulatory requirements and medical legal environment information (eg, Centers for Medicare and Medicaid, the Joint Commission Standards)
- Locate and research technology and instrumentation using resources from vendors and user groups
- Seek expert consultation as needed to help improve laboratory practices (eg, laboratory and pathology practice guidelines, CAP Cancer Protocols)

Competency Area: Use of Evidence-Based Data
- Understand levels of evidence for studies of diagnostic accuracy as well as studies of therapeutic effectiveness and how to use them appropriately to analyze your practice
- Apply knowledge of study design and statistical methods to critically analyze clinical studies (eg, how patient populations change value of literature)
- Select relevant evidence to help prioritize risks and define improvement strategies

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Supporting Committees
N/A
Competency: Practice Analysis

Competency Definition:
Using data to identify practice patterns, and evaluating practice variations within a well-defined process to ensure patterns reflect current standard of care in pathology and laboratory medicine.

Competency Areas:
A. Development of Metrics and Data Systems
B. Data Analysis
C. Risk Assessment

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Development of Metrics and Data Systems
• Develop approaches to acquiring relevant health care data and identifying patterns using analytical/statistical techniques
• Understand the metrics and measurement systems (eg, statistical benchmarking and dashboard construction) used by the laboratory to track lab activities and current practice patterns
• Understand the difference between and components of pre-analytical, analytical, and post-analytical variables
• Develop new metrics as needed for data collection and outcome measurement
• Set thresholds for performance using appropriate reference tools

Competency Area: Data Analysis
• Analyze baseline data and identify potential areas for improvement
• Collect and synthesize performance data (eg, error frequencies)
• Recognize trends in performance data
• Identify variation/gaps between actual and targeted performance using thresholds
• Develop reporting strategies for presenting data to stakeholders (eg, how data should be summarized and graphed)

Competency Area: Risk Assessment
• Identify the performance factors and processes that result in a situation being considered a risk
• Identify potential practice variation risks based on data and gap analysis
• Evaluate the impact of potential risks to patients and/or the institution
• Review data and risk assessment with stakeholders and modify metrics and measurement systems as needed

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Supporting Committee(s)
N/A
Competency: Process and Outcome Improvement

Competency Definition:
Using a systematic methodology to plan practice improvements that reduce risk to patients, address root causes, have well-defined and measurable goals, involve key stakeholders and monitor effectiveness over time.

Competency Areas:
A. Intervention Planning
B. Intervention Design
C. Outcome Monitoring

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Intervention Planning
- Understand the various process improvement methodologies (PDSA, six-sigma, DMAIC, Lean) and their strengths and weaknesses
- Select the best process improvement methodology for a given problem
- Define and prioritize areas for improvement using data, evidence and a systematic process and tools (eg, SWOT analysis, risk matrix, informatics tools)
- Target well-defined problems that present the greatest risk to patients and where medical knowledge and/or other evidence exists to point to best practices
- Define the scope of the problem clearly and avoid scope "creep"
- Set clear and measurable goals for improvement
- Be able to identify all the pertinent stakeholders in a complex process
- Involve stakeholders in prioritizing improvement opportunities and setting goals

Competency Area: Intervention Design
- Determine the baseline status and source of a problem using data, external evidence, process flow-charting and root cause analysis tools (eg, Ishikawa or fishbone diagram)
- Design intervention strategies that address root causes
- Design process-related improvements with an emphasis on consistent behavior and well-defined protocols in order to reduce and control for variation
- Share improvement strategies with stakeholders and refine plan based on feedback
- Create well-defined metrics to monitor the intervention including units of measurement, collection frequency, data quality, and thresholds
- Lead pathology and laboratory initiatives to train personnel to implement the intervention

Competency Area: Outcome Monitoring
- Test the initial implementation of the intervention using iterative cycles for feedback and improvement (eg, rapid cycles of change)
- Measure and monitor the effect of the intervention over time and make adjustments to intervention design as needed
- Create a remediation plan if the intervention involves behavioral changes for pathologists
- Share performance data and progress of the intervention with stakeholders
- Look for broader applications of successful improvements

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Supporting Committees
N/A
MOC Category: Professionalism

Demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to diverse patient population.

Competencies
Click a competency name to access the competency page.

Ethics
Leadership
Respect for Diversity
**Competency: Ethics**

**Competency Definition:**
Demonstrating appropriate values, supporting policies and procedures that encourage ethical behavior, working to strengthen credibility in the field of pathology, and communicating and storing patient data appropriately.

**Competency Areas:**
A. Adhere to Ethical Principles  
B. Maintain Compliance  
C. Focus on Patient Interest

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Adhere to Ethical Principles**
- Be honest with patients and colleagues  
- Avoid conflicts of interest  
- Report in the appropriate manner any health care professional whose actions put patients at risk  
- Refrain from discussing colleague performance outside of the appropriate forum  
- Convey a positive attitude and demeanor in the workplace toward colleagues, techs, administrators, and other medical staff  
- Demonstrate a constructive, positive attitude toward the employing entity (Hospital, University or Corporation)  
- Behave in accordance with the professional standards outlined by CAP and ethical principles outlined by AMA

**Competency Area: Maintain Compliance**
- Maintain confidentiality of patient information  
- Comply willingly with legal and regulatory requirements for lab practices  
- Support implementation of required corrective actions or upgrades to improve overall laboratory quality  
- Acknowledge and correct medical errors

**Competency Area: Focus on Patient Interest**
- Put the best interest of the patient first  
- Be committed to excellence in professional education and competence  
- Consult colleagues appropriately on patient issues  
- Be aware of and respect the financial interests of patients, the hospital and third party payers

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N/A
**Competency: Leadership**

**Competency Definition:**
Demonstrating behaviors and characteristics that exemplify the skills of an effective leader within the laboratory environment and medical home; applying proven management skills to develop others and achieve results; practicing continuous improvement for both personal and staff development and to meet or exceed institutional goals in support of patient care.

**Competency Areas:**
A. Demonstrate Integrity  
B. Participate in Life-long Learning  
C. Serve Others  
D. Develop Others  
E. Influence Outcomes  
F. Advance the Field  
G. Think Strategically  
H. Solve Problems  
I. Achieve Goals  
J. Lead Change

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Demonstrate Integrity**
- Am honest with others  
- Demonstrate through actions a commitment to principles over personal gain  
- Establish credibility by consistently achieving results and being recognized as competent  
- Follow-through on commitments  
- Address sensitive issues with objectivity and respect for others  
- Maintain composure and lead during difficult times  
- Model appropriate behavior and set an example for employees

**Competency Area: Participate in Life-long Learning**
- Assess personal strengths and weaknesses and make improvements (eg, reflect on and learn from failures; ask for and accept constructive feedback from others)  
- Strive for innovation and excellence in area of expertise or responsibility  
- Participate actively in ongoing professional development (eg, CME and non-CME; independent study and research; seek a mentor)

**Competency Area: Serve Others**
- Serve the goals of the organization and effectively manage its resources  
- Encourage and demonstrate openness to others’ ideas  
- Share successes and give credit where credit is due  
- Ensure that those they lead have the resources, equipment and organizational support to successfully do their work

**Competency Area: Develop Others**
- Establish clear expectations and give feedback on performance  
- Identify and promote new responsibilities, project opportunities, or education for others  
- Empower others to take ownership for their work and project activities  
- Inspire and motivate others to meet organizational goals and to do their best work  
- Foster long term growth and career development in others through mentoring
Competency Area: Influence Outcomes
- Effectively organize committees or groups to accomplish initiatives
- Persuade others through information, logic and effective communication rather than by authority and/or intimidation
- Communicate own point of view with confidence and effectively manage resistance
- Become involved in key organizational groups to ensure that laboratory concerns are represented

Competency Area: Advance the Field
- See oneself as a physician actively involved in the patient care team
- Promote the current value of the laboratory and laboratory professionals to internal and external audiences
- Look for new opportunities for the profession and new ways in which pathologists can serve patients

Competency Area: Think Strategically
- Understand the vision, mission and critical success factors of the department in the context of the larger organization/institution
- Ensure that tactics and decisions are aligned with the organization`s mission and goals
- Be aware of trends and innovations in the field of pathology and use this knowledge to guide long-term planning efforts
- Identify key stakeholders who are influential in laboratory related decisions

Competency Area: Solve Problems
- Recognize when to engage and address problems and issues
- Participate in problem-solving discussions when appropriate and provide input on resolutions
- Seek out alternative points of view and/or additional information to resolve issues when appropriate
- Understand how to assess and interpret data (or ask for assistance) in order to make data-driven decisions
- Make decisions when appropriate, even in ambiguous and/or time-sensitive situations

Competency Area: Achieve Goals
- Establish goals, timelines and metrics to measure project outcomes based on the analysis of data and stakeholder input
- Complete tasks in a timely fashion despite competing demands
- Achieve goals as measured by objective criteria (eg, profit, turnaround)
- Delegate tasks effectively

Competency Area: Lead Change
- Promote necessary change even when it is difficult or not desired
- Help others to move in another direction by effectively communicating the reasons and benefits of change
- Provide input to implementation plans for change initiatives
- Lead change initiatives that involve the laboratory

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Supporting Committee(s) N/A
Competency: Respect for Diversity

Competency Definition:
Recognizing and respecting the value that diverse backgrounds bring to the work setting; cultivating a professional environment that discourages discrimination based on ethnicity, religion, gender, disabilities and age; and using differences to create effective work teams and achieve results.

