ENTRY LEVEL CURRICULUM
for
Medical Laboratory Scientist (MLS)
and
Medical Laboratory Technician (MLT)

This document belongs to all practicing medical laboratory professionals. It is our right to define its contents, our responsibility to monitor and update it, and our privilege to use it to promote the profession and build and maintain accredited educational programs.

Medical Laboratory Science Entry Level Curriculum
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Introduction to the *Entry Level Curriculum*

"The mediocre teacher tells, the good teacher explains, the superior teacher demonstrates, the great teacher inspires.”
- William Arthur Ward

I. The first Entry Level Curriculum (ELC) was published in 2002 and created by educators and practitioners using the Body of Knowledge (BOK) published by ASCLS. Entry Level is defined as the knowledge and skills that a *new graduate* at the MLT or MLS level should possess upon entry into the workforce.

The ELC is designed for several purposes; to
- develop a new program,
- assist the new instructor/professor with course development, and
- update a current program or course.

II. **Development Process**
A sub-committee of the Education Scientific Assembly (ESA) Committee for Educational Programs and Initiatives (CEPI) was assembled in the fall of 2015 to facilitate the process of updating the ELC. The 2015-16 ELC Committee was charged with two main goals:
- Use the recently updated (2014 version) ASCLS Body of Knowledge (BOK) and personal expertise in entry level practice to update the curriculum by removing dated topics and adding new items.
- Ensure differentiation of the MLT and MLS curriculum based on the level of education required for each.

The ELC committee received comments from MLS and MLT educators who attended CLEC 2016 and continued to solicit comments from educators who could not attend. With these comments, a second version was created and distributed to all ASCLS members for comments. These comments were used to create a third revision. Consulting each other, ELC committee members finalized all documents by applying the
Beck/Moon algorithm introduced at CLEC 2016. The algorithm included three basic questions:

- Is it current practice?
- Is it entry level?
- Is it foundational?

In situations where conflicting comments were received, this algorithm provided the criteria for removing dated information from the documents. Upon completion, the third version was submitted to the ASCLS Board of Directors for adoption at the 2016 House of Delegates.

III. **Curriculum Format**

The MLS and MLT entry-level curricula are defined as the knowledge and skills expected of a *new graduate* upon successful completion of a formal educational program. It assumes no work experience other than that required as part of a clinical education affiliated with the program.

The curriculum format is delineated by discipline area within the MLS and MLT levels. Each discipline area is further delineated by major topics which include a sequence and coordination of concepts, principles and theories, and skills.

The curriculum represents a consensus by reviewers of the minimum knowledge and skills required to be successful in an entry level role. The committee developed the final documents with the understanding that all listed technical items may not be available at each educational institution so that in some programs, only cognitive aspects (state, explain, describe) will be taught and at others the psychomotor may also be taught (perform or observe). The committee also expects that some programs will teach beyond what may be included, based upon regional needs of their graduates and availability of resources.

Molecular diagnostics is a new addition to the 2016 version of the ELC. Other changes included moving body fluids from the Chemistry section to create a new Urinalysis and Body Fluids section.
Where there is overlap in some discipline areas, it is cross-referenced to another section within the ELC disciplines. For example, microscopic analysis in Hematology, Urinalysis & Body Fluids, and Microbiology are all cross-referenced to the more detailed microscope section in the General Practice document.

Finally, to assist educators in easily knowing which items were deleted from the previous edition of the ELCs and which items were added, a summary list is included at the end of each discipline section. This information could be useful when revising and updating course material.

IV. Taxonomic Levels
The taxonomic levels within the ELC are identified and based upon a simplified version of Bloom’s taxonomic levels as described in *Clinical Laboratory Education*, written by Susan J. Beck, PhD, MLS(ASCP)CM and Vicky A. LeGrys, DA, MT(ASCP) and published in 2014 by ASCLS.

The cognitive domain includes:
- Level 1: recall of basic knowledge and comprehension
- Level 2: application and interpretation of content
- Level 3: critical analysis, decision making, and problem solving, which relates to the evaluation and processing of knowledge

The psychomotor domain includes:
- Level 1: readiness; an awareness of and ready to perform; observes
- Level 2: competence and confidence with performing a task
- Level 3: proficiency and adaptation, ability to alter performance successfully when encountering unexpected or new situations

The affective domain includes:
- Level 1: awareness of an activity or situation
- Level 2: valuing; attachment of worth and beginning to express behaviors demonstrating value of an activity or situation
- Level 3: commitment; ability to justify values
Taxonomic levels were included to assist new instructors and new programs. For a complete list of verbs, visit the NAACLS website which differentiates cognitive, psychomotor and affective (http://www.naacs.org/PDFviewer.asp?mainUrl=/docs/announcement/writing-objectives.pdf).

V. The Future
This document will be updated every 5 years using the revised BOK. The newly established BOK Review Committee will guide the process.

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Joan Polancic, MSEd, MLS(ASCP)CM & Kyle Riding, PhD, MLS(ASCP)CM
Entry Level Curriculum Committee Co-chairs
Acknowledgements

No project of this magnitude is ever accomplished without the support, advice, and consultative services of many people, including educators, ASCLS members, the ASCLS Board of Directors, and ASCLS Staff. Special thanks to ASCLS staff members Elissa Passiment, Karrie Hovis and Jim Flanigan for their support and assistance.

Medical laboratory professionals from all over the country donated their time, effort, and expertise by serving as reviewers of the document. Thank you to all for your contributions.

Thanks to Marcia Armstrong and Brenda Bouchard, the editors of the 2002 ELC and all contributors. They undertook a major task in developing the curriculum from which this version is based.

Contributors to this Entry Level Curriculum were selected from educational programs by the co-chairs of the ELC Committee. The committee was selected to guarantee equal MLT and MLS representation and to produce documents that were job-related as well as academically appropriate.

Committee members put in innumerable hours to update, collate and review comments, and create final documents. A special thanks to all committee members for your time, expertise and efforts.
<table>
<thead>
<tr>
<th>Co-chairs</th>
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<tbody>
<tr>
<td>Joan Polancic, MSEd, MLS(ASCP)CM</td>
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<tr>
<td>Denver Health School of MLS, Denver, CO</td>
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<tr>
<td>Kyle Riding, PhD, MLS(ASCP)CM</td>
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<td>Instructor, Keiser University MLT Program, Orlando, FL</td>
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<tr>
<th>Administration/Management; Education; General Practice</th>
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<tr>
<td>Kyle Riding, PhD, MLS(ASCP)CM</td>
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<td>Instructor, Keiser University MLT Program, Orlando, FL</td>
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<table>
<thead>
<tr>
<th>Clinical Chemistry and Urinalysis and Body Fluids</th>
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<td>Joan Polancic, MSEd, MLS(ASCP)CM</td>
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<tr>
<td>Denver Health School of MLS, Denver, CO</td>
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<tr>
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<tr>
<td>Saint Paul College MLT Program, St. Paul, MN</td>
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<tr>
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<td>Kyle Riding, PhD, MLS(ASCP)CM</td>
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<tr>
<td>Cathy Shaffner, MLS(ASCP)CM SH</td>
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<tr>
<td>The University of Toledo MT Program, Toledo, OH</td>
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<tr>
<td>Kathleen Finnegan MS, MT(ASCP) CM SH</td>
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<tr>
<td>Clinical Laboratory Sciences, State University of New York at Stony Brook</td>
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Immunohematology and Immunology

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Rebecca Silva, MS, MT(ASCP)  
New England Institute of Technology, Lab Technology Program, East Greenwich, RI
Health care reform environment

Describe the forces affecting changes in the health care environment  Level 1
State changes occurring in laboratories related to health care changes  Level 1

Federal regulations, government organizations/agencies and national organizations

Define the functions and impact on laboratory practice of the following:  Level 1

- Health and Human Services (HHS)—Lab Reimbursement/Fee Schedule
- Center for Medicare and Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Federal Drug Administration (FDA)
- Department of Transportation (DOT)
- Occupational Safety and Health Administration (OSHA)
- Bureau of Biologics (BOB)
- Clinical Laboratory Standards Institute (CLSI)
- Office of Inspector General (OIG)
- Clinical Lab Improvement Amendments (CLIA) regulations and accreditation requirements
- International Standards Organization (ISO)

Describe the governmental laws and regulations that affect the laboratory and their impact  Level 1

- Balanced Budget Act 1997 (BBA)
- CLIA ‘88
- Health Insurance Portability and Accountability Act (HIPPA)
- Federal and state bioterrorism statutes

Recognize the following organizations and agencies and describe their roles in laboratory accreditation  Level 1

- The Joint Commission (TJC)
- College of American Pathologists (CAP)
- State Health Departments
Commission on Office Laboratory Accreditation (COLA)
Substance Abuse and Mental Health Service Administration (SAMHSA)
American Association of Blood Banks (AABB)

State the components of and discuss the process for a laboratory accreditation survey to prepare for an inspection Level 1

**General Management Theory**

Define management, leadership, and administration Level 1

Recognize the features of a good decision and explain the steps to make a sound decision Level 1

Describe the role human behavior plays and its influence in the decision-making process Level 1

Recognize decision-making techniques to resolve the problems and decisions faced by the laboratory Level 1

State sources of conflict and resistance to change and discuss the change process and incorporation of the change process in the overall operations of the laboratory Level 1

Describe leadership within the functions of management Level 1

Recognize the factors that determine leadership success Level 1

List and compare the concepts and advantages of major leadership models Level 2

Explain leadership principles to the management of organizations Level 1

Explain the differences between management of health care organizations and other businesses Level 1

List and explain the major managerial “functions” Level 1

  - Financial management
  - Human resource management
  - Test system management
  - Operations management
  - Information systems/informatics management

State management and motivational theories, their author, and compare them to one another Level 2

  - Maslow’s Hierarchy of Needs
  - Herzberg’s Motivator-Hygiene Theory
McGregor’s Theory X and Theory Y
Management By Objectives (MBO)
Total Quality Management (TQM)
Quality Management System (QMS)

Apply the different managerial and motivational theories to individual case studies  Level 2
Recognize positive influences as well as major barriers to effective communications  Level 1

Financial Management
Explain cost analysis for selection of test methods, instrumentation and/or establishing test prices  Level 1
Explain laboratory productivity and state appropriate parameters  Level 1
Explain fixed versus variable costs for analyses  Level 1
Explain basic techniques used to plan and forecast trends and developments  Level 1
State the principles of third party payment using insurance coding and reimbursement parameters  Level 1
Describe current and future reimbursement for clinical laboratory services from government agencies, insurers, and managed care groups, e.g., third party payment  Level 1
Define medical necessity, advanced beneficiary notices, Medicare secondary payer documents, and diagnosis coding impact on laboratory reimbursement  Level 1
Define National Coverage Determination (NCD) and Local Coverage Determination (LCD) lists  Level 1
Explain the difference between operational and capital budgets  Level 1
Explain the difference between supply expenses and other budget items  Level 1
Explain the process of material management and inventory control  Level 1
Record inventory levels  Level 1

Information Systems
Demonstrate general information technology literacy  Level 2
(cross reference to General Lab Practice)
Use Laboratory Information Systems  Level 2
Use RFID Technology  Level 2
State the characteristics and activities of an information system Level 1
Recognize the features and purpose of networks Level 1
Define information technology terms and explain the use of information technology in the laboratory
Medical informatics
Bar codes
Define the goals and objectives of a laboratory information system Level 1
State the purpose of a procedural flow chart Level 1
State information technology system security Level 1
Use email and required privacy rule(s), encryption Level 2
Identify required mobile device security Level 1
Discuss electronic health records (EHR) and explain the laboratory role Level 2

Human Resources
State by name and function the professional organizations associated with the medical laboratory profession Level 1
American Association of Blood Banks (AABB)
American Association of Clinical Chemists (AACC)
American Medical Technologists (AMT)
American Society for Clinical Laboratory Science (ASCLS)
American Society for Clinical Pathology (ASCP)
American Society for Microbiology (ASM)
Clinical Laboratory Managers Association (CLMA)
Describe the key elements of a performance appraisal system Level 1
Explain the role of human resource management in the operation and functions of the management process Level 1
List, define, compare and contrast associated credentialing mechanisms Level 2
Certification
Licensure
Accreditation
List and compare the certification levels offered and the appropriate initials offered for two year, four year, and doctoral educated laboratorians and the level at which each certification level functions in a clinical laboratory.

- **Board of Certification (BOC)**
- **American Medical Technology (AMT)**
- **American Association of Bioanalysis (AAB)**

List items to be included in position descriptions; explain their use and purpose.

- Explain the use of conferences in employee evaluations
- Prepare a resume or curriculum vitae
- Recognize situations of unethical professional performance
- State appropriate action to correct unethical or unprofessional situations
- Describe CLIA personnel qualifications and responsibilities
  - Laboratory director
  - Technical consultant
  - Clinical consultant
  - General supervisor
  - Testing personnel

State principles of delegation and, given criteria, determine what and to whom to delegate.

- State various techniques to motivate employees
- List incentives for professional development
- Describe workflow productivity
- Review career ladders

**Operations Management**

- Describe elements of a Continuous Quality Improvement (CQI) plan
- Apply Clinical and Laboratory Standards Institute (CLSI) standards for technical procedures
- Maintain an effective quality systems assessment program
- Define Six Sigma
- Describe other/additional quality models
Describe standards for quality assessment       Level 1
Use an effective quality control system  (Cross reference to General Practice section)  Level 2
Explain the purpose of a proficiency testing (PT) program Level 1
State personnel standards including required competency assessment Level 1
Describe and utilize method evaluation and validation (Cross reference to General Practice section) Level 2
Utilize process improvement and problem identification Level 2
Explain data gathering, data process, and use of information systems for data comparisons, storage, transformation, and retrieval Level 1

General healthcare
Explain medical laboratory science’s impact on other healthcare providers and patients Level 1
Discuss the use of clinical laboratory data in the diagnosis and treatment of patients Level 1
Explain model hospital/facility organization Level 1
    Typical hierarchy
    Typical committee structure, laboratory role
    Clinical pathway development, laboratory role
    Expanded or other roles for administrative MLS
        a) Technical consultant
        b) Infection control professional
        c) Information technology professional
        d) Marketing or client relations
        e) Compliance officer
Describe how laboratory services impacts the delivery of care Level 1
Apply CLIA pre-analytical, analytical, and post-analytical aspects to patient care Level 2

Professionalism: Performance standards, roles, philosophy, communication, & ethics
Exemplify concepts and practice of professional standards Level 3
Discuss and apply confidentiality and legal requirements Level 2
Demonstrate ethical and professional standards Level 2
Explain and promote professionalism and professional development impact on laboratory operations Level 2
Explain impact of professionalism on profession and healthcare delivery  
Communicate to other healthcare professionals in an effective manner  

Personnel Safety
   Implement a laboratory safety program (Cross reference to Lab Safety in General Practice section)  
   Use Globally Harmonized System (GHS) of classification and labeling of chemicals  
   Apply OSHA standards  
   Apply ergonomic practices to laboratory tasks  
   Follow policies and procedures to address bioterrorism or other public health issues  
   Follow a disaster preparedness program  

Patient Safety and Testing
   Define patient safety and health care quality using the Institute of Medicine (IOM) definitions  
   Describe the total testing process including pre-analytic, analytic, and post-analytic processes  
   Describe components of health care quality as defined by the Institute of Medicine (IOM)  
   Safe: Avoiding injuries to patients from the care that is intended to help them  
   Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit by avoiding underuse and overuse  
   Patient-centered: Providing care that is respectful of and responsive to individual preferences, needs, and value and ensuring that patient values guide all clinical decisions  
   Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care  
   Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy  
   Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status  
   Explain and utilize methods to measure the effectiveness of laboratory testing  
   Testing performed for screening purposes
Testing performed to monitor progress of chronic diseases
Testing performed to monitor rates of disease diagnosis using measurements of positive and negative predictive values

Follow an effective patient safety program

Describe and apply changes in public health policy and oversight of healthcare delivery system that fosters and improves patient safety

Use facts and trends in sentinel event investigation

Explain overuse, underuse, and misuse of laboratory testing

Distinguish appropriate laboratory tests to order using evidence-based methods

Testing performed to screen for conditions and diseases
Testing performed for diagnosis of conditions and diseases
Testing performed to monitor prognosis after diagnoses of conditions and diseases
Testing performed to monitor therapy implemented to treat conditions and diseases

Recognize and utilize appropriate protocols to monitor utilization of blood products in transfusion services (Cross reference to Immunohematology)

Follow protocols for communicating current standards of laboratory practice for laboratory testing related to specific diagnosis or condition

Describe methods to provide patient-centered laboratory services

Pre-analytic phase of laboratory total testing process
Cultural differences
Patient preferences

Explain to others the how and why of the laboratory testing process

Identify and use methods to evaluate the impact of patient turnaround time on other aspects of healthcare delivery

Identify and use methods to quantify inefficiencies in the pre-analytic, analytic, and post-analytic phases of the total testing process, i.e., quantify savings due to improvement of efficiencies

Technical consultant
List the CLIA qualifications for a technical consultant (TC)
List the CLIA TC responsibilities
Deleted:
Federal regulations, government organizations/agencies and national organizations  
Removed old terms and updated  
HCFA to CMMS  
NCCLS to CLSI  
JCHAO to TJC

Tax Equity and Fiscal Responsibility Act (TEFRA)  
Hill Burton Act  
Medicare Act  
CLIA ‘67

General Management Theory  
Conduct an interview

Information Systems  
Define central processing unit (CPU)

Human Resources  
Define registration  
NCA  
BOR  
ISCLT changed to AAB

Added:
Federal regulations, government organizations/agencies and national organizations  
Balanced Budget Act (BBA) 1997  
HIPPA  
Federal and state bioterrorism statutes  
ISO

General Management Theory  
Features of a good decision  
Define leadership within the functions of management  
Quality Management Systems  
Describe current and future reimbursement for clinical laboratory services  
Define medical necessity, advanced beneficiary notices, Medicare secondary payor documents, and diagnosis coding impact on laboratory reimbursement  
Define National Coverage Determination (NCD) and Local Coverage Determination (LCD) lists
Explain the difference between operational and capital budgets
Explain the difference between supply expenses and other budget items
Explain the process of material management and inventory control

**Information Systems**
- IT accreditation standards
- HITECH
- IT system security

**Human Resources**
- BOC
- AAB
- DCLS

Key elements of a performance appraisal system
Role of human resource management in the operation and functions of the management process
CLIA personnel qualifications and responsibilities
Describe workflow productivity
Career ladders

**Operations Management**
- Six Sigma
- Personnel standards and competency assessment requirements
- Method evaluation and validation
- Process improvement
- Data gathering, data process, and use of information systems for data comparisons, storage, transformation, and retrieval

**General healthcare** – new section

**Professionalism: Performance standards, roles, philosophy, communication, and ethics** – new section

**Personnel Safety** – new section

**Technical consultant** -- new section
### MLS Entry Level Curriculum – Clinical Chemistry

#### Mathematics and Chemical Calculations

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<th>Task</th>
<th>Level</th>
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<td>Perform basic calculations</td>
<td>Level 2</td>
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<tr>
<td>Exponents</td>
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<td>Logarithms</td>
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<td>Molarity/Normality</td>
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<td>Percentage</td>
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<td>Ratios and proportions</td>
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<tr>
<td>Unit conversions (concentration relationships)</td>
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<td>Percent to molarity; molarity to percent</td>
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<tr>
<td>Hydrates</td>
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<td>Osmolality</td>
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<td>Standard solutions</td>
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<tr>
<td>Define Dilutions (Serial and Ratio)</td>
<td>Level 1</td>
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<tr>
<td>Calculate and Perform Dilutions (Serial and Ratio)</td>
<td>Level 2</td>
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<tr>
<td>Define units of systems of measurement</td>
<td>Level 1</td>
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<tr>
<td>Metric</td>
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<td>International system of units (SI units)</td>
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<td>Define conversions between and among systems of measurement</td>
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<tr>
<td>Metric</td>
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<td>SI to metric</td>
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<td>Perform temperature conversions</td>
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<td>Fahrenheit to Celsius</td>
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<tr>
<td>Celsius to Fahrenheit</td>
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<td>Define statistical data for quality control and statistical analyses</td>
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<tr>
<td>Calculate and utilize statistical data for quality control and statistical analyses</td>
<td>Level 2</td>
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<td>Mean, Median, Mode</td>
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<td>Standard deviation</td>
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<td>Confidence limits</td>
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<td>Reference intervals</td>
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<td>Scales, graphs, Levey Jennings charts</td>
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<td>Percentiles</td>
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<td>Define predictive statistics</td>
<td>Level 1</td>
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<td>True positive and negative</td>
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<td>False positive and negative</td>
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<td>Clinical sensitivity and specificity</td>
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<td>Positive predictive value (PPV)</td>
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<td>Negative predictive value (NPV)</td>
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<td>Calculate and utilize statistical data for method verification and comparison studies</td>
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<tr>
<td>Precision</td>
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<td>Coefficient of variation (CV)</td>
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<td>F test</td>
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Commented [JP1]: Cross reference to general practice
Accuracy
    t-test
Linear regression
    Slope
    y intercept
    Correlation coefficient
Define medical decision level and total allowable error

**Instrumentation: Troubleshooting**

Utilize troubleshooting techniques Level 2
Interpret maintenance manual
Correct problem, if possible
Notify manufacturer’s service department, if necessary