Competency Areas:
A. Demonstrates Sensitivity
B. Communicates Effectively with Diverse Groups
C. Fosters Team Diversity
D. Recruits and Retains Diverse Talent
E. Creates a Sense of Community

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Demonstrates Sensitivity
- Define diversity broadly to include ethnicity, religion, gender, disabilities, age, as well as professional background
- Demonstrate tolerance and patience when interacting with diverse groups
- Recognize the challenges of others (eg, disabilities) and be willing to help
- Be aware of cultural and religious influences on patients` participation in screening programs and adherence to treatment plans
- Respect patients` diverse healing traditions and beliefs
- Show respect for diverse cultural traditions at the end of life

Competency Area: Communicates Effectively with Diverse Groups
- Choose language, gestures, comments and jokes with sensitivity and respect towards others
- Avoid statements directed at one or more members of a diverse group that may appear pandering, obsequious, or insincere
- Use resources, such as interpreters, when language barriers may impair doctor-patient communication
- Adapt behaviors to show respect for cultural communication differences (eg, non-verbal communication, eye contact, gestures, etc.) when appropriate
- Recognize and respect customs and traditions of the host country when conducting business outside of the United States

Competency Area: Fosters Team Diversity
- See the benefit in having diverse perspectives and backgrounds on a team
- Discourage conversations about differences, and encourage conversations about competence and demonstrated ability
- Listen attentively and equally to the thoughts and perspectives of everyone on the team
- Focus on others` competence, skills and ideas rather than their personal profile (eg, age, gender, ethnicity etc.)
- Seek out and leverage people`s strengths verses focusing on how they are different
Competency Area: Recruits and Retains Diverse Talent

- Use fair and objective hiring criteria focused on an individual’s competence and demonstrated ability
- Build a team consisting of different perspectives and backgrounds but that fits with the organization’s culture, values and overall work ethic
- Refrain from making assumptions about others’ professional goals and desired responsibilities based on gender, age, culture, disabilities, etc.
- Give equal consideration and grant professional opportunities based on competence, skills and demonstrated ability

Competency Area: Creates a Sense of Community

- Strive to establish a sense of cohesion among diverse groups
- Address others’ attitudes and behaviors that may be seen as offensive or discriminatory
- Recognize the importance of shared, common goals
- Incorporate diversity objectives and values into everyday interactions
- Decipher when it’s appropriate to express one’s diversity versus when it’s appropriate to conform to the organization’s culture, norms and values

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Supporting Committees

N/A
MOC Category: Systems-Based Practice

Demonstrate understanding of and contribution to local, regional, and national health care systems, and support health care in system-based practice definition.

Competencies
Click a competency name to access the competency page.

Informatics
Practice and System Integration
Practice Finance
**Competency: Informatics**

**Competency Definition:**
Applying informatics and information technology principles in the practice of pathology to manage patient and lab information, facilitate workflow processes, improve clinical interpretations, communicate practice information, report patient diagnosis, and ultimately to improve patient care.

**Competency Areas:**
A. Technology Fundamentals
B. Laboratory Information Management in Health Systems
C. Data Analysis & Management Tools
D. Digital Pathology
E. Ongoing Laboratory System Management
F. Accreditation & Regulatory Compliance
G. Selection and Installation of Lab System

**COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS**

**Competency Area: Technology Fundamentals**
- Utilize medical literature search engines, bibliographic software and related computerized support services to maintain current knowledge in field(s) of practice
- Explain the differences among pathology informatics, bioinformatics, public health informatics, health care information technology and health knowledge informatics
- Use correct terminology to describe the major types and components of computer hardware, software, and computer networks
- Conversant in the fundamentals of databases, including data types, fields, records, database structure, and mechanisms for querying data; understands how data storage affects data retrieval options
- Describe the characteristics and appropriate applications of standard terminologies (e.g., CPT, ICD, SNOMED, LOINC) used to represent pathology data in the LIS and Electronic Health Record
- Recognize the advantages of standardized terminology for creating interchangeable data which can be retrieved and summarized
- Define the key features of communication standards used in Pathology, such as HL7 v. 2/3 and DICOM
- Understand the basics of the ISO standards development process
- Understand how patient and asset identification standards and tracking systems are used to improve patient safety and laboratory workflow

**Competency Area: Laboratory Information Management in Health Systems**
- Recognize what laboratory information systems (LISs) are, what they do, and the role they play in efficient lab operations and health care delivery
- Contribute to and, where appropriate, lead institutional information system strategies including decision support
- Identify opportunities to modify the LIS to improve operations
- Understand capabilities and limitations of electronic interfaces between an LIS and instrumentation, middleware, and other information systems
- Supervise specification setting, development and implementation of new systems interfaces
- Anticipate (and recommend remediation for) issues, potential problems, and challenges in EHR handling of laboratory test results
- Anticipate (and recommend remediation for) issues, potential problems, and challenges in EHR handling of laboratory test orders
- Articulate the role and connections of the LIS within the network of health care information systems (i.e., the local health care information ecosystem)
- Evaluate the functionality of middleware
- Recognize applications of ancillary information systems to optimize clinical, operational, and financial performance of the laboratory (e.g., middleware, financial systems, business intelligence)
Competency Area: Data Analysis & Management Tools
- Recognize limitations and information gaps resulting from the limitations of the data analysis capability of LISs
- Contribute to the definition and creation of integrated health care data sets from multiple disparate sources to support useful, accurate, and reliable data analysis
- Contribute to the analysis and interpretation of integrated pathology and enterprise data sets for improving care quality and increasing the efficiency of care delivery

Competency Area: Digital Pathology
- Utilize digital imaging systems, such as whole slide imaging (WSI) and dynamic telemicroscopy, as appropriate to practice setting
- Define the structure of a bitmap (raster) image and the common strategies for image compression
- Understand the potential role, use, and limitations of WSI in the laboratory environment
- Determine the appropriate digital image resolution for a particular need/purpose
- Determine the appropriate telemicroscopy technology to use for a particular application

Competency Area: Ongoing Laboratory System Management
- Work with information systems personnel to ensure that reports are properly formatted (eg, synoptic format and other standardized formats as appropriate)
- Supervise the LIS team in the creation and updating of the LIS procedure manual
- Understand the process and requirements for test definition and other information maintenance in the LIS

Competency Area: Accreditation & Regulatory Compliance
- Adhere to HIPAA and other security and privacy requirements for the communication and storage of patient data
- Maintain compliance with electronic information management requirements of regulatory and/or accreditation agencies as applicable
- Follow technology developments and identify opportunities for improving the security and quality of patient data
- Interpret new regulations to determine how they affect laboratory information management needs and the role of the lab within the health care system
- Recognize security practices consistent with HIPAA and other regulatory requirements including correct use of password protected accounts, firewalls, digital certificates, encryption, and two-factor authentication
- Recognize situations under which information technology may be subject to FDA regulation (eg, blood banking and whole slide imaging)

Competency Area: Selection and Installation of Lab Systems
- Prepare justification for acquisitions of new information technology such as an LIS
- Articulate departmental IS needs sufficiently to contribute to the production of IS request documents such as requirements analysis, scope document, technical specifications document, and RFP
- Provide input to the LIS selection team to ensure that an optimal fit between a purchased system and departmental needs is attained
- Lead LIS selection team such that an optimal fit between purchased system to departmental needs is attained
- Guide implementation team in optimal deployment of the LIS
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Supporting Committee(s)
Informatics Committee
Competency: Practice and System Integration

Competency Definition:
Using knowledge of one’s health care environment, its interdependencies, and pathology practice and delivery to anticipate implications for one’s pathology practice, improve integration within the health care environment, mitigate risks to patients and affect positive change.

Competency Areas:
A. Health Care Environment Fundamentals
B. Pathology Practice Structure and Function
C. Health Care Assessment
D. Standards for Laboratory Performance
E. Health Care Improvement

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: Health Care Environment Fundamentals
- Describe the types of organizations (e.g., insurance, hospitals, and government agencies) that comprise one’s health care environment
- Understand the components and organization of local, regional, national, and, if applicable, international health care environments and how each impacts the care of the patient
- Explain interdependencies within one’s health care environment and how pathology services and professional practices affect other areas of the patient care environment
- Recognize how interdependencies within the health care environment change over time

Competency Area: Pathology Practice Structure and Function
- Describe different models of pathology practices and how each interacts with the health care environment
- Understand how one’s current pathology practice structure impacts resource allocation, revenues and expenses
- Identify the infrastructure and organizational structure needed to support day-to-day operations of one’s pathology practice
- Recognize the roles and general functions of various leadership and management personnel
- Anticipate demand for pathology resources based on activities in the larger environment (e.g., hospital initiatives)
- Use evidence-based methods to evaluate the clinical effectiveness of new technologies or tests and determine the impact on the delivery of services
- Recognize the range of services available to pathology practices by external providers (e.g., reference laboratories, billing companies, accounting and legal organizations and professional associations)
- Identify strategies for improving the integration of the pathology practice and one’s health care environment

Competency Area: Health Care Assessment
- Recognize internal health care performance indicators for the laboratory and hospital (e.g., test turnaround times, inspection results, length of stay)
- Recognize regulatory and government (e.g., Center for Medicare and Medicaid Services) health care performance indicators (e.g., hospital never events)
- Differentiate between mandatory and self-imposed health care performance indicators
- Assess and monitor health care performance indicators
- Document health care performance indicators in a manner that facilitates understanding of long term improvement
- Understand rating systems used to measure health care (e.g., Press Ganey ratings)
• Understand how laboratory quality measures and performance metrics impact patient care and affect institutional-level metrics or benchmarks (eg, how lab turnaround time impacts length of hospital stay and ultimately the outcome of the patient)
• Identify errors and risks within one’s healthcare environment

**Competency Area: Standards for Laboratory Performance**
• Understand and contribute to the lab accreditation process and prepares for lab inspections
• Use knowledge of regulatory issues that impact the lab and the health care environment to monitor and maintain compliance (eg, CLIA, CAP, OIG, CMS, JC, OSHA, FDA, etc.)

**Competency Area: Health Care Improvement**
• Draw upon knowledge of health care performance indicators, errors and risks to improve health care delivery effectiveness
• Determine actions to be taken based on assessment of performance indicators
• Utilize resources within the health care environment (eg, information systems, multidisciplinary administrative committees) to improve service delivery
• Partner with health care managers to improve the quality of health care and minimize error and risks to patient care and safety
• Understand the role, strengths and limitations of using internal and external benchmarking measurements to monitor performance improvement

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**Supporting Committee(s)**
Practice Management Committee
Competency: Practice Finance

Competency Definition:
Using financial knowledge and information to make decisions that support quality care, optimize practice revenues, control expenses, and manage economic risks.

Competency Areas:
A. General Financial Knowledge
B. Financial Aspects of Administration
C. Financial and Compliance Risk Management
D. Contracting (Facility, Client, Employment, Payer and Supplier/Services)
E. Business Development

COMPETENCY AREA KNOWLEDGE & SKILL STATEMENTS

Competency Area: General Financial Knowledge
- Describe the basic models of commercial and government payment for pathologists’ services (e.g., fee for service, bundled payment and accountable care/ coordinated care models) and their revenue cycles
- Describe how pathologists provide value to patients, physician colleagues, and institutions in the context of total patient care
- Identify sources of and influences on pathologist’s revenue (e.g., payer mix, professional component of clinical pathology billing, “Part A”, “Part B” - professional and technical, pay-for-performance)
- Understand both the economics of the practice or group as well as the economics of its overall environment
- Identify sources of and influences on pathologists’ expenses including the cost of obtaining medical knowledge and providing patient care
- Describe the cost structure of a pathologist’s practice including fixed and variable costs and overhead concepts
- Explain the concepts of return on investment, cash flow, contribution to overhead, cost accounting, and interdepartmental charges
- Describe the concept and importance of capital budgeting

Competency Area: Financial Aspects of Administration
- Manage practice finances and allocate resources in a manner that supports both quality and efficiency of care
- Recognize aspects of physician compensation plans (e.g., salary, incentive plans, and benefits)
- Develop and manage a budget
- Forecast workload and finances (e.g., resource demand projection and cash flow management)
- Identify the information needed to obtain resources (e.g., personnel, equipment) to support patient care
- Establish and monitor financial and workload dashboard metrics (e.g., revenue per pathologist) for a pathologist’s practice

Competency Area: Financial and Compliance Risk Management
- Properly code and bill within the payment compliance framework of your medical practice and system setting
- Understand concepts of financial compliance and medical liability risk
- Apply knowledge of CPT coding, CMS regulations, fraud and abuse abatement, and financial integrity efforts (e.g., compliance plans, Recovery Audit Contractors) to manage economic risks to a pathologist’s practice
- Adhere to government regulations on relationships (e.g., Stark, False Claims Act, HIPAA, Employment law, state laws)
Competency Area: Contracting (Facility, Client, Employment, Payer and Supplier/Services)
- Incorporate proper and effective provisions (eg, exclusivity, termination, intellectual property licensing) into a contract
- Evaluate proposals for compliance, profitability, and obligations
- Articulate the tax, malpractice and billing implications of the pathologist’s contract(s) with hospital and outreach customers
- Negotiate successful agreements with contractors
- Make appropriate outsourcing or partnering decisions with external providers (eg, billing, legal)

Competency Area: Business Development
- Develop a business plan for expanding a pathologist’s practice and client base
- Advocate the value of the pathologist’s resources and/or services in improving patient care outcomes, cost-effectiveness of care and patient satisfaction
- Respond to new developments that may impact the practice’s revenue stream (eg, TC/PC arrangements, pod, and joint venture labs)

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Supporting Committee(s)
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Meet the Authors

Authors – Interpersonal and Communication Skills

Building and Maintaining Relationships
Communication
Teamwork

**Gene N. Herbek, MD, FCAP**, is the President-Elect of the College of American Pathologists. He serves as medical director of the Methodist Women’s Hospital Laboratory and medical director of the Transfusion and Coagulation Services for the Pathology Center at Methodist Hospital in Omaha, Nebraska. He is Board certified in anatomic and clinical pathology and is a graduate of the University of Nebraska Medical Center and Residency Training Program. Dr. Herbek has been actively involved in the CAP for more than 22 years and has served on the CAP Board of Governors, formerly serving as Chair of the Finance Committee, Chair of the Council on Membership and Public Affairs, and Vice Chair of the Council of Scientific Affairs among others. Among his many professional honors and awards, Dr. Herbek has received the CAP Outstanding Communicator Award and the St. Luke’s Regional Medical Center, Sioux City, IA, Physician Hero Award. Most recently, Dr. Herbek launched CAP’s first See, Test & Treat™, a program that provides free breast and cervical cancer screening to underserved women in the United States. See, Test & Treat™ is made possible through the volunteer services of CAP member pathologists and their clinical health care colleagues and supported through the generosity of CAP Foundation donors. In 2012, the first Gene and Jean Herbek Humanitarian Award will be presented to a CAP member pathologist to celebrate their impact in the lives of women in need through a See, Test & Treat™ program.

**James S. Hernandez, MD, MS, FCAP**, is the medical director and Chair, Division of Laboratory Medicine, Assistant Professor of Laboratory Medicine and Pathology, Mayo Clinic in Scottsdale and Phoenix, Arizona. He is board-certified by the American Board of Pathology in Anatomic and Clinical Pathology, in May, 1986, and a CAP member since he was a resident. He has served as the Chair of the CAP Self-Assessment (SAM) Committee (2008-2011); Curriculum Committee (2008-2009); the Council on Education (2008-present); and the laboratory medical director Working Group (2010-present). He has been a CAP inspector since 1981. Dr. Hernandez has a Bachelor of Science degree from the University of Notre Dame, Medical Degree from the University of Colorado Health Sciences Center in Denver, and a Masters of Science in Preventive Medicine and Administrative Medicine from the University of Wisconsin-Madison, encompassing both MBA and MPH skills. Dr. Hernandez has spoken at numerous CAP conferences and has a special interest in leadership, management, lab utilization, quality process improvements, safety and cost-effectiveness. He was awarded the Management and Patient Safety Award by the American Association for Clinical Chemistry (AACC) in 2010 and he was named the AACC Mentor of the Month in January, 2011.
Authors – Medical Knowledge/Patient Care

Autopsy

Stephen A. Geller, MD, FCAP is Chairman Emeritus, Department of Pathology and Laboratory Medicine, Cedars-Sinai Medical Center, Los Angeles and Professor, Pathology and Laboratory Medicine, David Geffen School of Medicine, UCLA. Internationally recognized as an expert in hepatopathology, he is also an authority in autopsy pathology and the history of medicine. He has published approximately 200 scientific articles, monographs, and book chapters, and co-authored two textbooks, including Biopsy Interpretation of the Liver; now in its second edition. Former President of the California Society of Pathologists and the Los Angeles Society of Pathologists, he served as Vice-President of the New York Pathological Society when Professor and Vice-Chairman at Mount Sinai School of Medicine, New York. He served the College of American Pathologists on the Anatomic Pathology committee, including as Chairman, and the Autopsy Committee. Co-founder and former Secretary-Treasurer of the Hans Popper Hepatopathology Society, he is also a member of the Rodger Haggitt Gastrointestinal Pathology Society. He has been recognized for his teaching contributions, including the Excellence in Teaching Award from the City University of New York, and is a five-time winner of the Golden Apple Award at Cedars-Sinai. The Los Angeles Society of Pathologists recognized him with its Lifetime Achievement Award.

Jody E. Hooper, MD, FCAP, is an Assistant Professor of Pathology at Oregon Health and Science University (OHSU) and is the Associate Director of the Autopsy Service. She is a member of the CAP National Autopsy Committee and has originated a Rapid Autopsy program at OHSU for recovery of tumor and other tissue for research. After medical school at George Washington University in Washington DC., Dr. Hooper went on active duty as a Lieutenant in the United States Navy with a one year Surgical Internship and four years as a General Medical Officer including two years as the Department Head on the San Diego based ship USS Comstock. Dr. Hooper then completed Pathology residency at Cedars Sinai Medical Center in Los Angeles, CA. After residency she proceeded to Surgical Pathology Fellowship at OHSU and currently remains there. Dr. Hooper has published original articles in Human Pathology and Archives of Pathology and Laboratory Medicine, as well as case studies, reviews, and autopsy education and training materials in various other venues. She is the Vice President of the Oregon Pathologists Association (OPA) and the liaison to the Oregon Medical Association for the OPA.

Patrick Alexander Lento, MD, FCAP, is Professor of Clinical Medicine and Pathology at New York Medical College in Valhalla, NY. As a graduate of Georgetown University School of Medicine, Dr. Lento received his residency training in Internal Medicine and Pathology at The Mount Sinai Medical Center in New York City, where he obtained board certification in Internal Medicine and Anatomic and Clinical Pathology. His main interests include the Autopsy and Medical Education.
Breast Pathology

Patrick L. Fitzgibbons, MD, FCAP, received his B.S. and M.D. degrees from Creighton University School of Medicine, in Omaha, Nebraska. He completed a pathology residency at LA County’s University of Southern California Medical Center followed by a surgical pathology fellowship at Stanford University. Dr. Fitzgibbons has been practicing at St. Jude Medical Center, in Fullerton, California since 1988. He has served on numerous committees for the College of American Pathologists, and is past chairman of both the Surgical Pathology and Immunohistochemistry Committees. Dr. Fitzgibbons is an Associate Editor for Archives of Pathology & Laboratory Medicine, and is the author of almost fifty scientific publications with emphasis on diagnosis and reporting of breast cancer.

David G. Hicks, MD, FCAP, is currently the director of Surgical Pathology at the University of Rochester Medical Center. Dr. Hicks earned his medical degree from the University of Rochester School of Medicine and Dentistry. Dr. Hicks’ current research interests focus on the molecular genetic profiling of clinical samples from patients with cancer. Dr. Hicks has co-authored over 140 peer reviewed articles that have appeared in a variety of journals, including Clinical Cancer Research, The American Journal of Pathology, Cancer and the American Journal of Surgical Pathology. He also serves on the editorial boards of the Archives of Pathology & Laboratory Medicine, Biotechnic and Histochemistry and Applied Immunohistochemistry and Molecular Morphology. As part of the working group for the CAP BPFT AP Program, Dr. Hicks has contributed significantly to the overall direction and development of the BPFT curriculum and assessments.

Cardiovascular Pathology

Dylan V. Miller, is the Director of the Electron Microscopy laboratory at Intermountain Central Laboratory in Salt Lake City, Utah and Associate Professor of Pathology at the University of Utah. He is a cardiovascular pathologist who also practices renal and general surgical pathology. He is currently chair of the CAP Autopsy Resource Committee, Council Member for the Society of Cardiovascular Pathology, and Chair of the Pathology Scientific Council for the International Society for Heart and Lung Transplantation.

Vidhya Nair, MBBS, MD, FRCP, is a cardiovascular pathologist at Hamilton Health Sciences and Assistant Professor of Pathology at McMaster University in Hamilton, Canada. Her special interests include molecular mechanisms of cardiomyopathies, sudden cardiac death, and mechanisms of failure in prosthetic valves.