**Instrumentation: Spectrometry**

Recognize and explain basic concepts of spectrophotometry Level 1
    Principles of light absorption
    wavelength
    spectrum
    Beer’s law
    complementary spectra
Recognize and describe the function of spectrophotometer components Level 1
    Light source
    Monochromator
    Cuvettes
    Light detectors
    Read-out systems
Describe the operation of a spectrophotometer Level 1
    Function controls
    Explain maintenance/quality assurance of instrumentation Level 1
    Stray light
    Sensitivity
    Linearity
    Wavelength calibration

Establish procedures in the use and calibration of a spectrophotometer Level 2
Perform test procedures on standards, controls, and unknowns Level 2
    Establish a standard curve according to SOP
    Calculate, if necessary, and record quality control (QC) data
    Evaluate quality control data and results
    Accept/reject results
    Take appropriate corrective action, if necessary
    Report results, if acceptable
Perform routine maintenance checks on all spectrophotometers Level 2
    - Follow a maintenance procedure for all spectrophotometers Level 1
    - Follow a documentation tool and procedure for all spectrophotometers Level 1
Correlate test results with other laboratory tests and patient diagnosis  Level 2

**Instrumentation: Turbidimetry and Nephelometry**

Explain basic concepts of turbidimetry and nephelometry  Level 1

- Principles of light absorption and scatter
- Reflectance

**Instrumentation: Atomic Absorption Spectrometry**

Recognize and explain basic concepts of atomic absorption spectrophotometry  Level 1

- Principles of light absorption
  - Generation of atoms from molecules
  - Absorption and emission spectrum
- Identify basic components  Level 1
  - Burner assembly
  - Gas regulators
  - Light source (hollow cathode lamp)
  - Monochromator
  - Light detector
  - Signal conversion electronics
  - Read-out systems

**Instrumentation: Fluorometry**

Identify and explain basic concepts of fluorometry  Level 1

- Principles of light absorption and emission by molecules
- Absorption and emission spectrum

Recognize basic concepts and use of fluorescent polarization

Principles of fluorescence polarization

**Instrumentation: Luminometer**

Recognize basic concepts (Level 1)

- Principles
- Components
- Operation
- Maintenance/quality assurance

Correctly operate luminometer (Level 2)

Perform routine maintenance checks on the luminometer (Level 2)

**Instrumentation: Osmometry**

Recognize and describe unique components relative to Osmometry  Level 1

- Principles of osmolality
- Definition
- Colligative properties

Recognize and describe unique components relative to freezing point instrumentation  Level 1

Basic components
Operation
Maintenance/quality assurance
Calibrate osmometer following established laboratory procedure  Level 2
Describe the measurement of osmolality of solutions  Level 1
Differentiate osmolality and osmolarity  Level 1
Discuss colligative properties of solutions  Level 1
- Boiling point
- Freezing point
- Vapor pressure
- Osmotic pressure
Discuss solute concentration  Level 1
Explain the most common colligative property used to detect concentration  Level 1
Calculate osmolality and osmolal gap  Level 2
Explain the significance of results  Level 1
- Reflection of electrolyte-fluid balance
- Assessment of renal concentrating ability
- Abnormal osmolal gap
Perform test procedures on standards, controls, and unknowns  Level 2
- Accept/reject results
- Interpret and record quality control data
- Report results, if acceptable
- Perform routine maintenance checks on the osmometer
- Correlate test results with other laboratory tests and patient diagnosis

Instrumentation: Electrochemistry
Recognize and explain basic concepts of electrochemistry  Level 1
Principles of electrochemistry
- Potentiometry
- Electrodes
Summarize the use of the Nernst equation  Level 1
Describe the basic components of electrochemistry  Level 2
- Reference electrode
- Indicator electrode
- Salt bridge
Describe the basic concepts of Ion-selective electrodes  Level 2
- Glass
- Solid state
- Liquid membrane
- Immobilized enzyme
Explain the difference between a direct and indirect ISE  Level 1
Electrolyte exclusion effect
Correct common malfunctions according to manufacturer’s protocol  Level 2
Perform test procedures on standards, controls, and unknowns  Level 2
Evaluate quality control data (QC)
Accept/reject results
Take appropriate corrective action, if necessary
Report results, if acceptable
Correlate test results with other laboratory tests and patient diagnosis  Level 2

**Instrumentation: Blood Gas Analyzers**
Recognize and explain basic concepts of blood gas analyzers  Level 1
Describe basic components of blood gas analyzers  Level 2
- pCO2 electrode
- pO2 electrode
- pH electrode
- ISE electrode (if applicable for Ca^{2+}, lactate, etc.; see electrochemistry section)
- Cooximetry
- Sample chamber
- Temperature maintenance system
- Readout systems
Describe operation of blood gas analyzers  Level 2
- Function controls
- Electrode balance with standard gases
- Adjust slope with standard gases
- Sample handling
Perform routine maintenance/quality assurance of blood gas analyzers  Level 2
- Standard gases
- Electrode and membrane care
- Interference
Calibrate the blood gas analyzer following established laboratory procedure  Level 2
Perform test procedures on standards, controls, and unknowns  Level 2
- Accept/reject results
- Interpret and record quality control data
- Report results, if acceptable
- Correlate test results with other laboratory tests and patient diagnosis

**Instrumentation: Refractometer**
Identify/explain basic concepts of refractometer/light refraction  Level 1
Principle
Components
- Prism
- Light source
- Temperature control or compensation
- Calibration scale
- Focusing eyepiece
Operation
- Zero calibration
- Sample selection
- Focus eyepiece
Maintenance/quality assurance
Calibrate refractometer following established laboratory procedure  Level 2
Perform test procedures on controls, and unknowns  Level 2
Accept/reject results
Interpret and record quality control data
Report results
Perform routine maintenance checks on the refractometers
Correlate test results with other laboratory tests and patient diagnosis

**Instrumentation: Balances**

- Identify basic mechanisms and types of balances (Level 1)
- Define balancing terminology (Level 1)
  - Capacity
  - Sensitivity
  - Precision
  - Readability
  - Tare
- Operate balances (Level 2)
  - Level device
  - Pan arrest
  - Weighing paper or boats
  - Cleanliness
  - Temperature
  - Elimination of drafts, vibrations, etc.
- Calibrate balances following established laboratory procedure (Level 2)
- Perform routine maintenance checks on all balances (Level 2)

**Instrumentation: Centrifuges**

- Explain basic concepts of centrifugation (Level 1)
  - Principles of centrifugal force
  - Tachometer
  - Relative centrifugal force
- Identify basic components of a centrifuge (Level 1)
  - Head (rotor)
  - Bowl and cover (chassis)
  - Shields, cups
  - Brushes
  - Cushion
- Describe operation of centrifuge (Level 1)
  - Function controls
  - Balancing
- Perform maintenance/quality assurance of centrifuge (Level 2)
  - Lubrication
  - RPM (tachometer) check
- Calibrate centrifuges following established laboratory procedure (Level 2)
- Operate centrifuges (Level 2)
  - Load and balance
  - Lock head
Select appropriate speed (temperature, if applicable)
Follow safety precautions
Perform routine maintenance checks on all centrifuges Level 2

Instrumentation: Heating Units
Perform routine maintenance on heating units following established laboratory procedure Level 1
Water baths
Heating Block
Check/calibrate temperature setting of heating units Level 2
Correct malfunction according to manufacturer’s manual Level 2

Instrumentation: Electrophoresis
Recognize and explain basic concepts of electrophoresis Level 1
Principles of electrophoresis
Voltage, current
pH
Ionic strength
Buffers
Temperature
Describe the basic components of electrophoresis Level 1
Support media: cellulose acetate/gel/agarose
Chamber
Buffer
Electrodes
Power supply
Densitometer
Describe the operation of electrophoresis Level 1
Sample application
Time
Temperature
Voltage, current
Stains
Densitometer
Perform analyses according to laboratory procedure Level 2
Accept/reject results
Evaluate and record quality control data
Report results, if acceptable
Correlate results with disease/diagnosis Level 2
Perform routine preventive maintenance checks on all electrophoresis systems Level 2
Develop a documentation tool and procedure for all electrophoresis systems Level 3
### Instrumentation: Chromatography

- **Recognize basic concepts of chromatography**  
  Level 1
- **Separation mechanisms (partition, adsorption)**
- **Describe basic chromatography techniques**  
  Level 1
  - Column
  - Thin layer (TLC)
  - Liquid (HPLC)
  - Gas (GLC)
- **Describe the basic components of a chromatography system**  
  Level 1
  - Flow regulation
  - Mobile phase
  - Stationary phase
  - Column
  - Detectors
- **Perform chromatographic calculations**  
  Level 2
  - Retention time
  - Retention volume
  - Rf
  - Efficiency
  - Resolution
  - Analyte identification and quantitation
- **Perform routine preventive maintenance checks on all chromatography systems**  
  Level 2

### Instrumentation: Mass spectrometry

- **Recognize and explain basic concepts**  
  Level 1
  - Principles
  - Components
  - Operation
  - Maintenance/quality assurance
- **Correctly operate, if available (Level 2)**
- **Perform routine maintenance checks (Level 2)**

### Instrumentation: Automation

- **Recognize and explain basic concepts of automated analyzers**  
  Level 1
  - Discrete sample systems, self-contained and special purpose (POC)
- **Describe operations and principles of the automated systems**  
  Level 1
- **Describe the basic components of an automated system**  
  Level 1
  - Sample/reagent pick-up/dilution
  - Transfer module/mechanism
  - Spectrophotometer module
  - Control/calibration module
  - Readout/recorder
  - Operation/calibration
  - Maintenance/quality assurance
  - Troubleshooting

*Commented [U2]: Cross reference to general practice*
General Clinical Chemistry

Evaluate quality control data Level 3
Select control materials for use
Analyze data for acceptability
If data unacceptable, identify problems or causes
Take corrective action to resolve problem and document
Verify or establish reference intervals (“Normal ranges”) Level 3
List reference intervals for major analytes Level 1
Correlate all patient test data for acceptability Level 2
Review normal physiology and function (liver, cardiac, kidney, etc.)
Interpret patient test results using reference intervals and previous patient data
Discuss pathophysiology of “abnormal” results
Recognize and respond to abnormal or critical results
Assess pre-analytic and analytic factors that can affect patient results Level 3
Sample integrity, draw time, preservation or storage
Age, gender, ethnicity
Diet, nutritional status, fasting, post prandial
Exercise, position or posture
Sample processing and identification
Sample preservatives (EDTA, heparin, etc.)
Method interfering substances/sources of error
Recording of results
Report results according to laboratory protocol Level 2
Routine
STAT
Action limits (critical values/read back)

General Clinical Chemistry: Carbohydrates

Define and explain carbohydrate structures and classifications Level 1
Monosaccharide
Disaccharide
Polysaccharide
Glycosidic linkage
Aldose
Ketose
Hexose
Pentose
Isomer
State the components of the disaccharides Level 1
Lactose
Maltose
Sucrose
State the composition and function of each of the following polysaccharides Level 1
Starch
Glycogen
Proteoglycans (mucopolysaccharides)
Glycoproteins

Discuss carbohydrate metabolism Level 1
- Explain the process of digestion and absorption of dietary carbohydrates
- Explain the main transport routes and uptake of carbohydrates
- State the main physiologic functions of carbohydrates
- Explain the following glucose pathways:
  - Insulin and non-insulin routes of entry to cells
  - Glycolysis (aerobic and anaerobic)
  - Glycogenolysis
  - Glycogenesis
  - Gluconeogenesis
  - Kreb's cycle (citric acid or TCA cycle)
  - Pentose phosphate pathway (hexose monophosphate shunt)

Explain the effect of hormones in regulation of blood glucose levels Level 1
- Insulin
- Glucagon
- Cortisol
- Adrenocorticotropic hormone (ACTH)
- Epinephrine
- Thyroxine
- Growth hormone (GH)
- Human placental lactogen (HPL)

Discuss the maintenance of blood glucose levels in the “fed state” (parenteral) and “fasting state” Level 1

Discuss glucose metabolism in relationship to lipid and protein metabolism Level 1

Explain the formation and significance of hemoglobin A1C Level 1

Discuss disease states and disorders associated with carbohydrate metabolism Level 1
- Type 1; Type 2, and gestational diabetes mellitus (GDM)
- Cushing’s syndrome
- Hyperthyroidism
- Hyperpituitarism
- Pheochromocytoma
- Other diseases/conditions

Discuss the diagnostic criteria for Type 1, 2 (impaired glucose tolerance and provisional) and GDM Level 1

Explain etiology, symptoms, and diagnostic criteria of hypoglycemia Level 1

State the cause and resulting disorder(s) for inborn errors of metabolism Level 1
- Fructosuria
- Hereditary fructose intolerance
- Galactosemia
- Glycogen storage disorders
- Lactose intolerance

Discuss methodologies for carbohydrate determinations Level 1

Commented [JP3]: Cross-reference to Urinalysis
State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness of each Level 1
- Glucose oxidase
- Hexokinase
- Glucose dehydrogenase
- Glycated hemoglobin (A1C)
- Glycated serum protein (GSP) / fructosamine

Explain the usefulness of, patient preparation, and the procedure for a glucose tolerance test; include normal and diagnostic levels Level 1
- State the qualitative or quantitative method used for detection Level 1
- Other reducing substances
  - Ketones
  - Lactic acid
  - Urinary sugars
  - Cerebrospinal fluid (CSF) glucose

Explain the usefulness of miscellaneous tests Level 1
- Insulin and C-peptide
- Insulin antibodies
- Lactose tolerance

Perform carbohydrate analyses according to established laboratory protocol Level 2
- Determine acceptability of results
- Report results according to laboratory protocol
- Perform, document, and evaluate quality control
- Correlate all patient results and patient outcomes with disease state or disorder Level 2
- Discuss the usefulness of bedside or at-home glucose monitoring devices; compare results to non-point-of-care analyzer results and include effects of whole blood vs plasma Level 1
- Explain usefulness of estimated average glucose (eAG)
- Discuss recent advances in the measurement and detection of analytes associated with the diagnosis or monitoring of carbohydrate disorders Level 1

General Chemistry: Lipids
- Define lipid associated terminology Level 1
  - Lipid / Lipase
  - Simple /Complex lipid
  - Lipemia
  - Lecithin
  - Sphingomyelin
  - Glycolipid
  - Lipoprotein
  - Apoprotein
  - Esterification
  - Saturated/Unsaturated
- Differentiate among structural characteristics of lipids Level 2
  - Fatty Acids
Cholesterol
Triglycerides
Phospholipids
Steroids

Prostaglandins

Explain the usefulness of prostaglandins  Level 1
Explain and compare the lipoproteins using the difference in lipid and protein composition  Level 2

Chylomicron

Very low density lipoproteins (VLDL)
Low density lipoproteins (LDL)
High density lipoproteins (HDL)

Discuss lipid metabolism  Level 1

Explain the processes of emulsification, digestion, and absorption of dietary lipids
Explain the main transport route of dietary lipids
State the main physiologic functions of lipids
State the origin and main function of each lipoprotein; include major enzymes involved and apoprotein(s) required for normal function

Explain the lipid pathways; include cell and tissue location  Level 1
Fatty acid oxidation; include input and end products
Ketogenesis; include input and end products
Oxidation of ketone bodies
Fatty acid synthesis
Triglyceride synthesis
Cholesterol synthesis
Cholesterol elimination

For the following pre-analytical variations, recognize and explain the effects of each on serum lipid levels  Level 1
Intra-individual variation
Variation due to age, gender, and race
Lifestyle/behavior variations

Discuss lipid metabolism in the “fed state” and the “fasting state”  Level 1
Discuss lipid metabolism in relationship to glucose and protein metabolism  Level 1

Correlate disease states and disorders associated with hyperlipidemias  Level 2

Locate familial lipoprotein disorders nomenclature and the most likely defect  Level 1
State most common disorders/causes associated with secondary hyperlipidemia
State National Cholesterol Expert Panel (NCEP) lipid levels associated with an increased risk for coronary heart disease (CHD) or cerebrovascular accident (CVA)  Level 1
Explain the usefulness of the ASCVD (atherosclerotic cardiovascular disease) risk calculator (ACC/AHA recommendations); identify the six variables used in the ASCVD calculation  Level 1
Describe the most likely cause, clinical significance, and lipid levels associated with hereditary hypolipidemias  Level 1
abetalipoproteinemia
hypobetalipoproteinemia
Tangier disease
Explain the cause and/or effect of disorders associated with lipid imbalances Level 1
Atherosclerosis
Malabsorption states
Biliary obstruction
Pregnancy
Postmenopause
Ketosis
Fatty liver
Lipid storage diseases
Respiratory distress syndrome (Hyaline membrane disease)
Metabolic syndrome

Discuss and perform methodologies for lipid determinations Level 1
State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness Level 1
Cholesterol methods
Triglycerides
LDL methods
Explain the calculation for LDL
HDL methods
Explain the usefulness of apolipoprotein measurements and state the most common methods used for analysis Level 1
Explain the usefulness of patient preparation and the procedure for a fecal fat analysis; include normal and diagnostic levels Level 1
State the qualitative or quantitative method used to detect fat in the urine Level 1
Explain recommended patient preparation protocol, specimen requirements, and abnormal serum appearance when collecting or handling specimens for lipid analysis Level 1
Perform lipid analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2
Discuss the usefulness of Point of Care (POC) cholesterol monitoring devices and compare results to non-POC analyzer results Level 1
Discuss recent advances in the measurement and detection of analytes associated with the diagnosis or monitoring of lipid disorders Level 1

General Chemistry: Proteins
Define the following terms Level 1
Isoelectric point
Zwitterion
Amphoteric
Amino acid
Peptide bond
Complex or conjugated protein
Discuss protein structures and classifications Level 1
Differentiate among protein structures  Level 2
   Primary
   Secondary
   Tertiary
   Quaternary
Discuss protein metabolism  Level 1
   Explain the process of digestion and absorption of dietary proteins  Level 1
   Explain the main transport route of dietary amino acids  Level 1
Discuss synthesis  Level 1
   Non-essential amino acids
   Cellular proteins; include DNA and RNA involvement (including transcription and translation)
State the main physiologic functions of plasma proteins  Level 1
Identify the main site of synthesis for plasma proteins  Level 1
Discuss the degradation of amino acids  Level 1
   Transamination and oxidative deamination
   Ketogenic and glycogenic amino acids
State the electrophoretic fraction in which each is located, the normal function, and disease states associated with abnormal levels  Level 1
   Albumin
   Alpha-1-antitrypsin
   Alpha-2-macroglobulin
   Haptoglobin
   Ceruloplasmin
   Transferrin
   Fibrinogen
   C-reactive protein
   Immunoglobulins
   Explain the cause for elevated urine levels  Level 1
   Albumin (microalbumin)
   Immunoglobulin
   Immunoglobulin light chains (Bence-Jones protein)
   Beta-2-microglobulin
   Explain the role of fetal fibronectin in preterm delivery  Level 1
Correlate disease states and disorders associated with total protein levels and other test results  Level 2
State the reference range for serum total protein and albumin  Level 1
   Explain the cause for the abnormal serum protein  Level 1
   Dehydration
   Multiple myeloma
   Nephrotic syndrome
   Malabsorption
Liver disease
Hemolytic anemia
Acute phase reaction/inflammation/infection
Hypogammaglobulinemia
Congestive heart failure (beta-natriuretic peptide)

Correlate the serum protein electrophoresis pattern with disorders
Liver cirrhosis
Monoclonal gammopathy
Hypogammaglobulinemia
Acute phase reaction
Polyclonal gammopathy/inflammation

Discuss and perform methodologies for protein determinations
State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness
Biuret
Turbidimetry/nephelometry
Dye binding
Protein electrophoresis
UV absorption by peptide bonds

State the property of proteins that allows separation or classification
Electrophoresis
Isoelectric focusing
Ion exchange chromatography
Ultracentrifugation
Gel chromatography
Immunochemical assay
Immunofixation

Perform protein analyses according to established laboratory protocol
Determine acceptability of results
Report results according to laboratory protocol
Perform, document, and evaluate quality control

Perform DNA analyses according to established laboratory protocol
Determine acceptability of results
Report results according to laboratory protocol
Perform, document, and evaluate quality control
Correlate patient results with diseases state or disorder

General Chemistry: Enzymes
Explain/define the terms associated with enzymes
Enzyme

Commented [JP5]: Cross reference to Molecular ELC
Discuss enzyme classification and structure
State the chemical composition of an enzyme
Discuss the classification and naming of enzymes (types of reactions catalyzed)
Discuss enzyme metabolism
State the most common physiologic functions of enzymes
Discuss enzyme kinetics
Basic enzyme reaction/mechanism of catalysis
Activation energy
Active site
Discuss theories of substrate binding by enzymes
Lock and key
Induced fit
Identify the Michaelis-Menten equation/constant
Explain the usefulness of Km and Vmax (Michaelis-Menten curve/Lineweaver-Burke plot) and how to determine given the curve or plot
Discuss reaction orders (zero order/first order)
Discuss factors affecting enzyme reaction rates
Temperature
Substrate concentration
pH
Enzyme concentration
Time
Isoenzymes
Substrate specificity
Co-factors
Discuss function and type of activators
Discuss function and type of inhibitors (reversible/irreversible)
Discuss the synthesis and catabolism of enzymes
Describe the different types of enzyme regulation
Feedback
Product inhibition
Chemical modification (phosphorylation/dephosphorylation)
Synthesis
Proteolytic cleavage

Discuss disease states and disorders associated with enzyme measurement/assay and patient outcomes Level 1

Discuss clinically significant enzymes Level 1
Lactate dehydrogenase (LD)
Creatine kinase (CK)
Aspartate amino transferase (AST)
Alanine amino transferase (ALT)
Gamma glutamyl transferase (GGT)
Alkaline phosphatase (ALP)
Amylase (AMY)
Lipase (LIP)
Cholinesterase/pseudocholinesterase

Discuss the usefulness of measuring enzymes Level 1
Explain the difference in plasma specific vs. non-plasma specific enzymes Level 1
Explain the difference in origin of enzymes of secretion vs. organ specific enzyme Level 1

Discuss how plasma/serum levels are used to assess the extent or severity of disease or effectiveness of treatment Level 1
State the primary tissue source(s) of clinically significant enzymes Level 1
Explain the significance of abnormal serum levels of enzymes and correlate with specific disease states or disorders Level 2
Myocardial infarction
Liver disease
Muscle disease
Bone disease
Malignancy
Hematological disorders
Pancreatitis

Discuss the kinetic measurement (first order, zero order) that is preferred for use in an analytical method Level 1
Explain the difference between endpoint and continuous monitoring kinetic methods and the usefulness of each Level 1
Discuss the use of enzymes as analytical reagents and give examples Level 1
Discuss quantitative or qualitative methods for determining levels of the clinically significant enzymes Level 1
Chemical principle and reaction of the most commonly used methods
Method of quantitation (kinetic, endpoint, immunoassay, etc.)
Specimen required, special preservation, sample treatment
Most common interfering substances/sources of error
Reference interval and units

Perform enzyme analyses according to established laboratory protocol Level 2
Determine acceptability of results
Report results according to laboratory protocol
Perform, document, and evaluate quality control
Correlate patient results with disease state or disorder

**General Chemistry: Disease markers**

Explain the origin and the usefulness in the detection of and risk assessment for an MI

**Level 2**
- CK/MB (if applicable)
- Troponin
- Myoglobin (if applicable)
- hs-CRP
- Lp(a)
- Homocysteine

Explain the most common quantitative or qualitative chemical reaction used for detection

**Level 1**
- CK/MB (if applicable)
- Myoglobin (if applicable)
- Troponin
- hs-CRP

**General Chemistry: Non-protein nitrogen**

Explain the chemical structure, synthesis and mode of excretion of **urea**

**Level 1**

Discuss disease states and disorders associated with urea measurement

**Level 1**

Pre-renal causes
Renal causes
Post-renal causes
Decreased formation (liver disease)
Over-hydration; dilution
End stage renal disease

**Discuss methodologies for urea nitrogen**

**Level 1**

State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness

**Level 1**

Perform urea nitrogen analyses according to established laboratory protocol

**Level 2**

Evaluate acceptability of results

**Level 3**

Report results according to laboratory protocol

**Level 2**

Perform, document, and evaluate quality control

**Level 3**

Correlate patient results with disease state or disorder

**Level 3**

Explain the chemical structure, synthesis and mode of excretion of **creatinine**

**Level 1**

Discuss disease states and disorders associated with creatinine measurement

**Level 1**

Renal disease
Muscle wasting disease

**Discuss methodologies for creatinine**

**Level 1**
For the most common methods, state the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error Level 1
Perform creatinine analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2

State the reference range and explain the usefulness of the BUN/creatinine ratio Level 1
Discuss the advantage and disadvantages of substances for determination of renal clearance

Creatinine
Inulin
Cystatin C

Discuss factors that can influence creatinine clearance results (timing, complete collection, body size) Level 1
Use protocol for performing creatinine clearance tests Level 2
Calculate creatinine clearance results using body surface area normalization Level 2
Differentiate eGFR and GFR Level 2
Recognize factors that can influence eGFR results (age, muscle mass, gender, race)
Recognize optimal eGFR calculation formulas for clinical use

Explain the chemical structure, synthesis and mode of excretion of uric acid Level 1
Discuss disease states and disorders associated with uric acid measurement Level 1
Renal disease
Gout
Increased cell turnover (Leukemia, Chemotherapy, Tumor lysis syndrome)

Discuss methodologies for uric acid Level 1
Perform uric acid analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2

Explain the chemical structure, synthesis and mode of excretion of ammonia Level 1
Discuss methodologies for ammonia Level 1
For the most common methods, state the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error Level 1
Perform ammonia analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2
## General Chemistry: Electrolytes and Trace Elements

**Define terminology associated with electrolytes**  
Electrolyte  
Anion  
Cation  
Intracellular/extracellular  
Anion Gap  
Trace element

Discuss electrolyte metabolism  
Explain the physiologic function and distribution of the following  
- Sodium  
- Potassium  
- Chloride  
- Bicarbonate  
- Calcium  
- Magnesium  
- Phosphate

Describe the regulation of Sodium  
- Dietary intake  
- Aldosterone  
- Renin  
- Atrial natriuretic peptide (ANP)  
- Kidney function

Describe the regulation of Potassium  
- Dietary intake  
- Blood pH  
- Kidney function

Describe the regulation of Chloride  
- Follows sodium  
- Blood pH

Describe the regulation of Bicarbonate  
- Blood pH  
- Renal

Describe the regulation of Calcium/ionized calcium  
- Parathyroid hormone (PTH)  
- Calcitonin  
- Protein effects on total calcium  
- Blood pH  
- Vitamin D

Explain the regulation of Magnesium  
- Renal  
- PTH

Explain the regulation of Phosphate  
- PTH  
- Calcitonin  
- Vitamin D
Discuss trace element metabolism Level 1
   Explain the physiologic function and distribution Level 1
   Iron
   Copper
   Zinc
   Manganese
   Chromium
   Explain the regulation of Iron Level 1
   Intestinal absorption
   Transferrin
   Serum iron
   Ferritin
   Explain the regulation of Copper Level 1
   Absorption
   Ceruloplasmin

Discuss water metabolism Level 1
   Intracellular
   Extracellular
   Explain water movement Level 1
   Osmosis
   Maintenance of electrical equilibrium
   Effect of macromolecules
   Explain water regulation Level 1
   Anti-diuretic hormone (ADH) (vasopressin)
   Renin-angiotensin-aldosterone system
   Thirst center
   Effective arterial blood volume (EABV)
   Explain the lack of regulation Level 1
   Salt intoxication
   Water intoxication
   Edema

Discuss and perform methodologies for electrolyte and trace element measurement Level 2
   Describe the principle of operation and identify components of Ion-Selective Electrodes (ISE) / Colorimetric Procedures/ Atomic Absorption Level 1
   State specimen requirements of Ion-Selective Electrodes (ISE) / Colorimetric Procedures/ Atomic Absorption Level 1
   State most common sources of error of Ion-Selective Electrodes (ISE) / Colorimetric Procedures/ Atomic Absorption Level 1
   Perform electrolyte and trace elements analyses according to established laboratory protocol Level 2
   Determine acceptability of results Level 3
   Report results according to laboratory protocol Level 2
   Perform, document, and evaluate quality control Level 3
   Correlate patient results with disease state or disorder Level 2

Commented [JP7]: See Instrumentation section
Discuss disease states and disorders associated with electrolyte metabolism Level 1

Explain effect on electrolyte levels Level 1
- Edema
- Dehydration
- Dilution (water movement into plasma)
- Diuretic therapy

State reference intervals and critical values Level 1
- Sodium
- Potassium
- Chloride
- Bicarbonate
- Calcium
- Magnesium
- Phosphate

Given the following conditions, list and explain causes, symptoms and diagnostic levels associated with each condition Level 1
- Hyponatremia/pseudohyponatremia
- Hypernatremia
- Hypokalemia
- Hyperkalemia
- Hypochloremia
- Hyperchloremia
- Increased levels of bicarbonate
- Decreased levels of bicarbonate
- Hypocalcemia
- Hypercalcemia
- Hypomagnesemia
- Hypermagnesemia
- Hypophosphatemia
- Hyperphosphatemia

Define and explain the usefulness of the Anion Gap Level 1

Given electrolyte data, calculate the anion gap Level 2

Correlate an increased or decreased anion gap with specific disorders or conditions Level 2

Utilize the anion gap as a quality control measure when performing electrolyte analyses Level 2

Recognize electrolyte patterns that are consistent with disease and those that are consistent with error(s) such as hyperproteinemia, lipidemia, incorrect anticoagulant, etc. Level 1

Discuss disease states and disorders associated with trace element metabolism Level 1

Correlate each with specific diseases or disorders or iron deficiency or iron excess Level 2

- Serum iron
- Transferrin
- Total iron binding capacity (TIBC)
- Serum ferritin
- Free erythrocyte protoporphyrin (FEP)
- Hemosiderin
Correlate each with specific diseases or disorders Level 2
  Serum copper
  Urine copper
  Ceruloplasmin
List disorders associated with deficiency or excess Level 1
  Chromium
  Zinc
Discuss recent advances in the measurement and detection of electrolytes and trace elements Level 1

General Chemistry: Acid-Base and Blood Gas Studies
Define terminology associated with blood gas analysis Level 1
  Acid, acidosis, acidemia
  Base, alkalosis, alkalemia, base excess
  Buffer
  pH
  Partial pressure
  Oxygen saturation, PSO, oxygen capacity
  Hypoxia, hypoxemia
  Henderson-Hasselbalch equation
Discuss blood buffer systems Level 1
  Explain the plasma buffering systems Level 1
    Bicarbonate/carbonic acid
    Phosphate
    Proteins; imidazole group of histidine
  Explain the RBC/hemoglobin buffering mechanism Level 1
Discuss regulation of acid-base balance Level 1
  Discuss the use of the Henderson-Hasselbalch equation Level 1
Describe the reabsorption of bicarbonate by the renal tubules Level 1
  Mechanism/reactions for absorption
    Sodium-hydrogen exchange/H+ secretion
    Sodium-potassium exchange/secretion of K+
    Secretion of ammonia
  Explain factors affecting bicarbonate reabsorption Level 1
  Explain carbon dioxide excretion via the lungs Level 1
    Mechanism for expiration of CO2
    Factors affecting pCO2 or H2CO3
  Explain compensatory mechanisms Level 1
    Pulmonary compensation with primary metabolic change (change in HCO3)
      Hypoventilation if bicarbonate increased (increased pCO2 if increased HCO3)
    Hyperventilation if bicarbonate decreased (decreased pCO2 if decreased HCO3)
    Renal compensation with primary respiratory change (change in CO2)
      Retention of bicarbonate, if CO2 is retained
Excretion of bicarbonate, if CO2 is blown off

Discuss disease states associated with imbalance (may be uncompensated or partly compensated)

- List causes for metabolic acidosis = bicarbonate deficit
- List causes for metabolic alkalosis = bicarbonate excess
- List causes for respiratory alkalosis = decreased carbonic acid
- List causes for respiratory acidosis = increased carbonic acid
- List causes for mixed acidosis (metabolic and respiratory)
- List causes for mixed alkalosis (metabolic and respiratory)
- List causes for compensated metabolic acidosis or respiratory acidosis
- List causes for compensated metabolic alkalosis or respiratory alkalosis

Evaluate blood gas results to determine defect

Discuss oxygen metabolism

- Explain the availability of oxygen
- Alveolar oxygen tension
- Hemoglobin oxygen saturation

Explain factors that affect oxygen dissociation from hemoglobin
- 2,3-diphosphoglycerate (DPG)
- pH
- Temperature
- Carbon monoxide (CO)

Define and explain causes for a shift to the left

Define and explain causes for a shift to the right

Discuss blood gas analysis

- Explain the principle of blood gas analysis
- pH electrode
- pCO2 electrode
- pO2 electrode

Explain the principle of cooximetry

- O2 saturation
- Hemoglobin
- CO
- PSO

Explain specimen collection and handling requirements

Explain most common sources of error

If available, perform blood gas analyses according to established laboratory protocol

Determine acceptability of results

Report results according to laboratory protocol

Perform, document, and evaluate quality control

Correlate patient results with disease state or disorder

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**General Chemistry: Therapeutic Drug Monitoring (TDM) and Toxicology**

Define the terminology associated with drug monitoring

- Therapeutic drug monitoring
- Toxicology
- Pharmacodynamics
Pharmacokinetics

Steady State

Half-life (t1/2)

Therapeutic range

Peak and trough

Discuss pharmacokinetics Level 1

Explain the absorption process of a drug Level 1

Route of administration (oral, IM, subcutaneous, IV)

Transport across cell membrane (passive, active, facilitated)

Factors affecting absorption (size & shape, ionization, lipid solubility)

Explain the process of drug distribution in the body Level 1

Two-compartment model

Effect of body size

Effect of total water content

Effect of overall cardiac function

Effect of pKa of the drug

Plasma protein binding

Volume of distribution (VD)

Explain the basic metabolism or biotransformation in the body Level 1

Explain the mechanisms involved in metabolism/biotransformation Level 1

Exponential rate (t1/2)

Active metabolites

Cellular & tissue locations (liver, kidney, etc.)

Explain the reactions involved in basic metabolism/biotransformation Level 1

Conjugation

Oxidation

Hydrolysis

Reduction

Discuss factors causing enzyme induction or inhibition Level 1

Discuss other factors associated with biotransformation Level 1

Liver function

Kidney function

Change in GI motility or pH

Change in urine pH

Cardiac function

Explain the process of elimination Level 1

Kidney

Glomerular filtration rate

Tubular secretion or reabsorption

Bile

Sweat

Feces

Lungs

Saliva

Define and discuss terminology associated with clinical toxicology Level 1

Drugs of abuse (DOA)

Emergency toxicology

Chronic poisoning
Explain mechanisms of toxicity Level 1
- Interference with enzyme actions and systems
- Blockage of oxygen usage and transport
- Interference with cell function
- Hypersensitivity reactions

Explain factors that influence toxicity Level 1
- Nature of toxicant
- Exposure variables (Dose/route of administration/time)
- Biologic variables (age/race/ethnicity/genetics)

Discuss and perform analytical methods Level 1

Explain and demonstrate proper specimen collection Level 2
- Time of blood draw relative to last dose
- Requirements for legal samples
- Requirements for forensic samples

Explain the usefulness of screening methods Level 1

State the most common analytical methods Level 1
- Spectrophotometry
- Immunoassay
- Chromatography
- Atomic absorption
- Nuclear magnetic resonance (NMR)
- Mass spectroscopy

Perform drug analyses according to established laboratory protocol Level 2
- Determine acceptability of results Level 3
- Report results according to laboratory protocol Level 2
- Perform, document, and evaluate quality control Level 3
- Correlate patient results with disease state or disorder Level 2

Discuss recent advances in the measurement and detection of therapeutic drugs and toxicologic agents Level 1

**General Chemistry: Vitamins, Provitamins, Derivatives**

Recognize basic concepts relating to the clinical significance of vitamins Level 1

Identify classifications of vitamins Level 1

- Water soluble (Thiamine-B1, Riboflavin-B2, Niacin, Pyridoxine-B6, Pantothenic acid, Biotin, Folic Acid, Cyanocobalamin-B12)
- Fat soluble (A, D, E, K)

Describe the metabolism of vitamins Level 1

- Absorption, transport
- Ingestion/Digestion (lipase, bile salts)
- Transportation by LDL
- Storage (Liver, tissues, RBCs)
- Degradation or elimination
- Fat soluble-feces
- Water soluble-urine

Describe the synthesis of Vitamin D
State the function of vitamins as precursors for activators, coenzymes, and accelerators
Level 1

State the specific function of vitamins Level 1
- Vitamin A (vision, cell differentiation, growth, reproduction, immune system function)
- Vitamin D (mineralization of skeleton, calcium and phosphate homeostasis)
- Vitamin E (antioxidant, breakdown of peroxide, integrity of cells)
- Vitamin K (formation of coagulation factors)
- Vitamin C (H⁺ ion transfer, redox reactions, amino acid metabolism, collagen synthesis)
- Thiamine (coenzyme in energy metabolism)
- Riboflavin (precursor for coenzymes FMN or FAD, redox reactions)
- Niacin (precursor for coenzyme NAD, dehydrogenase reactions)
- Pyridoxine (amino acid metabolism & transport, heme synthesis)
- Pantothenic acid (component of Coenzyme A)
- Biotin (coenzyme for carboxyl unit transfer)
- Folic acid (coenzyme for one-carbon transfer reactions)
- Cyanocobalamin (hematopoiesis, fatty acid metabolism)

Describe the symptoms and consequences of vitamin deficiencies and excesses Level 1

General Chemistry: Porphyrins

Identify basic concepts relating to the clinical significance of porphyrins Level 1
Discuss the biochemical reactions involved in heme synthesis Level 1
- Amino levulinic acid (Δ-ALA)
- Porphobilinogen (PBG)
- Uroporphyrinogen (Type I and III)
- Coproporphyrinogen III
- Protoporphyrinogen IX
- Protoporphyrin IX
- Heme

Recognize diseases associated with primary porphyrins Level 1
- Erythropoietic
  - Congenital erythropoietic porphyria (CEP)
  - Erythropoietic protoporphyria (EPP)
- Hepatic
  - Acute intermittent porphyria (AIP)
  - Hereditary coproporphyria (HCP)
  - Variegate porphyria (VP)
  - Porphyria cutanea tarda (PCT)

State diseases associated with secondary porphyrins Level 1
- Lead poisoning
- Hereditary tyrosinemia
- Liver disease
- Iron deficiency anemia

Recognize basic principles of porphyrin analysis Level 1
- Porphobilinogen – Watson-Schwartz & Hoesch
- Delta-ALA
- Porphyrins – Chromatography, Fluorometry, Spectrophotometry
Zinc protoporphyrin
Heme biosynthetic enzymes

Discuss basic concepts relating to the significance of bilirubin Level 1
Heme catabolism
Bilirubin conjugation
Recognize and explain diseases associated with bilirubin metabolism Level 1
Prehepatic jaundice (neonatal/hemolytic anemia)
Dubin-Johnson syndrome
Rotor’s
Crigler-Najjar
Hepatitis
Cirrhosis
Post-hepatic jaundice

Discuss methods of analysis for total/direct bilirubin Level 1
Evelyn-Malloy
Jendrassik-Grof
Spectrophotometry
Perform porphyrin/ bilirubin analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Perform and document routine preventative maintenance Level 2
Correlate patient results with disease state or disorder Level 2

General Chemistry: Endocrinology

Define endocrine terminology Level 1
Hormone
Endocrine
Releasing factor/hormone
Tropic hormone
Effector hormone
Glucocorticoid
Mineralcorticoid
Diurnal variation
Discuss hormone structures and classifications Level 1
Describe the mechanism of action of protein hormones Level 1
Growth hormone
Adrenocorticotropic hormone (ACTH)
Thyroid stimulating hormone (TSH)
Follicle stimulating hormone (FSH)
Luteinizing hormone (LH)
Prolactin (PRL)
Antidiuretic hormone (ADH)/vasopressin
Calciitonin
Parathyroid hormone (PTH)
Insulin
Glucagon
Gastrin
Secretin
Human chorionic gonadotropin (HCG)

Describe the mechanism of action of steroid hormones Level 1
Cortisol
Aldosterone
Androgens
  Testosterone
  Dehydroepiandrosterone (DHEA)
  Dehydroepiandrosterone-sulfate (DHEA-S)
Progesterone
Estrogens/estradiol/estriol

Describe the mechanism of action of amine hormones Level 1
Catecholamines
Thyroxine (T4)
Triiodothyronine (T3)
Serotonin/5-hydroxyindolacetic acid (5-HIAA)

Discuss hormone metabolism Level 1
Explain the physiologic function and effects of hormones Level 1
Discuss biosynthesis of hormones Level 1
  Significant precursors
  Pathways/reactions
  Control of hormone secretion
  Source of hormone
  Target gland or tissue(s)
Discuss the catabolism of hormones Level 1
  Pathways/reactions
  Mechanism(s) for elimination
Explain how non-protein hormones are transported in the blood Level 1
Discuss disease states and disorders associated with endocrine metabolism Level 1
Explain the difference between primary, secondary, and tertiary disorders Level 1

Explain the cause and symptoms associated with each disorder Level 1
Explain most common screening and diagnostic testing for hypothyroid disorders Level 1

Hashimoto's thyroiditis
Myxedema
Congenital

Explain most common screening and diagnostic testing for hyperthyroid disorders Level 1
Grave's disease
thyroid adenoma
toxic multinodular goiter

Explain the primary causes of abnormal thyroid tests with non-thyroid illness (NTI) Level 1
Explain the most common screening and diagnostic testing for adrenal disorders Level 1

Conn’s syndrome (primary hyperaldosteronism)
Secondary hyperaldosteronism
Cushing’s syndrome
  Cushing’s disease
  Adrenal tumor
  Adrenal hyperplasia
  Ectopic production of ACTH
Congenital adrenal hyperplasia (CAH)
Hypoadrenocorticolism
  Acute
  Addison’s disease
Adrenal medulla disorders
  Pheochromocytoma
  Neuroblastoma
Pituitary dysfunction
  Hypopituitarism and panhypopituitarism
  Hyperpituitarism

Discuss factors that affect hormone levels other than endocrine diseases Level 1

Emotional stress
Time of day
Menstrual cycle
Menopause
Food intake/diet
Hormone therapy
Drugs

Discuss relevant hormone and/or metabolite determinations in Thyroid Testing Level 1

For each hormone/metabolite, state the principle of the method, any special patient preparation, sample types required, reference interval, most common interfering substance/source of error, and the usefulness of each (screening vs. diagnostic tests)

- TSH
- Free T4
- Free T3
- Reverse T3
- Thyroxine binding globulin (TBG)
- Antithyroid antibodies (TSI, TPO, ATA)

Discuss relevant hormone and/or metabolite determinations in Adrenal Testing Level 1