Stanley J. Radio, MD, FCAP, is the Director of the Cardiovascular Registry, Medical Director of the Cytotechnology Program and Professor of Pathology and Microbiology at the University of Nebraska Medical center in Omaha, Nebraska. He is a cardiovascular pathologist who also practices cytopathology and liver/small bowel transplant pathology. He has special expertise in the pathology of Congenital Heart Disease. He is also a Council Member for the Society of Cardiovascular Pathology.

Special acknowledgement to the Society for Cardiovascular Pathology for their support of this work.
Chemistry

**D. Robert Dufour, MD, FCAP**, a native of Milwaukee Wisconsin, received his B.S. in Chemistry from Marquette University and his MD from Medical College of Wisconsin before residency training in pathology at National Naval Medical Center. Dr. Dufour is a diplomate of the American Board of Pathology in AP/CP and in Chemical Pathology. He is a consultant, Pathology and Hepatology, Veterans Affairs Medical Center, Washington, DC, and Emeritus Professor of Pathology, George Washington University. He has authored one book and edited several others, and written over 200 papers, abstracts, and book chapters, with a major focus on endocrine testing and liver disease. He has received numerous educational awards, including the 2012 Excellence in Education Award from CAP and the 1999 Outstanding Contributions in Education award from AACC. Dr. Dufour is a fellow of the College of American Pathologists and the National Academy of Clinical Biochemistry, and a member of CAP’s Clinical Pathology Education Committee (CPEC).

**Thomas L. Williams, MD, FCAP**, is an anatomic and clinical pathologist who serves as the Medical Director of The Pathology Center at Methodist Hospital in Omaha, NE and directs the chemistry sections at Methodist and Children’s Hospitals. He currently is a member of the CAP Council on Education and a member of the Laboratory Medical Director Advanced Practical Pathology Program Working Group.

**Christian Wunsch, MD, PhD, FCAP**, is a member of the College of American Pathologists. He is an Associate Professor at the University of Miami where he is a clinical pathologist and director or codirector of Pathology Specialty Services, the Biochemical Genetics Laboratory and the core laboratory of the Anne Bates Leach Eye Hospital, all at the University of Miami School of Medicine. He is board certified in Clinical Pathology and has devoted most of his academic career to programming and developing clinical laboratory computer systems. His PhD is in biochemistry.

Cytopathology

**Manon Auger, MD, FCAP**, obtained her MD degree at McGill University, completed her residency training in Anatomical Pathology at the University of Toronto, followed by a Cytopathology Fellowship at the University of Texas M.D. Anderson Cancer Center in Houston. She is Director of the Cytopathology Laboratory at the McGill University Health Center and is an Associate Professor in the Department of Pathology at McGill University. She is a member of the College of American Pathologists’ Cytopathology Resource Committee. Her special interests relate to rapid pre-screening in gynecologic cytology and to fine needle aspirations, in particular, those from the thyroid.

**Cynthia C. Benedict, MD, FCAP**, is a staff pathologist and Director of the Fine Needle Biopsy Clinic at DCL Pathology in Indianapolis, IN. She is a member of the CAP Cytopathology Resource Committee. Dr. Benedict’s sub-specialty interests include cytopathology and ultrasound-guided fine-needle biopsies.
Cytopathology (continued)

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**Mohiedean Ghofrani, MD, MBA, FCAP**, is the Director of Cytopathology and Women’s Health at PeaceHealth Laboratories in Vancouver, Washington. He completed his anatomic and clinical pathology residency and cytopathology fellowship at Yale University. In addition to cytopathology, his special interests include breast and gynecologic pathology as well as pathology informatics. Dr. Ghofrani has coauthored a book chapter and several peer-reviewed articles that have appeared in a variety of journals, including *Cancer Cytopathology*, *Acta Cytologica*, *The American Journal of Surgical Pathology*, and *International Journal of Gynecologic Pathology*, and has presented at several pathology meetings and courses. He has served in the SNOMED International Authority and is currently a member of the CAP Cytopathology Resource Committee. Dr. Ghofrani is the recipient of several awards from a variety of pathology organizations including the CAP Foundation and Universities Associated for Research and Education in Pathology.

**Lydia P. Howell, MD, FCAP**, is Professor and Chair, Department of Pathology and Laboratory Medicine, University of California, Davis School of Medicine, Sacramento, CA; and member of the CAP Cytopathology Resource Committee.

**Daniel F.I. Kurtycz, MD, FCAP**, is the Medical Director of the University of Wisconsin’s State Laboratory of Hygiene (WSLH) (State Public Health Laboratory). He is a Professor of Pathology in the Department of Pathology and Laboratory Medicine of the University of Wisconsin School of Medicine and Public Health. He oversees the Sections of Cytology, Cytogenetics and Newborn Screening at the WSLH and participates in the Surgical Pathology Services of the University of Wisconsin Hospital. Dr. Kurtycz is a member of the CAP Cytopathology Resource Committee and member of the American Board of Pathology Cytopathology Test Development Committee. Dr. Kurtycz’s sub-specialty interests are in gynecologic cytopathology, HPV, and technological adaptations for education.

**Ann T. Moriarty, MD, FCAP**, is a cytopathologist and hematopathologist who works for AmeriPath Indiana. She has had a special interest in the diagnosis of hematopoietic neoplasms using cytological methods. Dr. Moriarty has been practicing cytopathology for 25 years, in both academic and private settings. She is currently the Chairman of the CAP Cytopathology Resource Committee.
Cytopathology (continued)

Rosamund Tambouret, MD, FCAP, is an Assistant Professor of Pathology, Harvard Medical School and Assistant Pathologist, Assistant Director of Cytopathology and Director of Cytopathology Fellowship Program, Massachusetts General Hospital. She is currently a member of the CAP Cytopathology Resource Committee.

Endocrine Pathology

Sylvia L. Asa, MD, PhD, FCAP, is the Pathologist-in-Chief and Medical Director of the Laboratory Medicine Program at the University Health Network and Professor in the Department of Laboratory Medicine and Pathobiology at the University of Toronto. A Clinician-Scientist with a focus on Endocrine Pathology, her research aims to identify the basis for development of endocrine tumors, to improve diagnostic tests, and to identify targets for therapy of those diseases. She has published more than 300 scientific articles, written four books, co-edited three books, and written more than 50 book chapters. Dr. Asa has served as President of the Endocrine Pathology Society (1997-1998) and the US-Canadian Academy of Pathology (2005-2006). As head of the largest pathology department in Canada, Dr. Asa has made innovative changes, with emphasis on subspecialization, automation, electronic initiatives, and telepathology. The department focuses on education and research to understand mechanisms of disease and translate new information into diagnostic and prognostic information for patient care.

Vânia Nosé, MD, PhD, FCAP, received her MD degree from Sao Paulo, Brazil and completed her pathology training at Harvard Medical School and Boston University Medical School. Dr. Nosé is board certified in both Anatomic and Clinical Pathology. Dr. Nosé was an Associate Professor of Pathology, Harvard Medical School; Associate Director of Surgical Pathology, Chief of Endocrine Pathology Service, Director of Quality Assurance, at Brigham and Women's Hospital, Boston, MA until recently. Dr. Nosé is currently the Chief of Endocrine Pathology Service and Director of Quality Assurance of the Department of Pathology at University of Miami School of Medicine, Miami, FL. Dr. Nosé’s main areas of interest include the clinicopathology and molecular genetic findings of endocrine tumors, and familial tumor syndromes. She was President of the Endocrine Pathology Society. Dr. Nosé has over 300 national and international invited lectureships and has served as member of over 12 pathology journal editorial boards. Dr. Nosé has published extensively on endocrine pathology, surgical pathology, and familial tumor syndromes, and has authored more than 125 peer-reviewed scientific publications, and over 20 book chapters. Dr. Nosé recently published the book Diagnostic Pathology: Endocrine part of the Diagnostic Pathology series from Amirsys.
Gastrointestinal Pathology

Andrew M. Bellizzi, MD, FCAP, is co-director of the Immunopathology Laboratory, associate director of the Surgical Pathology Fellowship, and co-director of GI Pathology for the Holden Comprehensive Cancer Center at the University of Iowa. Dr. Bellizzi is a gastrointestinal surgical pathologist, and his research interests include the diagnosis, classification, and etiopathogenesis of human disease, especially in regards to gastrointestinal, pancreatic, neuroendocrine, and hereditary tumors. His teaching emphasizes diagnostic accuracy, etiologic specificity, and therapeutic relevance. He also serves as a member of the College of American Pathologist's Immunohistochemistry Committee.

Chanjuan Shi, MD, PhD, FCAP, is a gastrointestinal (GI) surgical pathologist and molecular pathologist at Vanderbilt University Medical Center. Dr. Shi’s clinical focus is on providing expert cutting edge GI surgical and molecular pathology services. Her particular areas of interest are GI and pancreatic neuroendocrine tumors and pancreatic pathology. Her research mainly focuses on pathobiology of GI and pancreatic neuroendocrine tumors and identification of diagnostic, prognostic, and therapeutic biomarkers for colorectal and pancreatic cancer. She also serves as a member of CAP GI Cancer Protocol Review Panel.

Geoffrey A. Talmon, MD, FCAP, is an associate professor at the University of Nebraska Medical Center (UNMC) in Omaha, NE and specializes in gastrointestinal pathology, renal pathology, hepatopathology, and solid organ transplantation pathology. Dr. Talmon completed his anatomic and clinical pathology residency at UNMC and surgical pathology fellowship at the Mayo Clinic in Rochester, MN. He serves as program director for the pathology residency program, associate director of the gastrointestinal pathology fellowship, director of UNMC’s Tissue Science Facility, and director of pathology education for the second year medical student curriculum. He is currently completing his second term as the secretary-treasurer of the Nebraska Association of Pathologists.

Kay Washington, MD, PhD, FCAP, is professor of pathology and director of gastrointestinal and hepatic pathology at Vanderbilt University Medical Center. Her clinical practice and research focus on diagnosis and clinicopathologic correlation of digestive diseases, with emphasis on colorectal and gastric cancer. She formerly chaired the Cancer Committee for the College of American Pathologists and currently serves on the Council on Scientific Affairs.
Genitourinary Pathology

**Jae Y. Ro, MD, PhD, FCAP**, is a board certified surgical pathologist, specializing in genitourinary and pulmonary pathology at Houston Methodist Hospital, Weill Medical College of Cornell University. Dr. Ro did his pathology resident training at the Case Western Reserve University Hospital and fellowship at the University of Texas, MD Anderson Cancer Center (MDACC). He stayed at MDACC as a professor until 2001 and worked as a chairman and director of pathology at Asan Medical Center Ulsan University in Korea until 2005. He then moved to his current position in 2005. He has multiple appointments (MDACC, Yonsei and Ewha University Hospitals in Korea) besides Houston Methodist Hospital. He devotes most of his time to surgical pathology, but also teaches residents and fellows for one hour every day. He has published approximately 700 peer-reviewed scientific papers, five textbooks, and approximately 30 book chapters. He has served as a guest lecturer in the United States and abroad.

**Mukul K. Divatia, MD, FCAP**, is a board certified anatomic and clinical pathologist with subspecialty training in ophthalmic and genitourinary pathology and is presently an assistant professor in the Department of Pathology and Genomic Medicine at the Houston Methodist Hospital in Houston, Texas. He did his medical training at the Maharaja Sayajirao University of Baroda Medical College in Vadodara, Gujarat, India followed by an AP/CP residency and a fellowship in ophthalmic pathology at the Houston Methodist Hospital. He subsequently completed fellowship training in genitourinary pathology at Cedars-Sinai Medical Center, Los Angeles, California. Dr. Divatia combines his work covering the surgical pathology service with resident education and teaching responsibilities. In addition to ocular tumors, his areas of special interest include kidney tumors and testicular pathology.

Genomics

**Richard L. Haspel, MD, PhD, FCAP**
**Scott Boyd, MD, PhD**
**Jennifer Laudadio, MD, FCAP**
**Long Phi Le, MD, PhD, FCAP**
**Christina Lockwood, PhD**
**Cindy McCloskey, MD, FCAP**
**Gaurav Sharma, MD, FCAP**
**Karl Voelkerding, MD, FCAP**
Gynecologic/Obstetric Pathology

Elizabeth D. Euscher, MD, FCAP, is the section chief of the Gynecologic Pathology Section at The University of Texas M.D. Anderson Cancer Center in Houston, Texas. She has interests in all areas of diagnostic gynecologic pathology with a focus on low grade endometrial carcinoma and sentinel lymph nodes in the setting of gynecologic malignancy.

Oluwole O. Fadare, MD, is a professor of pathology at the University of California San Diego, where he is also the director of surgical pathology. He has clinical interests in all aspects of gynecologic pathology. He is a section editor for Archives of Pathology and Laboratory Medicine and for Diagnostic Pathology, and previously served as an associate editor for Expert Reviews in Obstetrics and Gynecology. He is an editorial board member for several journals, including Human Pathology, Journal of Clinical Pathology, and Advances in Anatomic Pathology.

Olga B. Ioffe, MD, is a gynecologic and breast pathologist and director of anatomic pathology at the University of Maryland School of Medicine. She has authored numerous scientific articles and book chapters in the areas of gynecologic and breast pathology. She is faculty of the ASCP 5-day Gynecologic Pathology course. She also serves as a council member of the Association of Directors of Anatomic and Surgical Pathology.

Miriam D. Post, MD, FCAP, is a board-certified anatomic pathologist at the University of Colorado who completed a fellowship in OB/Gyn pathology and specializes in diagnostic gynecological and obstetric pathology and medical student/resident education. She has authored numerous publications in these areas and is a member of the International Society of Gynecological Pathologists.

Joseph T. Rabban, III, MD, MPH
Head and Neck Pathology

**Susan Muller, MD, DMD** is a Professor in the Department of Pathology, Department of Otolaryngology Head and Neck Surgery, and the Winship Cancer Institute. She has been on the faculty at Emory University School of Medicine since 1995. Dr. Muller completed her Oral and Maxillofacial Pathology training at Emory University, and a Head & Neck Pathology fellowship at the University of Pittsburgh under the tutelage of Dr. Leon Barnes. She has lectured extensively on Oral Pathology both nationally and internationally, and has more than 140 peer-reviewed publications and abstracts. Dr. Muller has contributed more than 35 chapters to textbooks on head and neck pathology. In 2009, Dr. Muller was elected to the American Board of Oral and Maxillofacial Pathology. Since 2008 Dr. Muller has been Editor-in-Chief of Head and Neck Pathology.

**Mary S. Richardson, MD, DDS, FCAP**, is currently the Director of Surgical Pathology at the Medical University of South Carolina. Dr. Richardson earned her medical degree from the Medical College of Georgia and her dental degree from Georgetown University. She is AP/CP certified and board certified in Oral and Maxillofacial pathology. Dr. Richardson’s current research interests focus on head and neck neoplasia, in particular, squamous dysplasia, and sino-nasal tumors. Dr. Richardson has co-authored numerous articles, book chapters, and books. She serves as an ad hoc member to the editorial board for the Archives Otolaryngology. She has served on several CAP committees including Surgical Pathology and as a member of the CAP Head and Neck Cancer Protocol Group.

**Raja R. Seethala, MD, FCAP**, is Associate Professor of Pathology and Otolaryngology and Section Director for Head and Neck/Endocrine Pathology at the Department of Pathology, University of Pittsburgh, Pittsburgh, PA. Dr. Seethala’s interests are in head and neck pathology, particularly salivary gland, bone and soft tissue, and parathyroid glands. Specific interests include biomarker validation in head and neck cancer and tissue banking. He is the author of numerous scientific publications.

**Lester D. R. Thompson, MD, FCAP** is a consultant pathologist with the Southern California Permanente Medical Group, in Woodland Hills, CA. He completed medical school at Loma Linda University and a Pathology Residency at University of California- Los Angeles. After doing advanced training in Cytopathology, he joined the United States Navy (CAPT, MC, USNR) and worked for a decade at the Armed Forces Institute of Pathology, Washington, DC, developing an interest and expertise in Head and Neck and Endocrine organ pathology. He has co-authored over 160 research papers, while lecturing around the world at various national and international society meetings. He currently serves as the co-editor of Head and Neck Pathology; was a founding member and past president of the North American Society of Head and Neck Pathology; and serves on many editorial boards of scientific journals. He has published 6 books in both head and neck and endocrine organ pathology, as well as serving as a major contributor to the World Health Organization books on head and neck pathology and endocrine pathology.
Hematology
Hematopathology

Lydia C. Contis, MD, FCAP

Cherie H. Dunphy, MD, FCAP, is currently Professor of Pathology and Laboratory Medicine at the University of North Carolina at Chapel Hill. She will soon be joining Laboratory Corporation of America located in Research Triangle Park, NC as Director of Hematopathology. Dr. Dunphy earned her medical degree from the Louisiana State University School of Medicine in Shreveport, Louisiana. Her current research interests focus on the applications of flow cytometric, cytogenetic, and molecular techniques to diagnostic hematopathology. Dr. Dunphy has authored and co-authored over 125 peer reviewed articles that have appeared in a variety of journals, including Archives of Pathology and Laboratory Medicine, American Journal of Clinical Pathology, American Journal of Surgical Pathology, Blood, Nature, Modern Pathology, and numerous others. She has authored or co-authored and edited four textbooks. She has also served as a member of the CAP’s Diagnostic Immunology Resource and Instrumentation Resource Committees.

Tracy I. George, MD, FCAP, is Assistant Professor of Pathology at the Stanford University School of Medicine. She received her undergraduate degree from the University of California, Berkeley, followed by medical school and residency in anatomic and clinical pathology at the University of California, San Francisco, including an American Heart Association Research fellowship. She completed fellowships in hematopathology and surgical pathology at Stanford. She serves as Director of Stanford’s Clinical Hematology Laboratory, Bass Center Laboratory for Childhood Cancer and Blood Diseases, Mary Johnson Pediatric Ambulatory Care Center Laboratory and as Associate Director of the RBC Special Studies Laboratory. Dr. George’s research is in the areas of laboratory hematology and translational hematopathology, including the study of myeloproliferative neoplasms. She is currently the pathologist on two clinical trials for patients with mastocytosis. Dr. George is on the editorial board for the American Journal of Clinical Pathology and the International Journal of Laboratory Hematology and she has published numerous peer-reviewed articles, review articles, book chapters and is an author of the AFIP Atlas of Nontumor Pathology, Benign and Reactive Conditions of Lymph Node and Spleen. She received Excellence in Teaching Awards in 2008, 2010, and 2011 from Stanford and is currently chair of the CAP Hematology and Clinical Microscopy Resource Committee and a member of the Council on Scientific Affairs.
Hemostasis Pathology

Charles S. Eby, MD, FCAP

Vandita P. Johari, MD, FCAP received her MD degree from Seth G.S. Medical College, Mumbai, India. After training in Clinical Hematology at St. Mary's Hospital and Imperial College, London, UK, she moved to the US and completed her pathology residency followed by a Hematopathology fellowship at the University of Minnesota. Dr. Johari is the Chief of Clinical Pathology at Baystate Medical Center in Springfield, Massachusetts, and Assistant Professor of Pathology, Tufts University. She is currently serving on the Coagulation Resource Committee for the College of American Pathologists. She has co-authored several scientific publications and two book chapters (including one for Wintrobe's Clinical Hematology) with emphasis on benign hematologic disorders and coagulation.

Histocompatibility

Arthur Bradley Eisenbrey III, MD, FCAP, is a specialist in Transfusion Medicine and Transplant Immunology, board certified in Anatomic and Clinical Pathology with subspecialty board certification in Blood Banking/Transfusion Medicine. Dr. Eisenbrey is an Associate Clinical Professor of Pathology at the University of Toledo Medical College and Clinical Assistant Professor of Pathology at Wayne State University School of Medicine. Colonel (retired) Eisenbrey has additional clinical and research interests in Air and Space Medicine, Immunogenetics, Molecular Diagnostics, and tissue banking. Dr. Eisenbrey is a consultant for clinical and laboratory management services.

Mark Kin Fung, MD, PhD, FCAP, is the Vice Chair of Clinical Affairs, and Director of the Blood Bank and HLA Laboratories at Fletcher Allen Health Care and Associate Professor of Pathology and Laboratory Medicine at the University of Vermont. He is a clinical pathologist with a special interest in transfusion practices and histocompatibility testing, with a more general research interest in health services practices and outcomes research. He is currently a member of the CAP Histocompatibility and Identity Testing Committee, the AABB Clinical Transfusion Medicine Committee, the chair of the AABB Patient Safety Organization's Recipient Advisory Workgroup, and the co-team leader for the Clinical Studies/Transfusion Safety Team for the BEST Research Collaborative.