- Cortisol
- Urinary/Primary free cortisol
- ACTH
- DHEA-S
- Dexamethasone suppression test
- Metyrapone test
- ACTH stimulation test
- Aldosterone
- Renin
- Catecholamines

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Vanillylmandelic acid (VMA) and metanephrines
Discuss relevant hormone and/or metabolite determinations in Metastatic carcinoid tumor
analysis Level 1
Serotonin
5'-HIAA
Discuss relevant hormone and/or metabolite determinations in Infertility Testing
Level 1
FSH
LH
Testosterone
Progesterone
Estrogens
Discuss relevant hormone testing for pituitary/hypothalamus testing
ADH
ACTH
GH
Prolactin
Perform hormone analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2

Genetic Disorders
Define genetic disease Level 1
Categorize and list examples of genetic diseases Level 1
Chromosomal aberration
Inborn errors of metabolism
Polygenic disorders
Describe tests used to evaluate the risk of fetal chromosomal abnormalities
Human chorionic gonadotropin (hCG)
Estrogens
Alpha fetoprotein (AFP)
Pregnancy-associated plasma protein-A (PAPP-A)

Commented [JP9]: Cross reference to UA
**Math and Instrumentation**

Perform basic calculations – specific gravity
Define units of systems of measurement – nonmetric
Define conversions between and among systems of measurement – metric to nonmetric, nonmetric to metric and SI, SI to nonmetric
Calculate and utilize statistical data for quality control and statistical analyses – sampling
Discuss principles of basic electronics: Components, Voltage, current, resistance concepts – OHM’s law
Activate and calibrate spectrophotometer following established laboratory procedure
Establish procedures to be used in the activation of a spectrophotometer
Identify basic concepts of coulometric amperometry
Instrumentation: pH meter (a stand-alone meter)
Develop a maintenance procedure for all balances
Develop a maintenance procedure for all centrifuges
Perform routine maintenance on a hot plate
Establish lab procedures for electrophoresis

**Proteins:**

Discuss the role of gene therapy in treating genetic disorders
Compare recent advances in the measurement and detection of analytes associated with the diagnosis or monitoring of protein disorders

**Enzymes:**

Discuss clinically significant enzymes – CK isoforms, Acid phosphatase
Ischemia modified albumin (IMA)

**Electrolytes and Trace Elements:**

Correlate UIBC with specific diseases or disorders or iron deficiency or iron excess

**Endocrine:**

Total T4, Total T3, T uptake, Free thyroxine estimate/index (FTE/FTI)
Genetic Disorders:
Perform laboratory screening procedures for the diagnosis of each metabolic disorder
- Urine color
- Urine odor
- Urine crystals
- Colorimetric tests on urine

Math and Instrumentation
Perform basic calculations – normality
Define predictive statistics: True positive and negative, False positive and negative, Clinical sensitivity and specificity, Positive predictive value (PPV), Negative predictive value (NPV)
Calculate and utilize statistical data for method verification and comparison studies
  - Precision - Coefficient of variation (CV); F test
  - Accuracy - T-test, Linear regression- slope(m), - y intercept(b); Correlation coefficient(r)
Identify basic components of atomic absorption- Burner assembly, Gas regulators, Light source (hollow cathode lamp), Monochromator, Light detector, Signal conversion electronics, Read-out systems
Identify basic concepts and principles of fluorescent polarization
Identify basic concepts of a luminometer: Principles, Components, Operation, Maintenance/quality assurance
  - Correctly operate luminometer
  - Perform routine maintenance checks on the luminometer
Calibrate an osmometer following established laboratory procedure & perform test procedures on standards, controls, and unknowns
Identify/explain basic concepts of refractometer/light refraction; calibrate; perform testing
Identify basic concepts of mass spectrometry
  - Principles
  - Components
  - Operation
  - Maintenance/quality assurance
Correctly operate (if available) and perform routine maintenance checks

Carbohydrates:
State the components of the disaccharides: Lactose, maltose, sucrose
State the composition and function of each of the following polysaccharides: starch, glycogen, proteoglycans (mucopolysaccharides), glycoproteins
Explain the following glucose pathways:
- Insulin and non-insulin routes of entry to cells
- Glycolysis
- Glycogenolysis
- Glycongenesis
- Gluconeogenesis
- Kreb’s cycle (citric acid or TCA cycle)
- Pentose phosphate pathway (hexose monophosphate shunt)

Explain diagnostic criteria for Type 1, 2 (impaired glucose tolerance and provisional diabetes mellitus), and GDM

Explain the difference between adrenergic and neuroglycopenic symptoms

Explain the usefulness of estimated average glucose (eAG)

**Lipids:**
Given serum appearance, and cholesterol and triglyceride levels, classify the lipoprotein disorder according to familial lipoprotein disorders nomenclature and explain the most likely defect

State most common disorders/causes associated with secondary hyperlipidemia

State National Cholesterol Expert Panel (NCEP) lipid levels associated with an increased risk for coronary heart disease (CHD) or cerebrovascular accident (CVA)

Explain the usefulness of the ASCVD (atherosclerotic cardiovascular disease) risk calculator (ACC/AHA recommendations); identify the six variables used in the ASCVD calculation

**Proteins:**
Explain the role of fetal fibronectin in preterm delivery

Congestive heart failure (beta-natriuretic peptide)

**New Disease Markers:**
Explain the origin and the usefulness in the detection of and risk assessment for an MI
- hs-CRP
- Lp(a)
- Homocysteine

**Non-protein nitrogen:**
Discuss the advantage and disadvantages of cystatin for determination of renal clearance

Differentiate eGFR and GFR

**Electrolytes and Trace Elements:**
Explain the role of atrial natriuretic peptide (ANP) in sodium regulation
State the most common methods of analysis - nuclear magnetic resonance (NMR), mass spectroscopy

**Genetic disorders:**
Describe tests used to evaluate the risk of fetal chromosomal abnormalities
- Human chorionic gonadotropin (hCG)
- Estrogens
- Alpha fetoprotein (AFP)
- Pregnancy-associated plasma protein-A (PAPP-A)
Education
MLS Entry Level Curriculum

Compare and contrast competency and proficiency Level 2
Describe the characteristics and qualities of an effective instructor Level 1
Define basic educational terms Level 1
  Competence or competency
  Objectives
Curriculum (as it applies to laboratory science programs)
Articulation (as it applies to laboratory science programs)
Continuing education unit (CEU)
Accreditation
Certification
Continual Maintenance Program (CMP)
Licensure
Reciprocity
Evaluation
Discuss the three domains of learning Level 1
  Cognitive
  Psychomotor
  Affective
Describe the three modified taxonomy levels for the cognitive domain Level 1
  Level 1: Recall of information (knowledge)
  Level 2: Understand information and applying it to other material or new situations (comprehension/application)
  Level 3: Problem solving (analysis/synthesis/evaluation)
Explain the purposes and uses of objectives Level 1
List the components of a well written objective Level 1
Given an example of an objective, distinguish the domain and taxonomic level Level 2
Given an example of a learning activity, identify the domain and taxonomic level  

State the purposes for evaluating learner performance and the type of evaluation instruments available for use with each educational domain  

Define terms used with various evaluation instruments  
  Criterion referenced and norm referenced examinations  
  Formative and summative evaluation  
  Subjective and objective evaluation  

Choose the most objective and effective evaluation method to use for a given learner performance  

Develop effective examination questions  
  True-false  
  Multiple choice  
  Matching  
  Short answer  
  Essay  

Analyze multiple choice questions to evaluate whether the question is correctly written; strengthen the item when needed  

Prepare an examination correlating objectives with test items  

Explain at least three common errors made by evaluators when using “rating scales”  

Describe and contrast instructional methods; give examples for the appropriate use of each method  
  Lecture  
  Discussion/tutorial  
  Demonstration  
  Simulation/role playing/practice  
  Individualized/self-instruction/computer instructional unit  
  Problem-based learning  
  Cooperative learning  

Use instructional technology while delivering educational materials using best practices  

Audio-visual program
Computer assisted programs
Blended/hybrid methods
Online instruction
Simulation models

Prepare, deliver, and evaluate an effective experience Level 3
A presentation
A one-on-one clinical teaching activity

State the elements needed to create an effective environment for clinical education, including the relationship of clinical methods to theoretical knowledge Level 1
Describe the accreditation process Level 1
Discuss the importance of staff development programs and continuing education Level 1
MLS ELC Education

Deleted and added items

**Deletions**

Define Registration

Establish in-service programs

**Additions**

Define reciprocity

Compare and contrast competency and proficiency

Replaced *distance learning* with hybrid, online, simulation, etc.

Changed *establish* staff development programs to *discuss the importance* of staff development
Laboratory Safety

Identify the following safety equipment and explain their use  Level 1

- Fire extinguishers, blankets
- Fume hood
- Eye wash
- Safety shower
- Personal Protective Equipment
- Splash guards
- Vented storage cabinets
- Acid storage cabinets
- Flammable storage cabinets
- Broken glass/sharps containers
- Spill kits
- Biological safety cabinet
- Engineering controls

Inspect and maintain safety equipment  Level 2

- Follow procedures and techniques for maintenance, inspection and use of safety equipment
- Determine location of safety of safety equipment
- Monitor inspection, maintenance and documentation of safety equipment
- Locate, maintain, and utilize safety data sheets (SDS)

Recognize and report hazardous situations  Level 2

- Identify potential sources of lab hazards
  - Fire
  - Electrical
  - Chemical
  - Biological/bioterrorism
Document laboratory accidents and unsafe procedures Level 2

Utilize appropriate safety equipment and procedures according to established laboratory protocol Level 2

Stock and maintain emergency medical supplies Level 2

Follow laboratory protocol for disposal of contaminated materials Level 2

Properly decontaminate work surfaces Level 2

**General Laboratory Supplies and Equipment**

**Glassware/Plasticware**

Identify attributes, advantages, advantages and disadvantages of specific type of labware Level 1

Select appropriate labware for specific procedures Level 2

- **Nonvolumetric**
  - Beakers
  - Flasks
  - Cuvettes
  - Pipettes

- **Volumetric**
  - Flasks
  - Pipettes

- **Automated pipets**

Correctly use labware Level 2

Correctly dispose of used labware Level 2

Describe how to clean nondisposable labware Level 1

Describe or perform calibration of pipets Level 1

**Reagent water**

Describe methods of water purification Level 1

- Distilled
- Deionized
- Reverse osmosis
Explain types of (CLSI) reagent grade water Level 1

**Chemicals**

Explain grades of purity Level 1

- Commercial or technical
- Commercially pure
- Reagent grade
- United States Pharmacopeia certified (USP)

Perform solution preparation Level 2

- Select correct chemical
- Perform necessary calculations
- Weigh/measure concentrates
- Label and store
- Observe safety requirements

**Standards/controls**

Define types of standards Level 1

- Primary
- Secondary

Define types, uses and limitations of controls Level 1

- Assayed
- Unassayed

**Microscopes**

Prepare microscope for optimized viewing Level 2

- Clean microscope components using appropriate care
- Adjust light source for proper illumination level
- Place filters (e.g., neutral density) in light path appropriately
- Protect microscope from dust when not in use, i.e., dust cover
- Select type of microscopy and adjust appropriately for optimum viewing (brightfield, phase contrast, polarizing, interference contrast, red compensating filters)
- Optimize condenser position
  - Height
Centration

Adjust diaphragms appropriately for optimum viewing  Level 2
Field iris
Condenser aperture

Check and perform phase ring alignment for phase microscopy, if available  Level 2
Place polarizing filters in light path correctly for polarizing microscopy, if available  Level 2
Operate microscope, i.e., place, focus, and scan mounted specimen  Level 2
Secure microscope slide on mechanical stage  Level 2
Check and perform interpupillary and diopter adjustments  Level 2
Select and interchange objectives  Level 2
Use coarse and fine adjustments  Level 2
Use mechanical stage adjustment knobs to scan mounted specimen  Level 2

Information Technology

Define the essential components of software  Level 1
Operating systems
Drivers
Application programs
Word processing
Spreadsheet
Data base management
Graphics
Communication (e-mail)
Internet/web-based options
Presentation programs (PowerPoint, etc.)

Perform basic operation of computer systems  Level 2
Enter data
Transmit
Retrieve data
Present data/information
Quality Control (cross reference to clinical chemistry)

Define and apply basic QC theory, methods, and statistics Level 2

Mean
Mode
Median
Standard deviation
Coefficient of variation
Reference intervals
Variance
Linear regression
Correlation coefficient
Gaussian distribution
Scales, graphs, charts
Levey-Jennings charts
Westgard Multirule system

Define and properly utilize controls and reference materials/standards Level 2

Assayed/unassayed controls
Primary/secondary standards

Define type of laboratory errors and biases Level 1

Preanalytical
Analytical
  Random
  Systematic
Postanalytical

Identify sources of lab error Level 1

Monitor and prevent laboratory errors Level 2

Explain quality control programs Level 1
  Internal
  External
Interpret statistical data  Level 2
Define, explain and interpret patterns  Level 2
  Shifts
  Trends
Perform all quality control procedures according to established protocol  Level 2
  Collect data and perform statistical analyses
Monitor and interpret quality control data  Level 2
  Recognize shifts, trends and other deviations
  Identify sources of error
  Verify laboratory proficiency
  Implement corrective action

Control of equipment and supplies
  Perform maintenance, calibration and storage of laboratory supplies and equipment  Level 2
  Document quality assurance schedules  Level 2
  Maintain and troubleshoot quality control logs  Level 3
  Define and/or use a document control system  Level 1

Method selection and evaluation  (cross reference to clinical chemistry)
  Discuss why new tests or methods may need evaluation and implementation  Level 1
    Physician request
    Method replacement
  Define basic concepts of method selection and evaluation  Level 1
    Positive Predictive Values
    Negative Predictive Values
    Pediatric method
    Stat method
    Routine procedure
  Perform cost analysis of new methods  Level 2
    Reagents
List and explain basic concepts of equipment selection and evaluation

Supplies
Space requirements
Sample requirements
Throughput/turnaround time
Waste requirements
Chemical hazard and safety considerations
Laboratory information system interface
Service contracts

Explain analytical performance parameters

Accuracy
Precision
Sensitivity
Specificity
Linearity/reportable range
Comparison studies
Regression analysis
Interference studies
Recovery studies
Verification of manufacturer’s performance

Explain how to determine a reference interval

Review literature
Selection of population for specimens
Collections and handling of specimens
Statistical analysis of data

Review literature for new methodology Level 2

Perform evaluation studies according to accepted protocol Level 2

**Management of Services and Quality**

- Comply with federal laws, regulations, and guidelines e.g., HHS, CDC, OSHA, EEOC, CLIA, HIPAA Level 3
- Comply with voluntary accrediting and inspection requirements e.g., CAP and Joint Commission Level 3
- Maintain patient confidentiality Level 3

**MLS ELC General Lab Practice**

**Deleted and Added items**

**Deletions**

- Basic elements of a computer
- Basic elements of software – languages, authoring
- Identify types, use and correct disposal of plasticware
- Method evaluation – ROC curve

**Additions**

- Define or use a document control system
- Microcomputers section changed to Information Technology
- Microscope section
Normal hematopoietic system

Define and describe hematopoiesis

- Theory of pluripotent stem cell development
- Stem cell kinetics: Generative cell cycle
- Hematopoietic inductive environment of regulatory growth factors and inhibitors
- Apoptosis

Describe phases and site of origin for cellular development of active hematopoietic tissue in embryo and fetus

- Yolk sac
- Mesoblastic phase
- Hepatic phase (extramedullary)
- Medullary/myeloid phase

Describe phases and site of origin for cellular development of active hematopoietic tissue in infants and young children

- All red marrow spaces (all cell lines)
- Thymus fully developed (T lymphs)
- Secondary lymphoid tissue (B-cell, T-cell and NK-cell)

Describe phases and site of origin for cellular development of active hematopoietic tissue in adult

- Red marrow (axial skeleton and proximal ends of long bones)
- Primary and secondary lymphoid tissue (B-cell, T-cell and NK-cell)

Explain the role of other organ systems in hematopoiesis

- Mononuclear phagocyte system
- Spleen (Structure, blood flow, function)
- Liver (Structure, blood flow, function)
- Lymph nodes (Structure, blood flow, function)
- Thymus (Structure, blood flow, function)

State the physical findings commonly present in hematologic disease

- Splenomegaly
- Hypersplenism
- Hepatosplenomegaly
- Lymphadenopathy

Bone Marrow Tissue

List indications for performing bone marrow examination

Describe bone marrow collection techniques

- Aspiration
- Core biopsy

Prepare and stain bone marrow smears

- Romanowsky polychrome stain
- Prussian Blue (Iron) Stain

Describe preparation and/or process specimen for specialized testing

MLS Hem 1
Flow cytometry
Molecular assays
Cytogenetics
Fluorescent in-situ hybridization (FISH)

Describe key terms used to assess bone marrow structure and function
Myeloid to erythroid ratio (M:E)/erythroid to granulocyte ratio (E:G)
Erythropoiesis
Granulopoiesis
Megakaryopoiesis
Non-hematopoietic cells
Cellularity: fat (yellow marrow) to cell (red marrow) ratio
Aplastic marrow
Hypoplastic marrow
Hyperplastic marrow

Describe concepts related to the assessment of iron stores and sideroblast population in the bone marrow
Type I
Type II
Type III

Peripheral Blood Examination

Distinguish between normal and abnormal hematopoietic elements found within the peripheral blood
Correlate bone marrow findings with peripheral blood evaluation
Prepare peripheral blood for routine hematologic procedure and smear analysis
Determine specimen acceptability
List appropriate anticoagulants and mechanism of anticoagulation
State acceptable ratio of anticoagulant to blood for specimens obtained from venipuncture and skin puncture
List reasons for rejecting specimens
Stain smears using Romanowsky dyes and techniques according to established procedures
Manual
Automated
List and define components of stains and explain the principle
Judge the acceptability of blood smears through microscopic evaluation and established criteria
Random distribution of cells
Good stain quality
Absence of artifact
Troubleshoot staining problems
Correlate peripheral blood evaluation with automated cell analysis
Enumerate and morphologically recognize and evaluate blood cells on Romanowsky stained smears

New concepts and emerging technologies
Describe advanced technologies
Therapeutic use of growth factors and stem cells to stimulate hematopoietic recovery
Bone marrow/stem cell transplant to treat hematologic disease
  Allogeneic
  Autologous
Immunophenotyping by flow cytometry
  Cell surface antigens
  Intracellular staining
Molecular diagnostic techniques
  DNA/RNA extraction and purification
  Identification of gene rearrangements and mutations
  Clonality in lymphocyte populations
  Polymerase chain reaction
  Reverse transcriptase
    Qualitative
    Quantitative
  Southern blot
  Fluorescent in-situ hybridization
  DNA sequencing
  Microarray analysis, comparative genomic hybridization array, molecular karyotype (SNP array)
Cytogenetics

**Erythropoiesis**

**Level 1**

- Describe the distinctive features used to characterize developing cells
  - Overall cell diameter or volume
  - Nucleus (diameter or volume, relative diameter or volume, staining reaction, chromatin pattern, presence or absence of nucleoli)
  - Cytoplasm (relative amount, staining reaction)
  - Nuclear:cytoplasmic ratio

- List the maturation sequence of developing erythrocytes given Romanowsky stained smears, electronic images or other visual means of representation of blood and bone marrow

- Distinguish nucleated erythrocyte precursors from other hematopoietic elements

- Categorize red cells on a Wright stained blood smear
  - Diameter or volume
  - Shape
  - Color
  - Inclusions
  - Distribution patterns

**Level 2**

- Discuss nutritional and regulatory factors associated with erythropoiesis
  - Erythropoietin (EPO)
  - Iron
  - Vitamins (B₁₂ / folate)

- List hormones associated with erythropoiesis
  - Estrogen/Androgens/Thyroxine/Growth hormone

- Discuss components of the mature red cell that are essential for

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survival and function
Membrane composition
  Lipids/Proteins/Skeletal proteins
Membrane Function
  Maintain RBC shape, deformability, and permeability
  Support system for surface antigens
  Transport and exchange of gases and ions (cationic pumps)
Describe metabolic pathways for maintenance of cell function
  Embden-Meyerhof/glycolytic
  Hexose monophosphate shunt
  Methemoglobin reductase
  Luebering-Rapoport

**Erthrocytic Hemoglobin**
Summarize the mechanisms by which normal hemoglobin is structured and synthesized in the developing red cell
  Iron transport, uptake, and supply
  Protoporphyrin IX (heme) formation
  Globin synthesis and genetic control (Chromosome 11 and 16)
  Embryonic hemoglobins (Gower I, Gower II, Portland)
  Adult hemoglobins (Hb A, Hb F, Hb A2)
Interpret the effect of various factors on the concentration of hemoglobin
  Age and gender
  Pregnancy
  Altitude
  Smoking
  Associated disease
  Altered hemoglobin derivatives
  (carboxyhemoglobin/methemoglobin/sulfhemoglobin)

**Erythrocytic Catabolism**
Summarize the mechanisms by which red cells are catabolized
Discuss mechanism of extravascular, intravascular hemolysis
Trace the basic steps associated with each mechanism
Define terms associated with red cell destruction
  Biliverdin
  Bilirubin (unconjugated/conjugated)
  Urobilinogen
  Urobilin
  Hemoglobin dimers
  Haptoglobin
  Hemopexin
  Hemoglobinemia
  Hemoglobinuria
  Hemosiderinuria
  Methemalbumin
Erythrocyte Evaluation