Patricia M. Kopko, MD, FCAP, is Professor of Pathology at the University of California, San Diego. She is also Director of Transfusion Medicine and Associate Director of the Immunogenetics and Transplantation Laboratory at the University of California, San Diego. She is a clinical pathologist with special interest in transfusion-related acute lung injury (TRALI). She is currently Vice Chair of the CAP Histocompatibility and Identity Testing Committee and a member of the AABB TRALI Working Group.

Paul J. McGowan, MD, FCAP, is an associate pathologist at Boyce and Bynum Pathology Laboratories in Columbia, Missouri. He is a hematopathologist who also practices general surgical pathology. He completed residency training in Anatomic and Clinical Pathology at the University of Missouri-Columbia and fellowship training at The Methodist Hospital in Houston, Texas. He is currently a member of the CAP Histocompatibility and Identity Testing Committee.
Histocompatibility (continued)

Manish J. Gandhi, MD, FCAP, is Associate Professor of Pathology and Laboratory Medicine at the Mayo Medical School, Rochester MN. He is a consultant in the Division of Transfusion Medicine and Director of the Tissue Typing Laboratory at the Mayo Clinic, Rochester MN. He is a clinical pathologist with special interest in blood donor collections and management, transplant immunology and histocompatibility testing. He is currently a member of the CAP Histocompatibility and Identity Testing Committee, UNOS Region 7 Histocompatibility representative and serves on multiple AABB and American Society of Histocompatibility and Immunogenetics (ASHI) committees.

James Lowell Wisecarver, MD, PhD, FCAP

Lesley Ann Kresie, MD, FCAP, is the Medical Director for Laboratory Services at Carter BloodCare in Bedford, TX. She is a board certified clinical pathologist with special interest in transfusion medicine, immunohematology and histocompatibility testing. She has served on several committees within CAP, AABB and ASHI and is currently a member of the CAP Histocompatibility and Identity Testing Committee.

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David Senitzer, PhD, ABMLI, ABHI, is clinical professor of hematology and hematopoietic stem cell transplantation at the City of Hope National Cancer Center. He is also the director of the Histocompatibility Laboratory at the City of Hope, with special interest in the effects of killer immunoglobulin genes (KIR) on hematopoietic stem cell transplantation. He has served on several committees within CAP and ASHI and is currently a member of the CAP Histocompatibility and Identity Testing Committee.

Identify and Relationship Testing

Victor W. Weedn, MD, JD, FCAP

James L. Wisecarver, MD, PhD, FCAP

George C. Maha, PhD, JD
**Immunohistochemistry**

Patrick L. Fitzgibbons, MD, FCAP received his B.S. and M.D. degrees from Creighton University School of Medicine, in Omaha, Nebraska. He completed a pathology residency at LA County - University of Southern California Medical Center followed by a surgical pathology fellowship at Stanford University. Dr. Fitzgibbons has been practicing at St. Jude Medical Center, in Fullerton, California since 1988. He has served on numerous committees for the College of American Pathologists, and is past chairman of both the Surgical Pathology and Immunohistochemistry Committees. Dr. Fitzgibbons is an Associate Editor for *Archives of Pathology and Laboratory Medicine*, and is the author of almost fifty scientific publications with emphasis on diagnosis and reporting of breast cancer.

Megan L. Troxell, MD, PhD, FCAP received her BA degrees from the University of Virginia, and went on to complete MD/PhD and pathology residency training at Stanford University Medical Center, including surgical pathology and renal/immunohistochemistry fellowship training. Since 2005, she has been a faculty member at Oregon Health & Science University in Portland, OR, where she is medical director of the Immunohistochemistry Laboratory. Dr. Troxell is currently a member of the College of American Pathologists’ Immunohistochemistry committee. Other special interests include renal and breast pathology.
Infectious Disease Pathology

Nancy E. Cornish, MD, FCAP is currently the medical officer in the Division of Laboratory Science and Standards in the Centers for Disease Control and Prevention. Before this role, Dr. Cornish worked in community practice as a general pathologist and the director of microbiology for 13 years at the Methodist Hospital and Children's Hospital in Omaha, Nebraska. She is board-certified in anatomic and clinical pathology with a special qualification examination in medical microbiology. Dr. Cornish received her BA in philosophy from the University of Vermont in Burlington, and went on to receive her MD from its College of Medicine. She completed her residency at the Medical Center Hospital of Vermont in Burlington. She completed a microbiology fellowship at the Cleveland Clinic Foundation in Ohio. For more than two decades, Dr. Cornish has been an active member of the College as a faculty, speaker, and presenter; and has made significant contributions to its Curriculum Committee. She also has been an active member with numerous professional pathology organizations, including the American Society of Clinical Pathologists, the American Society for Microbiology, and the Infectious Disease Society of America. Dr. Cornish is an active member of the Women in Medicine and Science Association at Creighton University.

Mary Klassen-Fischer, MD, FCAP, is a pathologist for Joint Pathology Center, Silver Spring, MD. Previously she had been Medical Director of Microbiology and Molecular for Inova Health System and a pathologist at Inova Fairfax Hospital. Dr. Klassen-Fischer spent the first fourteen years of her career at Armed Forces Institute of Pathology where she was chief of Infectious and Tropical Diseases. While at AFIP, she also served as chief of Fungal Diseases, chair of Biosafety, and pathologist for Pulmonary and Mediastinal Pathology, AIDS and Emerging Infections, and Walter Reed and Malcolm Grow Medical Centers. She received a BS in chemistry and biology from King's College, Wilkes-Barre, PA, and MD from University of Pittsburgh. Dr. Klassen-Fischer performed residency at Massachusetts General Hospital and Yale University and was Winchester Fellow of Clinical Microbiology at Yale. She is board certified in Anatomic and Clinical Pathology. Dr. Klassen-Fischer is a member of American Society of Microbiology, Binford Dammin Society of Infectious Disease Pathologists, Disease Transmission Advisory Committee of Organ Procurement and Transplantation Network, and United States and Canadian Academy of Pathology. She is photo and special section editor for Clinical Infectious Diseases.

Bobbi S. Pritt, MD, FCAP, is Director of Clinical Parasitology and Virology in the Division of Clinical Microbiology at the Mayo Clinic and a member of the CAP Microbiology Resource Committee. She completed a 5-year residency in Anatomic and Clinical Pathology at the University of Vermont, followed by a 1-year Clinical Microbiology fellowship at Mayo Clinic. She then joined the department as a Mayo Foundation Scholar and spent a year in the United Kingdom at the London School of Hygiene and Tropical Medicine. There, she was awarded a Masters degree in Medical Parasitology and a Diploma in Tropical Medicine. Her chief academic interests lie in trainee education, parasitology, molecular diagnosis of infections and infectious disease pathology.
Laboratory Medical Direction

Jared Jon Abbott, MD, PhD, FCAP
Curtis L. Buchholz, MD, FCAP
Michael J. Carey, MD, FCAP
Matthew David Carr, MD, FCAP

Edward W. Catalano, Jr., MD, FCAP has practiced Pathology for over 30 years at Palmetto Health Richland Hospital in Columbia, South Carolina and is currently the Vice President of Medical Affairs. He completed his residency at the Medical University of South Carolina and Johns Hopkins Hospital. He is a past President of the S.C. Society of Pathologists and the S.C. Medical Association. He is also a past Chairman of the Board of Pathology Service Associates and the S.C. Medical Malpractice Patient’s Compensation Fund. He has also served as Chairman of the CAP Practice Management Committee and is a member of the CAP Council on Membership and Professional Development.

Robert De La Torre is Chief Operating Officer for Pathology Specialists of Arizona, a 60 member limited liability partnership. The group provides pathology services in the hospital, ambulatory surgery and outreach markets of Arizona. Operations within the corporation in addition to pathology services include a stand alone billing company and a histology/molecular pathology laboratory. He has served in this capacity for 21 years. Bob is a consultant member of the CAP’s Practice Management Committee. He is also an active speaker at CAP educational conferences, the American Society of Clinical Pathologists and the American Pathology Foundation. His prior experiences have included various management positions in hospital administration and the laboratory. He received his undergraduate degree from the University of Washington and his MBA from Arizona State University.

Jeremy S. Ditelberg, MD, FCAP is a gastrointestinal and surgical pathologist at Miraca Life Sciences (formerly Caris Diagnostics), a leading nationwide provider of subspecialty anatomic pathology and molecular pathology services. He is also Pathology Director of Quality Assurance and Improvement at Miraca. He was formerly Director of Anatomic Pathology at St. Vincent Hospital in Worcester, MA and Staff Pathologist at Tufts New England Medical Center in Boston. Dr. Ditelberg received his undergraduate degree from Harvard College and his medical training from the University of Massachusetts Medical School. He completed an Anatomic and Clinical Pathology residency and Gastrointestinal and Surgical Pathology Fellowship at Beth Israel Deaconess Medical Center. Dr. Ditelberg is board-certified in Anatomic and Clinical Pathology by the American Board of Pathology. Dr. Ditelberg is Assistant Clinical Professor of Pathology at Tufts University School of Medicine. He is a member of the College of American Pathologists Practice Management Committee and a former member of the Autopsy Committee and Transformation Case for Change Study Group. He is also a member of the American College of Gastroenterology Public Relations Committee.
Laboratory Medical Direction (continued)

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Juanita J.P. Evans, MD is currently the hematopathology fellow at Penn State Milton S. Hershey Medical Center. Dr. Evans earned her medical degree from the University of North Carolina at Chapel Hill School of Medicine. She served as a member of the CAP’s Practice Management Committee and as delegate to the CAP’s Resident’s Forum. With interests in pathology curriculum development, she has also had roles as Chief Resident and as a member of graduate medical education committee.

Patricia L. Hughey, Chief Executive Officer of UniPath, LLC Denver, Colorado, has 35 years of progressive experience in the administration of pathology. UniPath employs 25 pathologists and serves multiple Denver metropolitan hospitals, surgicenters, and clinicians. In addition, UniPath, LLC operates an independent laboratory, including a centralized facility as well as multiple satellites in associated hospitals. As CEO of UniPath, Tricia has implemented business development initiatives and engineered significant expansion. Tricia has grown their market with a focused commitment to aligning professional and technical resources with long-term strategic goals. Previously, Tricia has held positions within other pathology practice groups, hospital clinical laboratories and national anatomic pathology companies. She is a sought after speaker at many national conferences, and recently completed serving two terms on the CAP Practice Management Committee. She received her B.A. in Business Administration and Economics from Regis College in Denver, CO.

Robert L. Hunter, MD, PhD, FCAP

Molecular Genetics

John Albert Thorson, MD, PhD, FCAP

Angshumoy Roy, MD, PhD is currently a fellow in Molecular Genetic Pathology at Baylor College of Medicine. Dr. Roy earned his medical degree from the University of Calcutta, Medical College and his PhD in Molecular and Human Genetics from Baylor College of Medicine. His current research interests focus on the pathogenesis of embryonal cancers. Dr. Roy has co-authored over 20 peer reviewed articles that have appeared in a variety of journals, including Nature Reviews Endocrinology and American Journal of Surgical Pathology. He also served as a junior member of the CAP Biochemical and Molecular Genetics Resource Committee and is the recipient of awards from the CAP Foundation.
Molecular Oncology

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Chung-Che Chang, MD, PhD, FCAP is a Professor of Pathology, University of Central Florida and Medical Director, Hematology and Molecular Pathology, Florida Hospital. Before joining FL, Dr. Chang was a Professor of Pathology, Cornell University and Chief of Hematopathology Division, The Methodist Hospital. He currently serves as Associate Editor for Archives of Pathology and Laboratory Medicine, is a member of the Molecular Oncology Resource Committee and Diagnostic Immunology/Flow Cytometry Resource Committee for the College of American Pathologists (CAP) and is the CAP Liaison to the NCI Biomarker Committee. He was the Principle Investigator of several NIH/NCI funded grants to study myeloma, myelodysplastic syndromes (MDS), and lymphoma. Dr. Chang completed an M.D. degree at National Yang-Ming Medical University, Taipei, Taiwan and obtained a Ph.D. degree in Biomedical Engineering from Case Western Reserve University (CWRU), Cleveland, Ohio. Dr. Chang completed pathology residency training at CWRU and hematopathology fellowship training at University of Utah. Dr. Chang served as a faculty member at Medical College of Wisconsin and Baylor College of Medicine after training.

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Molecular Oncology (continued)

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**Marina N. Nikiforova, MD, FCAP** is Associate Professor of Pathology and Director of the Molecular Anatomic Pathology laboratory at the University of Pittsburgh Medical Center. Dr. Nikiforova’s clinical interests are focused on molecular diagnostics of solid tumors including thyroid cancer, lung cancer, colorectal cancer, melanomas and brain tumors and on the development of new molecular diagnostic and theranostic assays for cancers including next generation sequencing. Her research interests are in microRNA dysregulation in thyroid cancer with emphasis on identifying microRNA markers for cancer diagnosis. Dr. Nikiforova currently serves on the Molecular Oncology Resource committee, College of American Pathologists and on Laboratory Practice Committee, American Thyroid Association. She is Chair-Elect for the Solid Tumors subdivision at the Association for Molecular Pathology and member of the Advisory Panel for Lung Cancer Biomarker Project, CAP. Dr. Nikiforova has published over 70 peer-reviewed journal articles including publication in Science (*Nikiforova et al. Science 2000, 290: 138-141*) and five book chapters, most of which are focused on various aspects of molecular diagnostics. Dr. Nikiforova has a long standing interest in thyroid diseases, with particular focus on molecular genetics and molecular diagnostics of thyroid cancer and she is one of the leaders in this field.

Orthopedic Pathology

**Dariusz Borys, MD, FCAP**

**Andrew E. Horvai, MD, PhD**

**Gene P. Siegal, MD, PhD, FCAP**

**Shi Wei, MD, PhD, FCAP**
Pediatric Pathology

Michael J. Caplan, MD, is an assistant professor in the Department of Pathology & Laboratory Medicine at Medical University of South Carolina (MUSC). His current focus is teaching but he also practices pediatric pathology and performs forensic autopsies. A particular area of interest is the understanding of differences between the infant and adult head and how those differences affect the particular patterns of blunt-impact head injury in infants and adults. He received an undergraduate degree in criminalistics from Michigan State University, and following graduation, attended medical school at the University of Connecticut School of Medicine. He trained in pathology at The University of Michigan and completed a forensic fellowship at the New York City Office of the Medical Examiner. His first job was at University of Michigan where he trained residents in performing forensic autopsies. Following that, he worked as assistant medical examiner at the Delaware Office of the Chief Medical Examiner. He took a year-long fellowship position in pediatric pathology at Children’s Hospital of Pittsburgh and then took a pathology faculty position at the Medical University of South Carolina, where he had the opportunity to practice both forensic and pediatric pathology and to teach students, residents, and other individuals. After a brief period working in private practice, he returned to MUSC.

Jessica Comstock, MD, FCAP, is a Board Certified Pediatric Pathologist with the University of Utah’s Department of Pathology, Division of Pediatric Pathology, located at Primary Children’s Medical Center. She did her medical training in Iowa City, Iowa at the University of Iowa Carver College of Medicine, and completed an AP&CP residency and pediatric pathology fellowship at the University of Utah. Dr. Comstock devotes most of her time to autopsy and surgical pathology while at the same time teaching residents and fellows. She is developing a special interest in perinatal pathology, especially placental examination and fetal autopsy.

Gail H. Deutsch, MD, is a board certified pediatric pathologist at Seattle Children’s Hospital in Seattle, Washington, and associate professor of pathology at University of Washington Medical Center. Her expertise is in pediatric, developmental, and placental pathology, with a specific interest in characterization of neonatal lung disorders. She is currently co-investigator and lead pathologist of the Human Tissue Core for the NIH-funded Molecular Atlas of Lung Development Program (LUNGMAP), and provides guidance in procuring and evaluating fetal and pediatric lungs for the research centers.

Csaba Galambos, MD, PhD, is a board certified pediatric pathologist at the Children’s Hospital Colorado and an associate professor of pathology at the University Medical School of Colorado, Aurora Colorado. He has interest in all areas of diagnostic paediatric pathology with the focus of diagnostic pulmonary pathology and authored numerous scientific articles and book chapters. He is a lead investigator at the Pediatric Heart Lung Center at the University Medical School of Colorado with a strong clinical, translation, and basic science interest in the regulation of pulmonary vessel development and how its defects contribute to respiratory dysfunction, pulmonary disease, and lung underdevelopment in infants, children, and adults.

Ana Maria Gomez, MD, PhD, FCAP
Pediatric Pathology (continued)

Philip J. Katzman, MD, FCAP, obtained his B.A. in Biochemistry at Brandeis University in 1985. After a position as a technician in the lab of Dr. Michael Carroll at Children’s Hospital, Boston, working on the genetics of the major histocompatibility complex, he completed medical school in 1992 at the University of Vermont including a one-year student pathology fellowship. He undertook several years of pediatric training at the University of Rochester Medical Center from 1992-1995, then completed pathology training in 1998 at the same institution. He obtained subspecialty training in pediatric pathology at Children’s Hospital, Boston from 1998-2000 when he also studied maternal floor infarctions and cardiac disease in DiGeorge syndrome. In 2000 he returned to the University of Rochester Medical Center as faculty in the Department of Pathology and Laboratory Medicine and is currently associate professor specializing in pediatric and perinatal pathology. His research interests over this tenure have included patterns of acute inflammation in ascending intrauterine infections, the inflammatory components of chronic villitis, and he has been supervisor and co-principal investigator of the Placenta Processing Center for the National Children’s Study.

Sarah J. Keating, MD is the director of Perinatal Pathology at Mount Sinai Hospital, Toronto, and is an associate professor in the Department of Laboratory Medicine and Pathobiology at the University of Toronto with a cross appointment to the Department of Obstetrics and Gynecology. Since 2001, she and her colleagues have built a diagnostic, research, and educational perinatal pathology program at Mount Sinai Hospital. Her department offers a dedicated perinatal pathology fellowship program. Her areas of research interest include placental pathologic correlates of intrauterine growth restriction and stillbirth and the investigation of innovative methods of prenatal screening that will predict the development of placental insufficiency.

Portia A. Kreiger, MD, FCAP, is a board certified pediatric pathologist at The Children’s Hospital of Philadelphia and associate professor of clinical pathology and laboratory medicine at the Perelman School of Medicine of the University of Pennsylvania in Philadelphia, PA. She has interests in all areas of pediatric anatomic pathology, but specifically in pediatric lung pathology. She also has a strong interest in quality improvement. She has authored several articles and a book chapter on pediatric lung pathology.

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Pharmacogenomics

YashPal D. Agrawal, MD, PhD, FCAP is an Associate Professor of Clinical Pathology and Laboratory Medicine at the Weill Medical College of Cornell University. Dr. Agrawal is Director of the Central Laboratory and Point of Care Services at the New York Presbyterian Hospital (Cornell Campus), where he oversees the Toxicology and Therapeutic Drug Monitoring laboratory. He obtained his medical degree from India (Maharaja Sayajirao University) and his PhD in reproductive biology from the University of Kuopio, Finland. His specialist training in Pathology was at the Yale New Haven Hospital and at the Massachusetts General Hospital. Dr. Agrawal is board certified in Clinical Pathology from the American Board of Pathology and in Clinical Chemistry from the Medical Board of Finland. He has served as Regional Commissioner for the Veterans Administration. Dr. Agrawal has about 50 publications in peer-reviewed journals. He is a contributor to many books including the CAP Press text book, Clinical Toxicology Testing: A Guide for Laboratory Professionals. He is a recipient of numerous awards including a Docentship in Clinical Chemistry from the University of Kuopio. He currently serves as the vice-chair of the CAP’s Toxicology Resource Committee, and as a member of the CAP Pharmacogenomics and Pharmacogenetics working groups.

Wieslaw B. Furmaga, MD, FCAP graduated from the Collegium Medicum at Jagiellonski University in Poland. He completed a residency program in anatomic and clinical pathology followed by a fellowship in clinical chemistry. He practices pathology at the University of Texas Health Science Center at San Antonio, Texas as a staff pathologist and medical director of the clinical chemistry and molecular laboratories. Dr. Furmaga has served on the Instrumentation Resource Committee of the College of American Pathologists (CAP) since 2008. Since 2009, he has served on the Pharmacogenomics Working Group to develop Pharmacogenomics education. He was actively involved with the CLSI on a project Method Validation by Using Patient’s Sample. His main scientific interest is biomarkers for aggressive prostate cancer as well as biomarkers for monitoring trauma patients with hemorrhagic shock.