Describe procedures to evaluate erythrocytes and their physical properties using patient blood and quality control samples Level 1
Perform procedures to evaluate erythrocytes and their physical properties using patient blood and quality control samples Level 2
State the clinical utility of histogram review in erythrocyte evaluation Level 1
Evaluate if results are in accordance with prescribed criteria for accuracy and precision Level 3
Discuss and interpret results of automated hemogram parameters used for erythrocyte evaluation
- Hemoglobin
- Hematocrit
- Mean cell volume (MCV)
- Mean cell hemoglobin (MCH)
- Mean cell hemoglobin concentration (MCHC)
- Red cell distribution width (RDW)
Calculate red blood cell indices when provided appropriate data Level 2
State the principles of analysis for hemoglobin determination Level 1
- Hemoglobin measured at the point-of-care
- Cyanmethemoglobin method
- Other instrument methods for hemoglobin
Perform erythrocyte sedimentation rates Level 2
- Wintrobe
- Westergren and its modifications
- Automated
Interpret results of erythrocyte sedimentation rates Level 2
Recognize situations when results may be falsely high or low Level 1
Perform standard reticulocyte assays Level 2
- Supravital smear method with Miller disc
- Supravital smear method without Miller disc
- Automated methods
Perform and interpret calculations associated with reticulocyte assays Level 2
- Corrected
- Absolute
- Production index (RPI)
- Reticulocyte hemoglobin concentration
- Reticulocyte mean volume
- Immature reticulocyte fraction (IRF) or reticulated hemoglobin content (CHr)
Determine the appropriate area of a peripheral blood smear to evaluate red blood cell morphology Level 2
Distinguish between normal and abnormal red blood cell morphology Level 2
List red blood cell count and indices reference values that account for variations in gender and age Level 1
Correlate automated hemogram parameters and calculated indices with each other and with peripheral smear exam results Level 2
Calibrate and perform preventive maintenance on instruments used to evaluate MLS Hem 5
erythrocytes and their physical properties
Recognize and troubleshoot pre-analytical (pre-examination), analytical (examination), and post-analytical (post examination) causes of problems or unexpected results
Take corrective action to resolve unexpected results and/or events on instruments used to evaluate erythrocytes
Make decisions to recommend appropriate follow-up to prevent unexpected results and/or events from reoccurring

Leukopoiesis
State reference values that reflect variations in gender and age for the leukocyte counts in peripheral blood
Total leukocyte count
Relative and absolute values for neutrophil, lymphocyte, eosinophil, basophil and monocyte counts
State factors that alter leukocyte values
Physiologic variation
Pathologic abnormalities
Enumerate and/or calculate leukocyte counts
Relative values
Absolute values
List morphologic features used to differentiate developing leukocytes
Overall cell diameter or volume
Nucleus
Shape
Relative diameter
Nuclear to cytoplasmic ratio (N:C)
Staining reaction
Chromatin pattern
Presence or absence of nucleoli
Relative amount of cytoplasm
Cytoplasmic staining properties
Presence or absence of granules and staining reaction in cytoplasm

Leukopoiesis: Granulocytes
List the maturation sequence of neutrophils, eosinophils, and basophils
Differentiate distinguishing morphology for stages of developing blood granulocytes
Explain mechanisms that regulate and modulate granulopoiesis
Regulatory growth factors and inhibitors
Kinetics (life span, circulation)
Biochemistry (granule content and surface membrane receptors, energy metabolism)
Explain the functions associated with granulocytes
Chemotaxis
Phagocytosis and killing
Allergic response (eosinophils and basophils)
Host defense against parasites (eosinophils)
Hypersensitivity mediator (basophils and mast cells)
Leukopoiesis: Monocytes and Lymphocytes

Summarize structural and functional features that characterize monocytes and macrophages
- Kinetics (life span, circulation, tissue phase)
- Function (phagocytosis, antigen-presenting cells (APC), pathogen presenting cells)

List the maturation sequence of monocytes and macrophages

List the maturation sequence of lymphocytes

Summarize structural and functional features that characterize lymphopoiesis
- Sites of formation and production (Bone marrow, Thymus, Lymph nodes and secondary lymphoid tissue)
- Kinetics (Life span, Migration)
- Function
  - Humoral immunity (B lymphocytes and subsets)
  - Cell mediated immunity (T lymphocytes and subsets)
  - Natural killing and antibody dependent cellular cytotoxicity

Recognize morphology of developing monocytes and macrophages

Recognize morphology of developing lymphocytes

Describe the use of monoclonal antibodies to differentiate lymphocytes by immunophenotype
- B-cell lymphocytes and subsets
- T-cell lymphocytes and subsets
- Natural Killer (NK) cells
- Plasma cells

Leukocyte Evaluation

Perform commonly used methods to evaluate leukocytes

State the principles and clinical utility of histogram/scatterplot review

Determine absolute and relative white cell counts on patient and control specimens using manual and automated methods in accordance with prescribed criteria for accuracy and precision

Calibrate and perform preventive maintenance on instruments used to evaluate white cells

Determine differential cell counting using automated methods

Evaluate white cell histograms and scatterplots for diagnostic and quality control purposes

Classify normal and abnormal white cells on a properly stained Romanowsky blood smear

Correlate and verify automated cell counts and differentials with established criteria

Estimate the total white blood count from a smear

Correct leukocyte counts for the presence of nucleated red cells

Calibrate and perform preventive maintenance on instruments used to evaluate leukocytes and their physical properties

Recognize and troubleshoot pre-analytical (pre-examination), analytical (examination), and post-analytical (post examination) causes of problems or unexpected results

Take corrective action to resolve unexpected results and/or events on instruments
Nonmalignant Leukocyte Disorders

- Explain the classification of nonmalignant leukocytic disorders
  - Quantitative changes
  - Qualitative changes
- Calculate absolute and relative white blood cell values
- Compare and contrast absolute values with relative values
  - Neutrophilia
  - Neutropenia
  - Eosinophilia
  - Eosinopenia
  - Basophilia
- Associate quantitative and qualitative leukocyte disorders with expected results
  - Bone marrow production and release
  - Rate of entry into peripheral circulating pools
  - Shifts between circulating and marginating pools
  - Rate of exit into tissues
- Identify morphologic and quantitative changes in neutrophils that may accompany nonmalignant neutrophilic disorders
  - Shift to the left
  - Toxic granulation
  - Dohle bodies
  - Vacuolization
  - Leukemoid reaction
  - Leukoerythroblastic reaction
  - Agranulocytosis
  - Hyposegmentation
  - Hypersegmentation
- State characteristic abnormalities and clinical features for the qualitative/functional disorders of neutrophils
  - Pelger-Huet anomaly
  - Alder-Reilly anomaly
  - Chediak-Higashi anomaly
  - May-Hegglin anomaly
  - Chronic granulomatous disease (CGD)
  - Myeloperoxidase deficiency
  - Leukocyte adhesion deficiency
- Describe qualitative and quantitative alterations of monocytes
- Define monocytosis
- Compare absolute monocyte values with relative values
- State causes of monocytosis
- Identify abnormal lipid accumulations within monocytes and macrophages
- List causes of non-neoplastic disorders of lymphocytes and plasma cells
- Define lymphopenia/lymphocytosis
Compare lymphocyte absolute values with relative values Level 2
Compare and contrast morphologic features of reactive lymphocytes and normal lymphocytes
  Size
  Nucleus
  Cytoplasm
  Heterogeneity
Differentiate between reactive and resting lymphocytes on Romanowsky stained smears Level 2
State the causes of reactive lymphocytosis Level 1

**Red Blood Cell Disorders: Anemia**

Define anemia Level 1
State the clinical signs and symptoms of anemia
  Hemoglobin
  Hematocrit
  Red blood cell count
  RBC indices
  Red cell distribution width (RDW)
  Peripheral smear
  Reticulocyte count
  Bone marrow evaluation
List the categories used in a morphological classification of the anemias Level 1
Describe the expected laboratory results seen in the various pathophysiologic classifications of anemias
  Decreased red cell production (Bone marrow failure, ineffective hematopoiesis, Myelophthisic)
  Increased red cell destruction, hemolytic processes
  Loss of red blood cells
Discuss the clinical utility of the RBC indices as relates to physiologic conditions Level 1
Explain sources of error of the red cell indices Level 1
Use the RBC indices as a quality control mechanism for assessing the validity of the erythrocyte count, hemoglobin, and hematocrit values Level 2
Define common terms used to describe red cell morphology Level 1
  Anisocytosis
  Poikilocytosis
  Polychromatic
  Rouleaux
  Agglutination
  Acanthocyte/Spur Cell
  Codocyte/Target Cell/Leptocyte
  Dacryocyte/Tear Drop Cell
  Drepanocyte/Sickle Cell
  Echinocyte/Burr Cell
  Elliptocyte
  Keratocyte

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Schistocyte
Spherocyte
Stomatocyte
Basophilic stippling
Cabot rings
Heinz bodies
Howell-Jolly bodies
Malarial parasites
Pappenheimer bodies/siderotic granules
Hemoglobin crystals
Hemoglobin H
Describe the composition and morphology and list the possible pathologic conditions Level 1 of various red blood cell inclusions
Basophilic stippling
Cabot rings
Heinz bodies
Howell-Jolly bodies
Malarial and other blood parasites
Pappenheimer bodies/siderotic granules
Hemoglobin crystals (C, S, SC, H inclusion bodies)

Red Blood Cell Disorders: Erythrocytosis (Polycythemia)
Define polycythemia Level 1
Differentiate between absolute polycythemia and relative polycythemia Level 2
Differentiate between secondary polycythemia, and relative erythrocytosis Level 2
Etiology
Clinical features
Laboratory findings
Prognosis
Describe changes in the bone marrow and peripheral blood with polycythemia vera Level 1

Red Blood Cell Disorders: Microcytic Anemias
Define microcytic anemia Level 1
List the causes of microcytic anemias Level 1
Discuss the etiology and pathophysiology of microcytic anemias Level 1
Iron deficiency anemia
Sideroblastic anemia
Anemia of chronic disease
Thalassemia
Compare and contrast laboratory findings in iron deficiency anemia, anemia of chronic disease/inflammation and sideroblastic anemia Level 2
Serum ferritin
Serum iron
Transferrin/ Total Iron Binding Capacity (TIBC)
Percent transferrin saturation
Bone marrow evaluation for ringed sideroblasts
Free erythrocyte protoporphyrin (FEP)/zinc protoporphyrin (ZPP)
Transferrin receptor tests
Hepcidin

Outline a laboratory approach to the evaluation of a patient’s iron status Level 1

**Red Blood Cell Disorders: Megaloblastic Anemias**

Discuss the absorption and metabolism of vitamin B₁₂ and folate Level 1
Describe clinical features of megaloblastic anemia Level 1
Identify the hematologic abnormalities present in megaloblastic anemia Level 1
  - Peripheral blood changes
  - Bone marrow-morphological changes
Compare and contrast pernicious anemia to the other types of vitamin B₁₂ deficiency Level 3
Outline a sequential approach to the differential diagnosis of megaloblastic anemia using the following laboratory procedures Level 1
  - Mean corpuscular volume (MCV)
  - Blood and bone marrow smear evaluation
  - Serum B₁₂
  - Serum folate
  - Red cell folate
  - Anti-intrinsic factor antibodies
  - Anti-parietal cell antibodies
  - Methylmalonic acid
  - Homocysteine

Differentiate nonmegaloblastic macrocytosis from megaloblastic anemia Level 3
  - Peripheral blood and bone marrow characteristics
  - Serum vitamin B₁₂ level
  - Serum folate level
  - Red cell folate level
  - Reticulocyte findings


Define aplastic anemia Level 1
List common factors associated with the development of hypoproliferative disorders Level 1
Describe the clinical features and pathophysiology Level 1
  - Acquired aplastic anemia
  - Fanconi’s anemia
  - Congenital pure red blood cell aplasia
  - Anemia caused by myelophthisis
Describe the laboratory findings Level 1
  - Peripheral blood changes
  - Bone marrow changes
  - Other laboratory findings
Define Fanconi’s anemia Level 1
Describe the genetics and possible pathophysiology Level 1
Describe the laboratory findings Level 1
  - Peripheral blood changes
  - Bone marrow changes
Other laboratory findings
Define pure red cell aplasia (Diamond-Blackfan anemia) Level 1
Describe the clinical features and pathophysiology Level 1
Describe the laboratory findings Level 1
   Peripheral blood changes
   Bone marrow changes
   Other laboratory findings

Define and differentiate Congenital dyserythropoietic anemias (types I, II, and III) Level 2
Describe the clinical features Level 1
Describe the laboratory findings Level 1
Define myelophthisis Level 1
Describe the clinical features Level 1
Describe the laboratory findings Level 1
   Peripheral blood changes
   Bone marrow changes
   Other laboratory findings

Red Blood Cell Disorders: Hemolytic Anemias
Describe the etiology, pathophysiology, clinical features, and laboratory findings of red cell membrane defects Level 1
   Hereditary spherocytosis
   Hereditary elliptocytosis
   Paroxysmal nocturnal hemoglobinuria (PNH)
   Hereditary pyropoikilocytosis
   Hereditary acanthocytosis
   Hereditary stomatocytosis (hydrocytosis)
   Hereditary xerocytosis
Correlate data from laboratory tests that are used to detect increased RBC destruction and production due to RBC membrane abnormalities Level 2
Describe the clinical features Level 1
Describe the laboratory findings Level 1
Perform /observe the procedure Level 2
Apply appropriate quality control procedures Level 2
Evaluate results Level 3
Describe the utility of flow cytometry in assessing red cell membrane defects Level 1
Discuss the principles of G6PD assay, pyruvate kinase assay and staining for Heinz Bodies Level 1
Identify laboratory test results based upon Level 1
   Describe the laboratory findings Level 1
   Perform /observe the procedure Level 2
   Apply appropriate quality control procedures Level 2
   Evaluate results Level 3
Red Blood Cell Disorders: Hemoglobinopathies

Define hemoglobinopathy Level 1
Distinguish between qualitative and quantitative hemoglobin defects Level 2
Describe clinical and laboratory findings of hemoglobinopathies Level 1
  Hb SS
  Hb AS
  Hb CC
  Hb AC
  Hb DD
  Hb EE
  Hb SC
State the amino acid substitutions associated with sickle cell anemia and hemoglobin C disease Level 1
Describe the physiologic abnormality associated with hemoglobin variants with altered oxygen affinity (Unstable hemoglobins, Methemoglobinemia) Level 1
Describe the hemoglobin gene defect in alpha and beta thalassemia Level 1
Define the hemoglobin defect in thalassemia Level 1
Describe the terminology associated with thalassemias Level 1
  Alpha thalassemia
    4 gene deletion
    3 gene deletion (Hb H disease)
    2 gene deletion
    1 gene deletion
  Beta thalassemia
    Beta-thalassemia major
    Beta-thalassemia intermedia
    Beta-thalassemia minor
Describe the clinical features associated with different gene combinations in alpha and beta thalassemia Level 1
Describe the pathophysiology of thalassemias Level 1
  Hemoglobin Lepore
  Hb H
  Bart’s hemoglobin
  Hereditary persistence of fetal hemoglobin
List the characteristic clinical and laboratory findings associated with thalassemia Level 1
Describe the peripheral blood morphology associated with different gene combinations in alpha and beta thalassemia Level 1
Discuss the principle of the solubility test for sickling hemoglobin Level 1
  Describe the laboratory findings Level 1
  Perform/observe the procedure Level 2
  Apply appropriate quality control procedures Level 2
  Evaluate results Level 3
Discuss the principles of hemoglobin electrophoresis (cellulose acetate, alkaline pH vs. citrate agar, acid pH) Level 1
  Describe the laboratory findings Level 1
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Perform /observe the procedure
Apply appropriate quality control procedures
Evaluate results
Describe the separation of hemoglobin by capillary electrophoresis
Discuss the principles of hemoglobin quantification (HbA, HbA2, HbF)
Describe the laboratory findings
Perform /observe the procedure
Apply appropriate quality control procedures
Evaluate results
Describe the separation of hemoglobin by capillary electrophoresis
Discuss the principles of hemoglobin quantification (HbA, HbA2, HbF)
Describe the laboratory findings
Perform /observe the procedure
Apply appropriate quality control procedures
Evaluate results
Describe acid elution test (Kleihauer-Betke) or flow cytometry in regards to
Hemoglobinopathies
Correlate screening test for sickling hemoglobin with peripheral blood morphology
and electrophoretic patterns of hemoglobin
Identify the electrophoretic patterns (cellulose acetate, alkaline pH vs. citrate agar,
acid pH)
Hb F, Hb A, Hb S, Hb C, Hb D, Hb E, Hb A2
Recognize specialized testing used to detect abnormal hemoglobins,
e.g., DNA/globin chain testing

**Hemolytic Anemias**

Describe mechanisms of immune hemolytic anemias
Define and describe the etiology and clinical features and laboratory findings of
Autoimmune hemolytic anemias
  - Acute hemolytic transfusion reaction
  - Delayed hemolytic transfusion reaction
  - Hemolytic disease of the newborn and fetus (HDNE)
Define and describe the etiology and clinical features and laboratory findings of
Autoimmune hemolytic anemias
  - Warm autoimmune hemolytic anemia (WAIHA)
  - Cold autoimmune hemolytic anemia
  - Cold agglutinin syndrome (Idiopathic, Secondary)
  - Paroxysmal cold hemoglobinuria
State mechanisms of drug-induced immune hemolytic anemia
State the etiology of nonimmune hemolytic anemia
  - Infectious organisms
  - Mechanical agents
  - Chemicals
Describe the hematologic findings associated with nonimmune hemolytic anemias
  - Malaria
  - Babesiosis
  - Bartonellosis
  - Clostridium perfringens (welchii) infection
  - Cardiac prosthetic devices
  - Microangiopathic hemolytic anemia
  - Chemicals and venoms
  - Thermal injury
  - Disseminated intravascular coagulation
**Acute Blood Loss**
- Describe the etiology of anemia of acute blood loss
- List the clinical symptoms of acute blood loss
- Recognize the laboratory findings of acute blood loss

**Anemias associated with systemic disorders**
- Describe the clinical features and laboratory findings associated with nonhematologic disorders
  - Chronic disorders and inflammation
  - Connective tissue disorders
  - Malignant diseases
  - Renal disease
  - Liver disease
  - Alcoholism
  - Endocrine disease

**Neoplastic Disorders**
- List and define categories associated with Neoplastic Disorders of Leukocytes
  - Leukemias
  - Myelodysplastic syndromes
  - Myeloproliferative disorders
  - Lymphoproliferative disorders
- Apply major systems used to classify neoplastic disorders of leukocytes
  - French, American-British (FAB) Cooperative Group
  - World Health Organization (WHO)
- Observe and/or perform procedures, apply appropriate quality control procedures, and interpret laboratory findings for laboratory procedures used in the identification, classification and differentiation of neoplastic disorders
  - Complete blood count
  - Hemograms
  - Scatterplots and histograms
- Discuss the principles of various cytochemical stains and the cell lineages they react with
  - Myeloperoxidase
  - Esterases (specific substrate/non-specific substrate
  - Iron staining
- Describe the use of various diagnostic techniques used to assess neoplastic disorders of blood and bone marrow cells
  - Immunophenotyping
  - Terminal deoxynucleotidyl transferase (TdT)
  - Monoclonal antibodies
  - myeloid from lymphoid
  - T and B cell immunophenotypes
  - Acute myelocytic leukemia (AML) subgroups cell lineages
  - Cytogenetics
  - Molecular genetics
Interpret laboratory results and clinical syndromes that are unique to the leukocyte neoplasms

Review case studies of neoplastic disorders and apply knowledge and skills in interpreting laboratory results

### Acute Leukemias

Apply general criteria to classify leukemias

- Cell maturity (Acute/Chronic)
- Cell lineage (Myeloid /nonlymphoid)
- Lymphoid

Describe the clinical findings and laboratory results for leukemia

Compare the FAB with the WHO acute myeloid leukemia subgroups and apply diagnostic blood and bone marrow findings to the differential identification

**FAB classification**

- M0--acute myeloid leukemia with minimal differentiation
- M1--acute myeloid leukemia without maturation
- M2--acute myeloid leukemia with maturation
- M3--acute promyelocytic leukemia
- M4--acute myelomonocytic leukemia
- M5--acute monoblastic leukemia
- M6--acute erythroleukemia
- M7--acute megakaryoblastic leukemia

**WHO classification**

- AML with recurrent genetic abnormalities
- AML with myelodysplasia-related changes
- Therapy-related myeloid neoplasms

List the WHO acute leukemia subgroups

- AML with recurrent genetic abnormalities
- AML with myelodysplasia-related changes
- Therapy-related myeloid neoplasms
- AML, not otherwise specified

Interpret findings from immunophenotypic, cytogenetic and molecular findings and apply to criteria used by WHO

Describe for each leukemia

- Clinical findings and symptoms
- Incidence and epidemiology
- Risk factors associated with the development of leukemia
- Hereditary or genetic abnormalities
- Environmental
- Viral infections
- Immunologic disorders