Jean Lopategui, MD, FCAP is Director of Molecular Pathology and Clinical Cytogenetics and the Director of the Molecular Genetic Pathology Fellowship Program at Cedars-Sinai. Dr. Lopategui’s primary areas of research interest include hematology/oncology molecular profiling, pharmacogenomics and engineered antibodies in cancer therapy. Dr. Lopategui has participated in molecular and personalized medicine advances including the development of a multiplex RT-PCR assay using a novel dual-probe technique, and a pilot project for genetic disease screening in the Los Angeles Persian Jewish community. He lectures nationally and internationally and is an active member of the College of American Pathologists Pharmacogenomics Committee. Additionally, Dr. Lopategui has been interviewed by PBS for the Nova television series, the New York Times Science section and CBS news for pieces on personalized medicine. Dr. Lopategui earned his medical degree from University of Marseilles Medical School in France and completed his residency in anatomic and clinical pathology at Georgetown University Hospital in Washington, DC and at Tufts University in Boston. Dr. Lopategui is board certified in anatomic pathology and clinical pathology, with subspecialty certification in molecular genetic pathology and hematology.
Pharmacogenomics (continued)

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Pulmonary Pathology

**Mary Beth Beasley, MD, FCAP**

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Toxicology/TDM

YashPal D. Agrawal, MD, PhD, FCAP is an Associate Professor of Clinical Pathology and Laboratory Medicine at the Weill Medical College of Cornell University. Dr. Agrawal is Director of the Central Laboratory and Point of Care Services at the New York Presbyterian Hospital (Cornell Campus), where he oversees the Toxicology and Therapeutic Drug Monitoring laboratory. He obtained his medical degree from India (Maharaja Sayajirao University) and his PhD in reproductive biology from the University of Kuopio, Finland. His specialist training in Pathology was at the Yale New Haven Hospital and at the Massachusetts General Hospital. Dr. Agrawal is board certified in Clinical Pathology from the American Board of Pathology and in Clinical Chemistry from the Medical Board of Finland. He has served as Regional Commissioner for the Veterans Administration. Dr. Agrawal has about 50 publications in peer-reviewed journals. He is a contributor to many books including the CAP Press text book, Clinical Toxicology Testing: A Guide for Laboratory Professionals. He is a recipient of numerous awards including a Docentship in Clinical Chemistry from the University of Kuopio. He currently serves as the vice-chair of the CAP’s Toxicology Resource Committee, and as a member of the CAP’s Pharmacogenomics and Pharmacogenetics working groups.

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Transplant Pathology (Solid Organ)

M. Elizabeth H. Hammond, MD, FCAP is a pathologist and recent Chair of the Department of Pathology at Intermountain Healthcare (Urban Central Region Hospitals), Salt Lake City. She is a Professor of Pathology at the University of Utah School of Medicine, and the Director, Section of Cardiac Pathology of the University of Utah School of Medicine. She is currently a consultant pathologist and board of trustee member at Intermountain Health Care. Dr. Hammond is a former Governor of the College of American Pathologists, and is currently subcommittee chair of the CAP Pathology and Laboratory Quality Center and longstanding member of the Education Counsel.
Authors – Practice-Based Learning & Improvement

Assimilation of External Evidence
Practice Analysis
Process and Outcome Improvement

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Authors – Professionalism

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Leadership

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Leadership (continued)

**Thomas L. Williams, MD, FCAP,** is an anatomic and clinical pathologist who serves as the Medical Director of The Pathology Center at Methodist Hospital in Omaha, NE and directs the chemistry sections at Methodist and Children’s Hospitals. He currently is a member of the CAP Council on Education and a member of the Laboratory Medical Director Advanced Practical Pathology Program Working Group.

Respect for Diversity

**James S. Hernandez, MD, MS, FCAP,** is the Medical Director and Chair, Division of Laboratory Medicine, Assistant Professor of Laboratory Medicine and Pathology, Mayo Clinic in Scottsdale and Phoenix, Arizona. He is board-certified by the American Board of Pathology in Anatomic and Clinical Pathology, in May, 1986, and a CAP member since he was a resident. He has served as the Chair of the CAP Self-Assessment (SAM) Committee (2008-2011); Curriculum Committee (2008-2009); the Council on Education (2008-present); and the Laboratory Medical Director Working Group (2010-present). He has been a CAP inspector since 1981. Dr. Hernandez has a Bachelor of Science degree from the University of Notre Dame, Medical Degree from the University of Colorado Health Sciences Center in Denver, and a Masters of Science in Preventive Medicine and Administrative Medicine from the University of Wisconsin-Madison, encompassing both MBA and MPH skills. Dr. Hernandez has spoken at numerous CAP conferences and has a special interest in leadership, management, lab utilization, quality process improvements, safety and cost-effectiveness. He was awarded the Management and Patient Safety Award by the American Association for Clinical Chemistry (AACC) in 2010 and he was named the AACC Mentor of the Month in January, 2011.

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Respect for Diversity (continued)

Elizabeth A. Wagar, MD, FCAP, Professor Department of Laboratory Medicine, University of Texas MD Anderson Cancer Center, Houston; Chair, Department of Laboratory Medicine, University of Texas MD Anderson Cancer Center; Jose M. Trujillo Endowed Chair, University of Texas MD Anderson Cancer Center. Received MD, 1981, Michigan State University, East Lansing; Internship, Residency, and Fellowship: University of California, San Francisco. Board Certified: Anatomic and Clinical Pathology. Dr. Wagar is a member of the College of American Pathologists, American Medical Association, American Society for Clinical Pathology, American Society for Microbiology. Microbiology Resource Committee, Standards Committee; Team Leader: Laboratory Accreditation Program. (Past) Member: CAP Nominating Committee, Inspection Process Committee, Management Resources Committee, Quality Management Committee. She was awarded with Distinguished Professor: University of Texas MD Anderson Cancer Center, 2010; Faramarz Naeim Teaching Award in Clinical Pathology: UCLA Department of Pathology and Laboratory Medicine, 2002.

Authors – Systems-Based Practice

Informatics

James H. Brassel, MD, FCAP, is Director of Clinical Laboratories at Westchester Medical Center, Valhalla, New York. He received his MD degree from Tufts University School of Medicine. After training in Anatomic and Clinical Pathology, he completed a Fellowship in Blood Banking and Transfusion Medicine at New York Blood Center. He is an active member of the CAP DIHIT Education and Accreditation Working Group, with a special interest in Transfusion Medicine and Medical Informatics.

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Ronald J. Elin, MD, PhD, FCAP is currently the Chair of the Department of Pathology and Laboratory Medicine at the University of Louisville. Dr. Elin earned his medical degree and PhD in biochemistry from the University of Minnesota. His current research interests focus on mineral metabolism particularly magnesium, host defense mechanisms and quality assurance in pathology. Dr. Elin has authored or co-authored over 225 peer reviewed papers that have appeared in a variety of journals, including the New England Journal of Medicine, Archives of Pathology and Laboratory Medicine, and Clinical Chemistry. He currently serves on the Economic Affairs Committee of CAP.

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**Practice and System Integration (continued)**

**Patricia L. Hughey, Chief Executive Officer of UniPath, LLC** Denver, Colorado, has 35 years of progressive experience in the administration of pathology. UniPath employs 25 pathologists and serves multiple Denver metropolitan hospitals, surgicenters, and clinicians. In addition, UniPath, LLC operates an independent laboratory, including a centralized facility as well as multiple satellites in associated hospitals. As CEO of UniPath, Tricia has implemented business development initiatives and engineered significant expansion. Tricia has grown their market with a focused commitment to aligning professional and technical resources with long-term strategic goals. Previously, Tricia has held positions within other pathology practice groups, hospital clinical laboratories and national anatomic pathology companies. She is a sought after speaker at many national conferences, and recently completed serving two terms on the CAP Practice Management Committee. She received her B.A. in Business Administration and Economics from Regis College in Denver, CO.

**Stephen Gerard Ruby, MD, MBA, FCAP,** is the Founder, President and Medical Director of 4path, Ltd. Dr. Ruby completed his fellowship in Surgical Pathology at William Beaumont Hospital, Royal Oak Michigan, with emphasis in Dermatopathology. He completed residency in anatomic and clinical pathology at St. John Hospital, Detroit, Michigan. Dr. Ruby’s professional achievements include a lifetime of innovation and commitment to the practice of pathology. He has authored over 35 peer reviewed articles for journals and is the founder of laboratories (4path, Ltd, and CAS reference laboratory) and businesses (Cell Control Sciences). Dr. Ruby is the President of the Illinois Society of Pathology, Chairman, CAP Practice Management Committee, Section editor, Quality assurance for *Archives of Pathology and Laboratory Medicine*, and in the past, served as president of the Chicago Pathology Society and numerous CPA and other society committees.

**Michael L. Talbert, MD, FCAP,** is chairman of pathology and director of the Pathology Residency Training Program at the University of Oklahoma Health Sciences Center. He serves as chief of service and medical director of pathology and laboratory services at OU Medical Center. Dr. Talbert is chairman of the CAP Graduate Medical Education Committee and serves on the Council on Education and Practice Management Committees.
Practice Finance

Jared Jon Abbott, MD, PhD, FCAP

Curtis L. Buchholz, MD, FCAP

Robert De La Torre is Chief Operating Officer for Pathology Specialists of Arizona, a 60 member limited liability partnership. The group provides pathology services in the hospital, ambulatory surgery and outreach markets of Arizona. Operations within the corporation in addition to pathology services include a stand alone billing company and a histology/molecular pathology laboratory. He has served in this capacity for 21 years. Bob is a consultant member of the CAP’s Practice Management Committee. He is also an active speaker at CAP educational conferences, the American Society of Clinical Pathologists and the American Pathology Foundation. His prior experiences have included various management positions in hospital administration and the laboratory. He received his undergraduate degree from the University of Washington and his MBA from Arizona State University.

Richard R. Ellis, MD, FCAP

Robert L. Hunter MD, PhD, FCAP