Describe the etiology and pathophysiology of leukemia

- Stem cell clonality
- Oncogene and tumor suppressor gene development

Describe the survival rates and prognosis

Describe the treatment options and correlation with hematologic complications

Chemotherapy
Bone marrow/stem cell transplant
List diagnostic findings on permanently stained blood and bone
marrow smears, photographs, or electronic images by which
the FAB cooperative group and WHO classify acute leukemia
Morphology, number, and differentiation of blast and immature cells
Greater than 30% (FAB)
Greater than 20% (WHO)
Predominant cell type
Auer rods
Define the reactivity of leukemic cells with specific cytochemical stains
Apply diagnostic blood and bone marrow findings to the differential identification
Acute myeloid leukemia (AML)
Acute nonlymphocytic leukemia (ANLL)
M0--acute myelogenous with minimal differentiation
M1--acute myelogenous without maturation
M2--acute myelogenous with maturation
M3--acute promyelocytic leukemia
M3m--acute promyelocytic leukemia variant
M4--acute myelomonocytic leukemia
M4Eo--acute myelomonocytic leukemia variant
M5--acute monocytic leukemia
M5a--poorly differentiated
M5b--well differentiated
M6--acute erythroleukemia
M7--acute megakaryocytic leukemia
Acute lymphocytic leukemia (ALL): L1,L2,L3-Burkitt's
List the subgroups (WHO) and apply diagnostic blood, bone marrow,
immunophenotype, cytogenetics and molecular findings to the differential
identification
B lymphoblastic leukemia/lymphoma, not otherwise specified
T lymphoblastic leukemia/lymphoma
Interpret findings from an immunologic workup to formulate an
immunophenotypic classification for ALL apply to criteria used by WHO
B lineage
Early B precursors
“Common” CALLA (CD10) positive
Pre-B
T-cell lineage and early T precursor (pro-T, pre-T, cortical-T, medullary-T)
Precursor lymphoid neoplasms
List cytogenetic and molecular abnormalities commonly associated with the major
acute leukemic subtypes

Myelodysplastic Syndromes (MDS)
Define and describe cellular features that characterize the MDS
Dyserythropoiesis
Dysgranulopoiesis
Dysmegakaryocytopoiesis

List subgroups recognized by the World Health Organization (WHO) Cooperative Level 1

Discuss the Groups for the MDS classification Level 1
Refractory cytopenia with unilineage dysplasia (RCUD)
Refractory anemia (RA)
Refractory neutropenia (RN)
Refractory thrombocytopenia (RT)
Refractory anemia with ringed sideroblasts (RARS)
Refractory cytopenia with multilineage dysplasia (RCMD)
Refractory anemia with excess blasts (RAEB)
RAEB-1
RAEB-2
Myelodysplastic syndrome, unclassifiable (MDS-U)
Myelodysplastic syndrome with isolated del (5q)

List subgroups recognized by the French, American, and British (FAB) Cooperative Group for the MDS classification Level 1
Refractory anemia (RA)
Refractory anemia with ringed sideroblast (RARS)
Refractory anemia with excess blast (RAEB)
Chronic myelomonocytic leukemia (CMML)
Refractory anemia with excess blasts in transition (RAEB-t)

Identify key morphologic features of MDS on permanently stained blood and bone marrow smears, photographs, electronic images or other visual means of representation Level 1

Correlate the diagnostic blood and bone marrow findings to the differential identification Level 2

Describe characteristics of MDS Level 1
Median age of onset
Epidemiology
Chromosomal association with pathogenesis
Clinical course with associated hematologic changes
Treatment options
Prognosis

Chronic Myeloproliferative Neoplasms

Classify Chronic Myeloproliferative Neoplasms affected by cell type Level 1
Granulocytes--Chronic myelogenous/granulocytic leukemia (CML/CGL)
Erythrocytes-- polycythemia vera (PV)
Megakaryocytes--essential thrombocythemia (ET)
Fibroblasts-- Primary myelofibrosis (PMF)

List Chronic Myeloproliferative Neoplasms subtypes Level 1
Chronic myelogenous leukemia (CML) BCR/ABL1 positive
Essential thrombocythemia (ET)
Primary myelofibrosis (PMF)
Chronic neutrophilic leukemia (CNL)
Chronic eosinophilic leukemia not otherwise specified (CEL, NOS)
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Mastocytosis
List subgroups recognized by WHO for the myelodysplastic/myeloproliferative classification and discuss the rationale for the classification
  Chronic myelomonocytic leukemia (CMML)
  CMML-1
  CMML-2
  Atypical chronic myeloid leukemia (aCML), BCR-ABL1 negative
  Juvenile myelomonocytic leukemia (JMML)
  MDS/MPN, unclassifiable

Compare features commonly shared by Chronic Myeloproliferative Neoplasms
  Clinical manifestations
  Pathophysiologic mechanisms
  Blood and bone marrow findings
  Transitional forms between stages
  Disease evolution with potential for blastic transformation

Identify key morphologic features of the MPN’s on permanently stained blood and bone marrow smears, photographs, or electronic images
Correlate diagnostic criteria to these findings for the differential identification

Chronic myelogenous leukemia (CML)
  Leukocytosis with absolute neutrophilia and left shift maturation
  Absolute basophilia and eosinophilia
  Thrombocytosis
  Bone marrow hypercellularity with granulocytic proliferation
  Cytogenetic (karyotype): t(9;22)(q34;q11)
  Molecular products: BCR/ABL fusion gene, fusion mRNA

Polycythemia vera (PV)
  Increased red blood cell (RBC) mass
  Leukocytosis with mild left shift maturation and basophilia
  Thrombocytosis
  Bone marrow hypercellularity with all cell lines increased
  Molecular studies (JAK2)
  Red cell morphology (Initial phase, “Spent” phase)

Essential thrombocythemia (ET)
  Marked thrombocytosis with platelet aggregates and abnormal forms
  Megakaryocytic hyperplasia of bone marrow
  Molecular studies

Primary myelofibrosis (PMF)
  Leukocythoblastosis with teardrop-shaped red cells
  Leukocytosis with left shift maturation to occasional immature myeloid cell
  Bone marrow fibrosis and relationship to megakaryocytic hyperplasia
  Molecular studies

Recognize effects of treatment on peripheral blood white cells,
  Chemotherapy
  Splenic irradiation/splenectomy
  Phlebotomy
  Bone marrow or stem cell transplant
  Targeted molecular therapy

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Chronic Lymphoproliferative Disorders

Name and classify the chronic lymphoid leukemias by T and B cell lineage

- Chronic lymphocytic leukemia (CLL)
- B-cell prolymphocytic leukemia (PLL)
- Plasma cell neoplasms
- Hairy cell leukemia (HCL)
- Adult T-cell leukemia
- Sézary syndrome
- Extranodal marginal zone lymphoma or mucosa-associated lymphoid tissue (MALT lymphoma)
- Follicular lymphoma
- Mantel cell lymphoma
- Diffuse large B-cell lymphoma, not otherwise specified
- Burkitt lymphoma

Identify key morphologic features on permanently stained blood and bone marrow smears, photographs, or electronic images

List diagnostic features CLL

- Median age of onset
- Symptoms and clinical findings
- Blood and bone marrow findings
- Peripheral blood absolute lymphocytosis
- Leukemic cell line of mature, small lymphocytes with monotonous morphology and smudge/basket cells
- Immunophenotypic cell surface markers and clonality
- Bone marrow lymphocytosis

Discuss the diagnostic features of PLL

- Median age of onset and gender
- Clinical finding of severe splenomegaly
- Blood and bone marrow findings
- Markedly elevated white count with absolute lymphocytosis
- White cell differential predominantly of prolymphocytes (greater than 55%)
- Immunophenotypic profile
- Chromosome and/or molecular

Discuss the diagnostic features of HCL

- Median age of onset and gender
- Clinical finding of severe splenomegaly
- Blood and bone marrow findings
- Pancytopenia
- Morphology: leukemic cell line of “hairy” cells
- Immunophenotypic B-cell profile
- “Dry” tap; marrow fibrosis and infiltrates

List diagnostic features of Adult T-cell leukemia

- T-cell large granular lymphocytic leukemia (LGL)
- Human T-cell lymphotrophic virus-1 (HTLV-1)
- Endemic areas
List diagnostic features of Sézary syndrome
   Relationship to mycosis fungoides
   Clinical findings--skin involvement
Review blood and bone marrow findings of Sézary syndrome
   Absolute lymphocytosis
   Morphology: lymphoid cell line of medium cells with cerebriform nucleus
   Immunophenotypic T cell associated profile

Lymphoma

Define lymphoma and generally classify using key terminology
   Hodgkin
   Non-Hodgkin
List laboratory findings used to diagnose and stage Hodgkin lymphoma
   Complete blood count (CBC)
   Liver function tests
   Renal function tests
   Blood and bone marrow findings of Hodgkin’s lymphoma
   Radiologic studies
   Physical examination
   Lymph node biopsy
Recognize key morphologic features and correlate with diagnostic criteria for the presence of lymphoma cells in peripheral blood

Plasma Cell Disorders

Name disorders based on proliferation of plasma cells and abnormal production of immunoglobulins
Discuss classification based on proliferation of plasma cells and abnormal production of immunoglobulins
   Multiple myeloma
   Waldenstrom’s macroglobulinemia
   Plasma cell leukemia (PCL)
   Heavy-chain disease
   Monoclonal gammopathy of undetermined significance (MGUS)
Compare and contrast classification based on proliferation of plasma cells and abnormal production of immunoglobulins
Compare and contrast the following for plasma cell disorders
   Pathophysiology
   Clinical findings
   Laboratory findings
   Complete blood count (CBC) and peripheral smear review
   Bone marrow biopsy including immunophenotypic cell markers
   Blood and urine protein electrophoresis and immunoelectrophoresis
   Quantitative immunoglobulins
   Chemistry panels--blood urea nitrogen, creatinine, calcium, lactic dehydrogenase
Serum viscosity
Beta-2-microglobulin
Radiologic studies of bones
Identify key morphologic features for plasma cell disorders on permanently stained blood and bone marrow smears, photographs, electronic images or other visual means of representation
Flaming plasma cell
Mott cells
Rouleaux formation of red blood cells

**Thrombopoiesis/megakaryopoiesis**

- List the maturation sequence for stages of developing megakaryocytes and platelets
- Cite reference values for absolute platelet counts in the peripheral blood
- Correlate quantitative variations with disease manifestations
  - Thrombocytopenia
  - Thrombocytosis
- Correlate functional or qualitative variations of platelets with disease manifestations
- Perform absolute platelet counts on patient and control specimens using manual and automated methods in accord with prescribed criteria for accuracy and precision
- State the principles of method analysis and histogram/scatterplot review
- Compare absolute count with those estimated from blood smear exam
- Identify platelets and platelet morphologic variations on a properly prepared Romanowsky stained blood smear and/or recognize factors that alter hemogram results
  - Platelet satellitism
  - Platelet aggregates
  - Giant platelets
  - Cell fragments
  - Extreme microcytosis
- Evaluate platelet histograms and scatterplots for diagnostic and quality control purposes
  - Platelet satellitism
  - Platelet aggregates
  - Giant platelets
  - Cell fragments
  - Extreme microcytosis
  - Agranular and hypogranular platelets
- Recognize and troubleshoot pre-analytical (pre-examination), analytical (examination) and post-analytical (post-examination) causes for problems or unexpected results
- Make decisions to recommend appropriate follow-up to prevent unexpected results and/or events from reoccurring
- Calibrate and perform preventive maintenance on instruments used to evaluate platelets
**Hemostasis / Coagulation**

**Define hemostasis**

**Explain the general interaction of systems involved in maintaining hemostasis**

Of systems involved in maintaining hemostasis describe how changes in one effect the other

- Vasculature
- Platelets
- Plasma coagulation factors
- Fibrinolysis

**Differentiate between primary and secondary hemostasis**

**Vascular**

**Explain the functions of the vascular system in maintaining hemostasis**

**Describe metabolic functions of the endothelium and substances contributing to the thromboresistance properties of endothelium**

- Heparan sulfate
- Thrombomodulin
- Tissue plasminogen activator
- Prostacyclin (PGI2)
- Tissue factor pathway inhibitor

**Platelets**

**Discuss the production of platelets**

**State the average time in circulation, normal peripheral count, and total body distribution of platelets**

**Describe the ultrastructural components of a platelet**

- Alpha granules
- Dense bodies
- Lysomes
- Microtubules
- Open canalicular system
- Platelet membrane
- Glycocalyx

**Discuss the physiological role of platelets in hemostasis**

- Platelet plug formation
- Maintaining normal vascular integrity

**Describe the series of morphologic changes that occur in platelets following physiologic stimulation**

- Adhesion
- Aggregation
- Activation

**Discuss the effect of aspirin on platelet function**

- Biochemical mechanism
- Duration of the effect

**Discuss principle for platelet aggregometry and platelet function analyzers**

**Interpret results of platelet function assay tests**

- Significance in terms of platelet function
- Associated abnormal conditions
- Sources of error
Discuss the principle and clinical significance of platelet aggregation  
Describe the principle of light transmittance, whole blood impedance and lumiaagregometry  
Perform the procedure  
Describe the procedure  
Describe appropriate quality control procedures and sources of error  
Interpret results and clinical significance  
Level 1

Plasma coagulation factors

Define the coagulation factors  
Roman numerals  
Common names  
Synonyms  
Discuss the physiological role of the coagulation phase within the hemostatic process  
Discuss characteristics of the coagulation factors  
Contact group  
Prothrombin group  
Fibrinogen group  
List the vitamin K-dependent factors  
Compare and contrast the plasma-based (in vitro) and cell-based (in vivo) mechanisms of coagulation (Level 3)  
Plasma-based (in vitro) mechanism  
Intrinsic  
Extrinsic  
Common  
Cell-based (physiologic, in vivo) mechanism  
Initiation  
Amplification  
Propagation  
Identify substances that are contact activators in vitro  
Summarize the interaction of the coagulation system with the vascular and platelet systems to form a hemostatic plug  
Describe the physiologic controls of hemostasis  
Blood flow  
Feedback inhibition  
Liver clearance  
Describe the inhibitors of hemostasis  
Antithrombin  
Heparin cofactor II  
Tissue factor pathway inhibitor (TFPI)  
Protein C  
Protein S  
Alpha-2-macroglobulin  
Alpha-1-antitrypsin  
C1 inactivator  
Z-dependent protease inhibitor (ZPI)  
Level 2

MLS Hem 24
State the special precautions that must be taken in the collection and subsequent handling of specimens for coagulation testing

- Anticoagulant
- Ratio of blood to anticoagulant
- Patient hematocrit values
- Centrifugation
- Storage conditions including temperature
- Transport
- Phlebotomy procedure (e.g., time tourniquet is on arm, needle gauge, probing, etc.)

Describe tests that are used to monitor the coagulation phase of Hemostasis

Discuss the principle and clinical significance of the Prothrombin time test

- Perform the procedure
- Describe the procedure
- Describe appropriate quality control procedures and sources of error
- Interpret results
- Describe the International Normalized Ratio (INR)
- Calculate an INR given the international sensitivity index of the thromboplastin
- Describe interferences and sources of error

Discuss the principle and clinical significance of the Activated partial thromboplastin time

- Perform the procedure
- Describe the procedure
- Describe appropriate quality control procedures and sources of error
- Interpret results
- Describe interferences and sources of error

Discuss the principle and clinical significance of the Activated clotting time

- Perform the procedure
- Describe the procedure
- Describe appropriate quality control procedures and sources of error
- Interpret results
- Describe interferences and sources of error

Discuss the principle and clinical significance of the Thrombin clotting time

- Perform the procedure
- Describe the procedure
- Describe appropriate quality control procedures and sources of error
- Interpret results
- Describe interferences and sources of error

Discuss the principle and clinical significance of the Fibrinogen assay

- Perform the procedure
- Describe the procedure
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Describe interferences and sources of error Level 1

Discuss the principle and clinical significance of Factor assays Level 1
Perform the procedure Level 1
Describe the procedure Level 1
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Describe interferences and sources of error Level 1

State technical conditions that cause false coagulation testing results and recommend corrective actions Level 1

Fibrinolytic system
Define fibrinolysis Level 1
Discuss the physiological role of the fibrinolytic system Level 1
State the major components of the fibrinolytic system Level 1
Discuss the mechanisms of the activation of plasminogen Level 1
  Intrinsic activators
  Extrinsic activators
  Exogenous activators
List the major fragments of fibrinogen degradation Level 1
Explain the role and clinical significance of physiologic controls Level 1
  Alpha-2-antiplasmin
  Alpha-2-macroglobulin
  Plasminogen activator inhibitors (PAI)
Describe laboratory procedures that are used to evaluate the fibrinolytic system Level 1
Discuss the principle and clinical significance of the FDP assay Level 1
  Perform the procedure Level 2
  Describe the procedure Level 1
  Describe appropriate quality control procedures and sources of error Level 1
  Interpret results Level 2
Discuss the principle and clinical significance of the D-Dimer Assay Level 1
  Perform the procedure Level 2
  Describe the procedure Level 1
  Describe appropriate quality control procedures and sources of error Level 1
  Interpret results Level 2

List technical conditions that cause false coagulation testing results and recommend corrective actions Level 1

Disorders of primary hemostasis
Differentiate between disorders of the vasculature Level 2
  Acquired purpura
Henoch-Schölein purpura
Hereditary hemorrhagic telangiectasia
Ehlers-Danlos syndrome
Pseudoxanthoma elasticum

Define the following terms associated with hemostasis disorders
Thrombocytopenia

Discuss the role of the vasculature in normal hemostasis
Thrombocytosis
Thrombocythemia

Describe the etiology, pathophysiology, clinical features, and laboratory findings of quantitative defects of platelets
Idiopathic thrombocytopenic purpura
Autoimmune thrombotic thrombocytopenic purpura
Post-transfusion purpura
Disseminated intravascular coagulation
Hemolytic uremic syndrome
MYH9 inherited thrombocytopenias, e.g. May-Hegglin anomaly
Wiscott Aldrich anomaly
Neonatal alloimmune thrombocytopenia
HELLP syndrome
Heparin-induced thrombocytopenia
Drug-induced immune thrombocytopenia
Myeloproliferative disorders
Secondary (reactive) conditions

Describe the etiology, pathophysiology, clinical features, and laboratory findings of qualitative defects of platelets
von Willebrand’s disease
Bernard-Soulier syndrome
Glanzmann’s thrombasthenia
Storage pool deficiencies
Acquired platelet function disorders

Disorders of secondary hemostasis
Describe the inheritance pattern, pathophysiology, clinical features, and laboratory findings
Factor I deficiency
Factor II deficiency
Factor V deficiency
Factor V Leiden
Factor VII deficiency
Factor VIII deficiency (Hemophilia A)
Factor IX deficiency (Hemophilia B)
Factor X deficiency
Factor XI deficiency
Factor XII deficiency
Factor XIII deficiency
Prekallikrein deficiency
High-molecular-weight kininogen deficiency
von Willebrand’s disease
Alpha-2-antiplasmin deficiency
Antithrombin deficiency
Heparin co-factor II deficiency
Protein C deficiency
Protein S deficiency
Plasminogen deficiency
Homocystinemia/homocystinuria

Describe clinical features and laboratory findings of acquired coagulation disorders

Vitamin K deficiency
Liver disease
Renal disease

Describe the significance and clinical implications of the development of circulating anticoagulants

Specific factor inhibitors
Nonspecific factor inhibitors
Global inhibitors

Describe laboratory procedures that are used to evaluate circulating anticoagulants or inhibitors

Discuss the principle and clinical significance of correction study using normal plasma

Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

Discuss the principle and clinical significance of APTT screening with moderate-high LA responsive reagent (LA-sensitive, low phospholipid)

Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

Discuss the principle and clinical significance of the Dilute Russell viper venom time (DRVVT)

Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

Discuss the principle and clinical significance of the Low-phospholipid (LA-sensitive) vs. high-phospholipid APTT

Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

Discuss the principle and clinical significance of the Platelet neutralization
procedure
  Perform the procedure       Level 2
  Describe the procedure       Level 1
  Describe appropriate quality control procedures and sources of error Level 1
  Interpret results       Level 2
Outline a protocol to follow when investigating a patient with an unknown bleeding disorder
  Factor assays with dilutions for detection of nonparallel results
  Bethesda titer for factor VIII or IX inhibitors
  Describe interferences and sources of error

Disorders of fibrinolysis
Define fibrinolysis       Level 1
Define disseminated intravascular coagulation (DIC)       Level 1
List mechanisms by which clotting is initiated during DIC        Level 1
Describe the effect of DIC on laboratory procedures       Level 1
  Prothrombin time
  Activated partial thromboplastin time
  Thrombin clotting time
  Platelet count
  Fibrinogen
  Fibrin/fibrinogen degradation products (FDP)
  D-dimer
  Blood smear
Describe conditions that are predisposing to recurrent thrombosis       Level 1
  Antithrombin deficiency
  Heparin cofactor II deficiency
  Primary antiphospholipid antibody syndrome
  Protein C deficiency
  Protein S deficiency
  Activated Protein C resistance
  Prothrombin gene mutation (G20210A)
  Hyperhomocystinemia
  Acquired risk factors to thrombophilia (e.g., age, malignancies, including leukemias, chronic inflammation, surgery, immobilization, obesity, pregnancy, hormone replacement therapy, oral contraceptives, PNH, autoimmune disorders)
Describe laboratory tests for antithrombin, protein C, and protein S comparing activity vs. antigen techniques       Level 1
  Perform the procedure       Level 2
  Describe the procedure       Level 1
  Describe appropriate quality control procedures and sources of error Level 1
  Interpret results       Level 2

Anticoagulant therapy
Explain the action of anticoagulant therapy       Level 1
  Vitamin K Reductase inhibitors
  Direct acting oral anticoagulants
Heparin high/low molecular weight
Antiplatelet agents
List laboratory tests used to monitor anticoagulant therapy, indicate therapeutic intervals and sources of error and discuss emerging assays
Oral anticoagulant therapy (warfarin) Vitamin K Reductase inhibitors
Direct acting oral anticoagulants
Oral direct Xa inhibitors; anti-Xa
Heparin high/ low molecular weight
Low molecular weight heparin; chromogenic anti-Xa
Unfractionated heparin; PTT and chromogenic anti-Xa
Pentasaccharide, e.g., fondaparinux sodium (chromogenic anti-Xa)
Direct thrombin inhibitors; APTT, ecarin clotting time, dilute thrombin assay
Antiplatelet agents; platelet aggregometry
Aspirin
Thienopyridines: Clopidogrel, prasugrel
Glycoprotein IibIIa inhibitors

Instrumentation
Discuss basic concepts of electrical impedance, optical detection, radio frequency, and of light scatter plus cytochemical stain of automated blood cell systems
Discuss the principle
List components
Describe operation
Perform Analysis
Describe maintenance and troubleshooting
Perform maintenance/ corrective action
Describe basic concepts of quality assurance for automated hematology cell counting systems
Describe acceptable practices
Perform basic quality assurance
Assess data to ensure quality
Monitor quality assurance program
Describe the limitations and list interfering substances
List and describe hemogram parameters
Evaluate patient data
Describe the flagging system
Correlate scatter plots, histograms and data plots with the peripheral smear
Describe the mathematical calculations used to monitor instruments
Recognize unexpected results
Troubleshoot and take corrective action
Discuss the principle of Automated reticulocyte counting
Describe acceptable practices
Perform basic quality assurance
Assess data to ensure quality
Monitor quality assurance program
Describe the limitations and list interfering substances  
Level 1

Describe basic concepts of electromechanical and photo-optical Coagulation systems  
Level 1
- Describe acceptable practices  
  Level 1
- Perform basic quality assurance  
  Level 2
- Assess data to ensure quality.  
  Level 3
- Monitor quality assurance program  
  Level 2
- Describe the limitations and list interfering substances  
  Level 1

Discuss basic concepts of quality assurance for automated coagulation systems  
Level 1
- Describe acceptable practices  
  Level 1
- Perform basic quality assurance  
  Level 2
- Assess data to ensure quality.  
  Level 3
- Monitor quality assurance program  
  Level 2
- Describe the limitations and list interfering substances  
  Level 1

Discuss basic concepts of spectrophotometric, chromogenic substrate assays in coagulation testing  
Level 1
- Describe acceptable practices  
  Level 1
- Perform basic quality assurance  
  Level 2
- Assess data to ensure quality.  
  Level 3
- Monitor quality assurance program  
  Level 2
- Describe the limitations and list interfering substances  
  Level 1

Describe basic concepts of laboratory quality assurance for coagulation testing  
Level 1
- Describe acceptable practices  
  Level 1
- Perform basic quality assurance  
  Level 2
- Assess data to ensure quality.  
  Level 3
- Monitor quality assurance program  
  Level 2
Deletions:

Cytochemical stains deleted from bone marrow stains

Research new concepts and emerging technologies
Describe therapeutic use of growth factors and stem cells to stimulate hematopoietic recovery
Discuss bone marrow/stem cell transplant to treat hematologic disease
Discuss molecular biologic techniques in hematology analysis

List the defect, substance accumulated, and clinical features for the major disorders characterized by an accumulation of lipids in monocytes and macrophages
- Gaucher’s disease
- Neimann-Pick disease
- Tay-Sachs disease
- Mucopolysaccharidoses
- Sea-blue histiocytosis

Identify from Romanowsky stained smears
- Gaucher’s cells
- Neimann-Pick cells
- Sea-blue histiocytes

Perform infectious mononucleosis evaluation
- Presence of reactive/variant lymphocytes
- Positive serologic tests
- Cytomegalovirus (CMV)
- Toxoplasmosis
- Pertussis (whooping cough)
- Infectious lymphocytosis
- Viral hepatitis

List the major immune deficiencies in relation to T and B cell development
Recognize hematologic alterations in acquired immune deficiency syndrome (AIDS)
- Lymphocytopenia (T cell CD4 and CD 8 ratio)
- Leukopenia
- Anemia
- Thrombocytopenia

Sugar water (sucrose hemolysis) test

Acidified serum (Ham’s) test

Describe normal hemoglobin oxygen dissociation curve
Hemochromatosis/Hemosiderosis
Porphyrias (in chemistry section)
Osmotic Fragility
Delta beta Thalasemia
Hgb Constant Spring

Removal of FAB system from myelodysplastics

Recognize and describe features associated with aggressive forms of CLL
  Autoimmune hemolytic anemia (AIHA)
  Chromosome abnormality–trisomy 12
  Richter’s syndrome

Name and compare systems used to stage disease severity and progress
  Modified Rai
  Binet

Prepare bone marrow stains: Esterase, Myeloperoxidase

Perform differentials counts on normal bone marrow

Review criteria used to classify nonmalignant leucocyte disorders:
  Quantitative/Qualitative
  Sudan Black, PAS, LAP, TRAP

Recognize and describe features associated with aggressive forms of the disease: autoimmune hemolytic
  Discuss treatment options: Splenectomy etc.

Apply diagnostic criteria to blood and Bone marrow findings: adult T, lymphoid and cell line etc.
  Reed Sternberg, Rye Modified

Additions:
Distinguish between normal and abnormal hematopoietic elements found within the peripheral blood

List and define components of commonly used stains

Distinguish nucleated erythrocyte precursors from other hematopoietic elements

Describe the purpose of the metabolic pathways used by erythrocytes

Differentiate band neutrophils, segmented neutrophils, eosinophils, and basophils
  Determine if a granulocyte is mature or immature
  Discuss the clinical utility of the absolute neutrophil count

Agranulocytes changed to lymphocytes and monocytes

List the maturation sequence of monocytes and macrophages
List the maturation sequence of lymphocytic cells

MLS Hem 33
Describe monocyte and macrophage function
Identify abnormal lipid accumulations within monocytes and macrophages.

Associate a given red blood cell morphology with routinely encountered conditions
   Iron deficiency/alterations in iron metabolism
   Vitamin B12/Folate deficiency
   Thalassemia
   Sickle Cell Disease/Trait/other hemoglobinopathies
   Malaria
   Hereditary membrane abnormalities (spherocytosis, elliptocytosis, ovalocytosis, etc)
   RBC Enzyme abnormalities (G6PD and PK deficiencies)
   Extracorpuscular (immune and non-immune) mediated RBC defects

Describe the utility of flow cytometry in assessing red cell membrane defects

Identify major systems used to classify neoplastic disorders of leukocytes

Incorporation of WHO system into Acute Leukemia

   MLS ELC Coagulation
   Deletions and Additions

Deletions:

Bleeding time tests

Remove III from Antithrombin III

Additions:

Describe the principle of the platelet function assay
MLS Entry Level Curriculum – Immunohematology

**Whole blood donation -- principles of donor selection**
Review donor information (testing and interview responses) and determine if the donor is suitable for his/her category of donor
   - Routine allogeneic
   - Therapeutic
   - Autologous
   - Apheresis (platelet, plasma, double RBC)

Maintain donor records Level 1

Respond to questions regarding donor suitability consulting with medical director as appropriate Level 2

**Blood collection**
List the different anticoagulant/preservative solution used in blood collection/storage bags Level 1

Use the formula to correct the amount of preservative solution When donor is less than acceptable weight Level 2

Perform the appropriate pre-donation testing for apheresis products (e.g., Platelet count for plateletpheresis) Level 2

Maintain produce sterility and integrity Level 2

**Donor reactions**
Describe the signs and symptoms of adverse donor reactions Level 1

**Processing donor blood**
Discuss the required standard of care tests and deferral criteria for infectious disease
   - Hepatitis B and C antibody and NAT
   - Syphilis
   - HIV 1 / 2 (antibody and NAT)
   - HTLV I/II
   - CMV (as necessary)
   - Chaga’s disease
   - Bacterial testing of platelets

Analyze results of infectious disease tests to determine acceptability of donor Level 2

Perform ABO grouping and Rh typing tests and record results Level 2
Interpret ABO group and Rh type results and determine if a discrepancy exists

Perform antibody screen

Interpret results of antibody screen, and if positive identify antibody(ies)

Monitor quality of blood products

Store blood products according to product requirements

**Autologous donors**

Compare advantages and disadvantages of autologous and allogeneic donation and transfusion

Discuss and compare criteria for autologous collection with that of random allogeneic donor

Test and label blood as required for autologous units

Dispose of unused autologous units as indicated

**Preparation of cellular and plasma components from donor units**

Describe the process for separating units of whole blood and/or preparing cellular components

- Packed red blood cells (PRBC)
- Leukocyte-poor PRBC
- Washed PRBC
- Frozen, deglycerolized PRBC
- Irradiated PRBC
- Platelet concentrate

Discuss the preparation of single donor platelets by plateletpheresis using automated methods

Store each component within required parameters

Prepare components according to protocol

- fresh frozen plasma (FFP)
- cryoprecipitate (CRYO) from fresh frozen plasma
- single donor plasma from whole blood

Discuss pathogen inactivation methods for platelet and plasma products
Discuss the indications for and use of plasma derivatives (e.g., Factor VII, VIII, IX)

Label units/component with required information
   Name of component
   Expiration date
   Amount of product
   Storage temperature
   Results of tests

List quality control standards for methods used in component preparation

Test components to determine if they meet the QC requirements

Document and evaluate QC results to determine if corrective action should be taken

**Storage of blood components**
List the biochemical changes that take place in stored blood units and relate to the specific anticoagulant used, time and temperature of storage

Monitor equipment
   Document temperatures for refrigerators and freezers at required intervals
   Check temperature sensors at required intervals
   Document corrective action when temperatures vary beyond limits

Package and ship components
   Select units for shipping to fill routine and emergency orders
   Prepare transfer records
   Package components for shipping to maintain required conditions
   Maintain inventory

Trace donor unit and components for final disposition

**Blood group serology**
Evaluate suitability of specimen
   List rejection criteria
   Ascertain that specimen has been correctly collected and labeled
   Discuss possible sources of error in testing that may result
Correlate specific factors with their effect on reactions  
- Incubation time / temperature  
- Class of antibody  
- Antigen/antibody ratio  
- Centrifugation time/speed  
- Suspending media (e.g., pH, saline, high protein, low ionic strength)

Prepare red blood cell suspension using required equipment and reagents  
- Choose appropriate reaction tubes and prepare saline cell concentrations  
- Dispense cells and reagents  
- Balance and use a centrifuge  
- Wash cells manually and using a cell washer

Perform testing (e.g., tube, gel and solid phase tests) and record results  
- Shake out tube tests without dispersing true agglutination  
- Read and grade hemolysis and agglutination  
- Use controls as appropriate

Interpret and evaluate results of tests (e.g., tube, gel, solid phase)  
- Identify any factors that may have affected reactions and/or interpretation of reactions to resolve discrepancies

**Antiglobulin tests**
- Compare the principle and purpose of the direct antiglobulin test and indirect antiglobulin test (antibody screen)

Discuss the use of appropriate controls including autocontrol

Explain the principle and purpose of IgG sensitized cells

Choose polyspecific and monospecific antiserum for the appropriate test

Perform the antiglobulin test according to protocol and record results

Interpret results including control and determine reportability

Investigate and resolve false positive and/or false negative results

**Special methods**
- Describe criteria and/or situations for use of specific elution techniques (e.g., Lui freeze-thaw, chemical)
Describe the principle of special methods and discuss procedure

- Prewarm
- enzyme
- adsorption
- elution
- absorption
- neutralization
- titration

Select appropriate cells, reagents, controls and/or cell preparation methods for special techniques

Perform special methods tests and document results

Evaluate results of special methods tests and determine reportability or necessity of further testing

Describe criteria and/or situations for use of autologous or allogeneic Absorptions

List cells used in each type of absorption

List antibodies that can be neutralized and the appropriate source of antigen/substance to use

Perform antigen typing (tube, gel, solid phase) and record results

Interpret results of antigen typing and determine if further testing is required

Discuss use of molecular genotype testing for prediction of red cell antigens

Perform (tube, gel and solid phase) testing for antibody screening & identification and document results

Interpret results of tests for antibody screen/identification and evaluate for further testing or reportability

Apply knowledge of limitations of test procedure to test results and interpretation
**Principles for recognition or differentiation of blood group antigens and antibodies**

For the more common blood group systems list and compare characteristics of red cell antigens with their specific antibody
   - Enzyme enhancement or inhibition
   - Dosage
   - Complement binding
   - Other optimal conditions or reaction (e.g., pH, temperature, enhancement media)

Name and use a source of information to identify characteristics reactions of rare unexpected antibodies

Apply characteristics of blood group antigens to interpret an antibody screen,

Evaluate clinical significance of antibodies identified, and determine safety of blood components for transfusion
   - Specificity and immunogenicity
   - Biochemistry (noting similarity in behavior of structurally similar antigens)
   - Variable expression of antigens
   - Dosage
   - Prevalence
   - Number and location of antigen sites
   - Modes of inheritance
   - Effects of genotype on expression of genes at other loci and effects of gene linkage
   - Antigen development including changes from newborn through adult to aged
   - Disease-related antigen changes
   - Correlation of genotype with disease and or cell membrane function
   - RBC blood group antigens present on other tissue
   - Soluble blood group substances
   - Molecular genotyping

Apply properties of antibodies directed toward blood cell antigens to interpret antibody screens,
   - Primary vs. secondary response
   - Non-red cell vs. red cell stimulation
   - Expected (e.g., A, B, H) vs. unexpected
   - Avidity
   - Titer
   - Effects of patient age, specimen age, disease
   - Clinical significance
   - Immunoglobulin class
   - Phase of reactivity (*in vivo* vs. *in vitro*)
Correlate immunoglobulin class with other properties
   Form of stimulation
   Class of antibody
   Subclass of antibody

Evaluate clinical significance of antibodies present, and determine safety of blood components to be issued

Explain the effects of complement on hemagglutination reactions
   Aid in enhancing Kidd system antibody reactions
   Interfere in immediate spin crossmatches

**Pre-transfusion testing**
Determine acceptability of recipient specimen based on specified criteria

Check records for previous ABO group and Rh type, antibody problems, and transfusion history of patient

Perform and document results for required tests on recipient blood sample
   ABO forward and reverse typing
   Rh typing including weak D when appropriate
   Antibody screen and identification
   Antigen typing for special antigens as necessary employing negative and weakly-reacting positive control cells

Interpret and evaluate results of recipient blood sample tests to determine if further testing is necessary

Correlate test results with potential causes of discrepant results
   Subgroups of A and B
   Weakened or altered antigen expression due to disease
   Missing antibody in newborn, elderly or immunosuppressed
   Unexpected alloantibody
   Autoantibody
   Transplantation of non-ABO–identical bone marrow/stem cells

Analyze patient history, diagnosis, transfusion history and antibody screen results and correlate with ABO discrepancies

Discuss regent variability between monoclonal typing reagents when interpreting discrepant results
Resolve discrepancies of ABO typing results
Perform and interpret tests using appropriate methods
(e.g., lectins, saline replacement, and reverse grouping with A2 and O cells)

Perform antibody screening and identification for antibodies that can be resolved using routine procedures
Perform and interpret antibody screening results including antiglobulin phase
Perform and identify antibodies using routine antibody identification panels on serum or eluate

Confirm antibody identification
Perform and interpret antigen typing of patient cells
Choose selected cells of appropriate phenotype
Select perform and interpret a cell panel using a 95% probability level of cells (3 cells positive and 3 cells negative) for the antigen against which a suspected antibody is directed

Resolve complex antibody problems

Evaluate clinical and/or laboratory data to determine when each specific technique is appropriate

Alter reaction conditions to include appropriate controls and interpret results
Increased serum volume
pH adjustment
Neutralization techniques
Pre-warm technique
Saline replacement technique
Autologous or allogeneic adsorption
Special antigen typings
Separation and identification of multiple antibodies by adsorption/elution procedure

Interpret multiple antibody reactions on a panel
Differentiate clinically significant and insignificant antibodies

**Compatibility of recipient and donor**

Evaluate the necessity for compatibility testing depending on component required and nature of request
Type and screen with negative screen results vs. positive screen results
Routine transfusion
Emergency transfusion
Massive transfusion
Intrauterine and neonatal transfusion
List the blood groups that are compatible with each ABO blood group  Level 1

Select blood for compatibility testing
  when group specific blood is available
  when groupspecific blood is not available
  if the patient has been recently transfused with non-group specific blood  Level 2

Prepare donor sample from attached sealed segment or segment with number matching it to donor sample  Level 2

Perform crossmatch and document results
  immediate spin crossmatch to detect ABO incompatibility
  routine antiglobulin crossmatch
  computer crossmatch  Level 2

Interpret crossmatch results and determine follow-up procedures if necessary  Level 3

Perform phenotype frequency calculations to determine the number of donor units needed to find compatible units for a patient with alloantibody(ies)  Level 2

Select blood for compatibility testing that is negative for the antigen against which clinically significant recipient antibody(ies) is/have been detected  Level 2

Discuss selection of blood or blood products requiring special criteria
  Hemoglobin S negative
  CMV negative
  Irradiated  Level 1

Release compatible units for transfusion and complete appropriate records  Level 2

Retain specimen from donor and recipient for appropriate length of time  Level 1

Resolve compatibility problems using methods used to resolve antibody identification problems  Level 3

Correlate results of compatibility testing with causes for incompatible results
  Atypical antibody(ies)
  Rouleaux
  Autoantibody(ies)
  Positive DAT on donor cells  Level 2

Apply appropriate labels/tags to units including cases of incompatibility, emergency release of non-crossmatched unis, least incompatible, etc.  Level 2
Testing for disease states associated with a positive direct antiglobulin test

Explain the principle of the direct antiglobulin test (DAT) Level 1

Perform DAT including use of IgG sensitized cells and record results
   Use monospecific antiglobulin sera as indicated and compare results with polyspecific serum results

Interpret results and correlate with the patient history to determine appropriate follow-up testing Level 3

Investigate and resolve cases of positive DAT
   Correlate patient history and perform appropriate testing to confirm warm autoimmune hemolytic anemia, cold agglutinin syndrome
   Correlate drug history, IVIG infusion and test results to confirm drug-induced DAT and/or drug-induced hemolytic anemia using appropriate procedure
   Correlate results of maternal and infant testing to confirm hemolytic disease of the fetus and newborn
   Perform adsorption / elution as necessary to aid in antibody identification

Hemolytic disease of the fetus and newborn

Describe the immune process which causes hemolytic disease of the fetus and newborn (HDFN) Level 1

Discuss the mechanism of fetal and neonatal alloimmune Thrombocytopenia Level 1

Predict the risk for HDFN from parental phenotypes
   Using parental phenotypes discuss the probability of infant phenotype
   Consider the mechanism of immunization for risk of ABO-HDFN, Rh-HDFN, and HDFN due to other antigens
   Discuss protective factors in determination of risk for HDFN Level 2

List the common antibodies responsible for HDFN and compare their characteristics with antibodies that do not cause HDFN Level 2

Perform prenatal testing
   Perform and interpret ABO and Rh typings and antibody screen on maternal sample
   Identify the antibody present in maternal sample and perform antibody titration if appropriate Level 2
Perform testing on fetal blood samples and report results  

Procure safe blood for intrauterine transfusion  
Select fresh blood of appropriate ABO and Rh type  
Select or prepare leukocyte-reduced, irradiated, washed, hemoglobin S negative and CMV negative units as necessary  

Perform and record results of compatibility testing using  
using maternal serum or eluate or fetal serum (when available through umbilical cord sampling)  

Interpret results of compatibility test and determine if results can be reported or if followup testing is necessary  

Perform neonatal testing  
Perform ABO (forward typing only) and Rh typing  
and direct antiglobulin test and record results  
Perform elution and antibody identification where indicated  
Perform ABO and Rh typing and antibody screen on maternal postnatal specimen  
Identify antibody (ies) if present  

Interpret results of neonatal testing on mother and baby and determine clinical significance and further testing if necessary  

Perform testing for exchange transfusion  
Select blood for transfusion that is appropriate to the clinical needs of the recipient  
Perform compatibility test using appropriate samples  

Interpret results of compatibility testing and determine reportability and further action if necessary  

Perform testing to determine necessity for administration of post-natal RhIg to prevent Rh-HDFN  
Review patient history for evidence of antenatal administration of RhIg  
Perform D and weak D tests on maternal and newborn samples  
Perform antibody screen on maternal serum  

Interpret and correlate results to determine eligibility for RhIg  

Perform testing to identify and quantitate fetal maternal hemorrhage  
Rosette  
Kleihauer-Betke  
Flow cytometry
Calculate dosage of RhIg based on test results  
Level 2

Issue product and complete records  
Level 2

**Issuing of blood and blood components**

Discuss the clinical necessity for, and effects of transfusion  
Level 1

Evaluate indications for transfusion of red cells, blood components, and factor concentrates  
Level 3

Interpret changes expected in patient function / laboratory values  
Level 2

Prepare blood and blood components for transfusion  
Level 2
  - Maintain adequate supply of appropriate blood and blood components
  - Inspect blood and components for date of expiration and evidence of contamination or deterioration
  - Perform confirmatory verification of ABO group and Rh type on donor units as specified
  - Verify patient identification and perform comparison checks on ABO and Rh of patient and complete records

Discuss bacterial testing for platelet units  
Level 1

Prepare products for transfusion  
Level 2
  - Wash cells
  - Irradiate product according to protocol
  - Pool platelets or cryoprecipitate
  - Thaw fresh frozen plasma and cryoprecipitate
  - Prepare red blood cells to specified hematocrit or small volume aliquot for pediatric patients
  - Perform volume reduction on apheresis units

Control return of unused blood or components  
Level 2
  - Note time and estimate conditions under which blood components were maintained when out of the laboratory
  - Inspect for evidence of improper storage
  - Determine whether blood components can be reissued, complete appropriate records and store as required
  - Appropriately dispose of blood components that cannot be reissued and complete paperwork
**Investigation of suspected adverse outcome to transfusion**

Perform required preliminary investigation to determine whether a hemolytic reaction has occurred

- Obtain and review completed transfusion report
- Check identification of pre-transfusion sample of donor and patient and of blood container
- Confirm correctness of interpretation of pre-transfusion test results
- Compare plasma of pre-transfusion and post-transfusion specimens for evidence of hemoglobin or icterus
- Perform and interpret a direct antiglobulin test (DAT) and ABO/Rh typing on post-transfusion sample and compare with pre-transfusion sample

Evaluate results of preliminary checks and correlate test results with clinical evidence to determine cause of transfusion reaction

- Acute hemolytic
- Febrile non-hemolytic
- TRALI
- Circulatory overload
- Allergic
- Anaphylactic
- Non-immunologic reaction caused by method of blood administration
- Hemolytic caused by an alloantibody
- Reaction (septic shock) caused by bacterial contamination (send unit to microbiology for gram stain and culture)
- Infectious disease transmission

Follow up reports of infectious disease transmission associated with transfusion

- Review test results on donor blood for markers of infectious disease or perform testing on patient sample as suggested by clinical symptoms and review
- Report positive test results to physician, blood suppliers and to appropriate regulatory agencies
- Perform a ‘look back’ procedure

Perform additional testing where appropriate to determine if a hemolytic reaction is the result of an alloantibody

- Repeat ABO, Rh, compatibility testing and antibody screening on patient pre-transfusion and post-transfusion samples and compare results
- Repeat ABO and Rh typing on donor unit and compare pre-transfusion and post-transfusion results
- Identify unexpected alloantibody found in patient serum
- Type donor cells for antigen corresponding to the recipient antibody identified
- When DAT on patient cells is positive with anti-IgG prepare and test a red cell eluate for unexpected alloantibody
Separate transfused from autologous cells by capillary centrifugation and perform appropriate testing on separated cells
Use molecular typing to identify cell populations

Advise health care team of appropriate blood for future transfusions Level 2

**Human leukocyte antigens (HLA)**

Describe the genetic origin, biological functions, and cell distribution of the major human leukocyte antigens Level 1

Discuss the clinical importance for identifying HLA antigens or antibodies and matching HLA antigens Level 1
  - Disease association
  - Transplantation
  - Platelet transfusion

Discuss results of HLA typing, antibody screening, and crossmatching procedures including DNA hybridization methodologies for more specific identification of HLA alleles Level 1
  - Flow cytometry bead techniques
  - Microlymphocytotoxicity assay for HLA-, HLA-B, and HLA-DR
  - SSP
  - RT-PCR
  - Oligonucleotide probes
  - DNA sequencing

**Quality assurance**

Follow good manufacturing practices for environment within the facility Level 1
  - Adequate space
  - Ventilation
  - Sanitation and trash disposal
  - Temperature control
  - Water systems

Maintain/follow a Standard Operating Procedure (SOP) manual for all procedures Level 2

Participate in laboratory quality assessment Level 2

Discuss competency assessment Level 1

Discuss process improvement indicators Level 1
Participate in personnel QA
  Provide and/or participate in continuing education programs
  Participate in proficiency testing

Perform calibration and preventive maintenance at required intervals,
  troubleshooting and complete appropriate records
  Centrifuge
  Refrigerators/freezers / platelet chambers
  Timers
  Automated cell washers
  Automated blood grouping or antibody screening instrumentation

Perform, interpret and record appropriate quality control (QC) on reagents
  Typing sera and cells
  Antibody screening and panel cells
  Antiglobulin sera and IgG sensitized control cells

Perform positive and negative control testing as required in tandem with
  patient tests when tests are not performed daily
  Lectins
  Special antigen typing sera

Monitor results of quality control procedures for reagents

Discuss the criteria for adequate recovery of prepared component

Test an appropriate percentage of blood units or components, interpret
  results for acceptability and determine corrective action
  Packed red blood cells for volume and hematocrit
  Number of platelets and volume
  Number of units of Factor VIII in cyoprecipitate

Maintain inventory records
  Have available the records for: ABO, Rh testing performed in the
  last 12 months and
difficulties encountered in transfusion testing according to state and
federal requirements
  Store and retrieve testing results and other information from a database

Maintain records of errors or adverse outcomes in patients
Report adverse events to the collecting facility and/or FDA Center for Biologics Evaluation and Research

- Report units implicated in post-transfusion disease transmission to the collecting facility
- Report fatalities related to blood collection or transfusion to the FDA

**Agencies regulating blood banks**

Maintain copies of standards/regulations for blood banks and evidence of compliance

- Have available current copies of regulations and standards: required by law (CLIA ’88) and those for agencies from whom licensure or accreditation is required (FDA) agencies from which the institution has voluntarily applied for /received accreditation (e.g., AABB, CAP, TJC)
- Maintain documentation of conformance to FDA nd CLIA ’88 regulations and to those of agencies from which the institution has voluntarily applied/for received accreditation

Interact/communicate with agencies according to regulations/standards

- Prepare accreditation documents
- Subscribe to appropriate proficiency testing
- Document and report adverse events/errors as required by regulating agencies
MLS – ELC Immunohematology  
Deletions & Additions

DELETIONS
Allogeneic Donation:
  o Removed section dealing with donors
  o Take donor history
  o Perform physical examination
  o Perform hemoglobin
  o Obtain informed consent
  o Perform phlebotomy use supplies for treating donor reactions

Autologous donation:
  o Select donor
  o Adapt history questions
  o Collect blood

Sections such as developing and modifying procedures/guidelines (not-entry level)

HLA
  o Changed “perform testing” to “observe testing “

ADDITIONS

Throughout the document updated test methods (e.g., include molecular, bacterial testing for platelets).
**MLS Entry Level Curriculum**

**Immunology**

**Basic Concepts**

Define innate immunity  
Define adaptive immunity  
Passive immunity  
Active immunity

List major components of innate immune system and their functions  
Physical barriers  
Phagocytic cells  
Innate lymphocytes and innate-like T/B cells  
NK cells  
pH  
lytic components  
Inflammatory response  
Soluble mediators (cytokines, complement, acute phase reactants)

Describe cellular and organ components of the immune system and their origins  
Lymphoid organs (primary and secondary including GALT, MALT, Peyer’s patches)  
Cells (e.g., T cells, B cells, macrophages)

Contrast primary and secondary immune responses

Discuss the features of an antigen molecule that determine immunogenicity  
Molecular size and complexity  
Foreignness  
Epitopes  
Dosage, timing, route of administration  
Cross-reactivity

Compare the basic characteristics of T-cell dependent and T-cell independent antigens

Discuss the structure, function, properties, and formation of an antibody molecule  
Class and subclass  
Light and heavy chain  
Regions  
Fragments (Fab and Fc)  
Gene rearrangement
Define the following and discuss the importance in the immune process

- Isotype
- Allotype
- Idiotype

**Cell-mediated immunity**
Discuss the concepts of T cell plasticity and polarization

Describe T cell development

Differentiate the functions of T cell subsets

- CD8+ (cytotoxic)
- CD4+ (Th1, Th2, Th9, Th17, Tfh)
- Treg (tTreg, pTreg)

Compare the response of T cells to intracellular vs. extracellular pathogens

Describe the process and interactions of antigen recognition and presentation for T cell subsets

- Role of activation and antigen-presenting cells
- MHC molecules involved
- Restricted recognition
- Co-receptors
- Signaling
- Cytokines stimulated or responded to
- Cells stimulated

Discuss and compare the effector functions of each T-cell subset

- Lysis
- Apoptosis
- Inflammation
- Regulation
- B cell activation

Discuss the characteristics, role, function and interactions of natural killer (NK) Cells

- CD markers
- Lack of MHC restriction
- Cytokines stimulated
- Expanded cell phenotyping using transcription factors, adhesion molecules
- Cytokine response
**Humoral immunity**
Discuss the interaction of cells in the generation of antibody
   - APC
   - CD4+

Define isotype switching and describe how it occurs

List and describe the characteristics of memory cell populations
   - Types of cells (B cell, T cells, ILC, NK, central, effector, resident tissue populations)
   - Numbers of cells
   - Titer of antibody
   - Affinity of antibody

Compare antigen independent and antigen dependent B-cell differentiation
   - Affinity maturation
   - Class switching
   - Gene rearrangement

Describe the process and interactions of mature B cell activation
   - Stimulatory molecules
   - Membrane bound Ig
   - Secreted Ig
   - Plasma cell

**Cytokines**
Discuss major cytokines involved in innate immunity (e.g., IL-1, IL-6, TNF-α) and compare major characteristics
   - Cells that produce
   - Functions
   - Cells that are affected

Discuss major cytokines involved in adaptive immunity (e.g., IL-2, IL-4, IL-5, IL-10, IFN-γ) and compare major characteristics
   - Cells that produce
   - Functions
   - Cells that are affected

Discuss soluble mediators affecting PMNs and macrophages (e.g., Chemotactic factor, migration inhibitory factor, GM-CSF)
   - Cells that produce
   - Functions
   - Cells that are affected
Immunologic techniques used in the clinical immunology laboratory

Discuss and compare the basic immunoassay principles and techniques
- Particle (e.g., precipitation, agglutination, flocculation, diffusion)
- Competitive & non-competitive binding (e.g., EIA, Chemiluminescent, fluorescent polarization)
- Enzyme immunoassay (e.g., competitive and, non-competitive)
- Microparticle assay
- DNA

Compare sensitivity, specificity of methods, and their usefulness
- Particle (e.g., precipitation, agglutination, flocculation, diffusion)
- Competitive & non-competitive binding (e.g., EIA, Chemiluminescent, fluorescent polarization)
- Enzyme immunoassay (e.g., competitive and, non-competitive)
- Microparticle assay
- DNA

Evaluate specimen suitability

Prepare appropriate materials, reagents and equipment for performing test procedures

Perform procedures according to established laboratory protocols using controls and standards (if applicable) and report results
- Particle (e.g., precipitation, agglutination, flocculation, diffusion)
- Competitive & non-competitive binding (e.g., EIA, Chemiluminescent, fluorescent polarization)
- Enzyme immunoassay (e.g., competitive and, non-competitive)
- Microparticle assay
- DNA

Evaluate acceptability/reportability of results

Identify sources of error in procedures according to laboratory protocol

Perform and document quality control

Evaluate results of quality control and determine reportability or action to be taken

Perform and document routine preventive maintenance

Correlate immunology test results with other laboratory data and patient diagnosis
**Immunologic Techniques used in Flow Cytometry**—cross-referenced to hematology

Discuss basic concepts and operation of flow cell cytometry instrument Level 2
- Fluid system
- Optical system
- Signal detection system
- Data management system
- Sample preparation
- Light scatter (forward angle –FALS and side scatter –SS)
- Gating

Discuss the role of monoclonal antibodies in Fluorescence assisted cell sorting (FACS) Level 1
- Cell sorting
- Production
- Cluster designations (CD)
- Fluorescent labeling
- DNA probes

Discuss the clinical applications of flow cell cytometry in diagnosis and treatment Level 2
- Lymphocyte immunophenotyping
- Leukemia/lymphoma immunophenotyping
- DNA ploidy analysis
- Reticulocyte enumeration

Perform flow cytometry testing and report results Level 2

Interpret and evaluate flow cytometry results Level 3

**Autoimmune Diseases**

Define immune tolerance Level 1

Discuss and compare the proposed mechanisms for autoimmunity Level 2
- Release of sequestered antigen
- Escape of tolerance at the T cell level
- Molecular mimicry
- Diminished cell regulation and balance

Differentiate organ-specific and systemic autoimmune diseases Level 2

Discuss MHC/HLA structure and diversity Level 1

Describe the role of MHC/HLA antigens in autoimmune disease Level 1
Describe underlying mechanisms, clinical symptoms, characteristic autoantibody(ies) and correlate laboratory findings for classic autoimmune diseases

Collagen vascular (systemic lupus erythematosus, rheumatoid arthritis, scleroderma, Sjogrens syndrome)
Idiopathic thrombocytopenia purpura
Thyroid (Hashimoto’s thyroiditis and Graves’ disease)
Myasthenia gravis
Multiple sclerosis
Addison’s disease
Type 1 diabetes mellitus
Celiac disease
Goodpasture’s syndrome
Wegener’s granulomatosis (granulomatosis with polyangitis)

Tumor Associated Antigens
Discuss the purpose and function of the immunosurveillance system for tumor recognition

List and discuss the most common antigens associated with tumors /specific cancers
Carcinoembryonic antigen (CEA)
Alpha-1 antitrypsin (Cross listed with chemistry)
Prostate specific antigen (PSA)
Beta-2 microglobulin (Cross listed with chemistry)
HCG (Cross listed with chemistry)
CA 125, CA-19-9, CA 15-3, CA 27-29

Discuss the problems associated with use of tumor marker test results

Primary Immunodeficiency Diseases
Correlate the underlying defect(s), clinical symptoms, and laboratory findings for congenital/genetic B cell immunodeficiencies
X-linked agammaglobulinemia (Bruton’s agammaglobulinemia)
Selective common variable immunoglobulin deficiencies
IgA deficiency
Correlate the underlying defect(s), clinical symptoms, and laboratory findings for congenital/genetic T cell immunodeficiencies
   Thymic aplasia (DiGeroge’s syndrome)

Correlate the underlying defect(s), clinical symptoms, and laboratory findings for combined congenital/genetic T cell and B cell immunodeficiencies
   Ataxia telangctasia
   Severe combined immunodeficiency disease (SCID)
   Wiskott-Aldrich syndrome

Discuss therapeutic approaches for primary immunodeficiencies

**Complement system deficiencies**
Correlate the underlying defects and mechanisms, clinical symptoms, and/or disease and laboratory findings for individual complement component or regulatory molecule deficiencies

**Phagocyte deficiencies**
Correlate the underlying defects, clinical symptoms, and or/disease and laboratory findings for phagocyte deficiencies
   Leukocyte adhesion deficiency
   Chronic granulomatous disease (CGD)
   Chediak-Higashi syndrome

**Acquired immunodeficiencies**
List factors that may cause an acquired immunodeficiency

Correlate the underlying defect(s) or mechanism(s), clinical symptoms, and laboratory findings for a patient with an acquired immunodeficiency syndrome
   Tests for antigen and antibody and the characteristic reactions at different phases of HIV infection
   Classic infections associated with AIDS
**Infectious diseases**
Correlate the clinical symptoms, phases of infection and complications and laboratory findings (e.g., Characteristic patterns of markers at specific stages, Viral load tests and NAAT for specific infections)
- Epstein-Barr infection (infectious mononucleosis)
- Hepatitis (A, B, C, D, E)
- Rubella
- Syphilis
- Group A streptococcal infection
- Cytomegalovirus (CMV)
- Sepsis/SIRS

**Hypersensitivity**
Compare the causes, molecular mechanisms, mediators, and clinical manifestations associated with the 4 types of hypersensitivity
- Type I
- Type II
- Type III
- Type IV

Correlate each type of hypersensitivity reactions with representative clinical conditions

List the characteristic testing for each type

Correlate laboratory findings with the clinical condition
MLS Entry level curriculum
Immunology

DELETIONS & ADDITIONS

DELETIONS:

- No significant deletions of sections
- However, did completely rearrange the basic immunology section to reflect components of immune system and newer cell types identified

ADDITIONS:

- Autoimmune disease:
  - Added additional diseases (e.g., celiac, autoimmune hepatitis)
  - Additional antibody tests
  - Role of HLA in autoimmune diseases

- Tumor markers:
  - Listed key tumor marker tests

- Cross referenced flow cytometry with hematology and tumor markers with chemistry.
A. Basic principles
1. Differentiate among microorganisms
   a. Bacteria
   b. Yeasts, molds
   c. Viruses
   d. Parasites
   e. Prions
2. Describe the classification of bacteria
   a. Taxonomy
   b. Nomenclature
   c. Identification
3. Describe the phenotypic characterization of bacteria
   a. Cell growth and reproduction
   b. Metabolism and nutrition
4. Describe the staining characteristics of bacteria
   a. Gram-positive, Gram-negative and Gram-variable
   b. Acid-fastness
5. Differentiate microscopic morphologies of bacteria
   a. Cocci in chains, clusters, tetrads, pairs
   b. Diplococci and coccobacilli
   c. Bacilli/Rods
   d. Lancet
   e. Fusiform
   f. Pleomorphic
   g. Branching
   h. Palisading
   i. Endospores
   j. Capsules
   k. Flagella
   l. Spirochetes
   m. Intra- and extra-cellular
6. Apply the use of bio and molecular technologies to taxonomy and clinical microbiology
   a. Deoxyribonucleic acid (DNA) relatedness
   b. Nucleic acid probes/hybridization
   c. Amplification procedures including but not limited to polymerase chain reaction
   d. Maldi-TOF (general theory)
7. Demonstrate proper use of the microscope (also found in General Lab Practice)
   a. Use
   b. Maintenance
c Troubleshooting

B. Role of the Clinical Microbiology Laboratory

1. Pre-analytical Phase
   a. Communicate with health professionals to insure quality specimens for submission  Level 2
   b. Recognize (Level 2) potential errors and resolve (Level 3) according to predetermined criteria

2. Analytical Phase
   a. Accurately perform appropriate and timely testing in a cost effective manner

3. Post-analytical Phase
   a. Provide accurate and timely results  Level 2

C. Laboratory examination of specimens for bacterial culture

1. Properly identify specimen type  Level 1
   a. CSF
   b. Blood and bone marrow
   c. Pleural
   d. Synovial
   e. Peritoneal
   f. Pericardial
   g. Amniotic
   h. Gastric
   i. Genital
   j. Eye/ear/throat
   k. Nasopharynx/sinuses
   l. Sputum/Bronchial
   m. Tissue, skin, and bone
   n. Catheter tips
   o. Urine
      i. Catheterized
      ii. Clean voided midstream
      iii. Suprapubic
   p. Wound
      i. Abscess aspiration/purulent material
      ii. Surgical
      iii. Soft tissue
   q. Gastrointestinal
   r. Autopsy

2. Provide proper accession of specimens  Level 2
   a. Log in
   b. Request form information/Laboratory information system orders
c. Labeling

3. Evaluate acceptability of the specimen
   a. Collection method/site preparation/aseptic technique
   b. Collection time
   c. Container/sampling device
   d. Transport system (temperature, atmosphere, media)
   e. Time in transit
   f. Patient therapy
   g. Number
   h. Quality/Rejection criteria
   i. Quantity
   j. Contamination/spillage

4. Choose appropriate storage temperature/environment if delay in processing

D. Growth and Media

5. Choose appropriate growth media and tests
   a. Choose proper routine primary isolation media
      i. Enriched
      ii. Selective (differential/enrichment)
      iii. Nutrient/general purpose
   b. Describe the purpose of each media
      i. Nutrients/constituents/supplements
      ii. Antibiotics
      iii. pH
      iv. Antibiotic removal
      v. Environment
   c. Select special isolation media
   d. Select special stains/direct tests

6. Prepare specimen for inoculation
   a. Centrifugation
   b. Homogenization

7. Perform proper inoculation of media
   a. Order of media for inoculation
   b. Quantitative
   c. Semi-quantitative
   d. Standard inoculation and streaking techniques
   e. Swab
   f. Loop sterilization
      i. Reusable metal
      ii. Plastic/disposable
      iii. Calibrated
   g. Streaking for isolation
h. Stab
i. Pipette
j. Automated plater

8. Determine appropriate media and conditions
   a. Choose appropriate atmosphere
      i. Aerobic-ambient
      ii. Capneic (3-5%, 5-10%, microaerophilic)
      iii. Anaerobic
   b. Choose appropriate temperature
      i. 4 C
      ii. 25 C
      iii. 30 C
      iv. 35 C
      v. 42 C
   c. Humidity
   d. Determine appropriate length of incubation

9. Prepare direct microscopic smears of specimen
   a. Prepare smear (one cell thick, dry, fixed)
   b. Stain smear appropriately
      i. Saline Wet mounts
      ii. Stained Wet Mounts
         1) Iodine
         2) KOH
         3) Methylene Blue
      iii. Gram
      iv. Spore
      v. Acid-fast
         1) Ziehl-Neelsen
         2) Kinyoun
         3) Modified Kinyoun
      vi. Fluorescent
         1) Acridine orange
         2) Auramine-rhodamine
         3) Calcofluor white
         4) Fluorescein conjugated (FITC)

10. Evaluate and interpret direct microscopic smears of specimen
    a. Wet mounts and Vaginal wet preps
       i. Saline
       ii. Iodine
       iii. KOH
    b. Gram
11. Evaluate and quantitate microscopically
   a. Bacteria
      i. Structures
      ii. Capsule
      iii. Spores
   b. Yeasts and hyphal elements
   c. White and red cells
   d. Epithelial cells - columnar and squamous, i.e. Clue cells
   e. Artifacts and background material

12. Quantitate organisms and cells

13. Evaluate quality of specimen and assess clinical significance of findings according to guidelines

14. Differentiate normal flora from potentially pathogenic organisms based on body site and specimen type

E. Bacterial Culture Examination

1. Distinguish colony morphologies
   a. Staphylococci
   b. Streptococci and Enterococci
   c. Gram-negative cocci
   d. Enterobacteriaceae
   e. Pseudomonads
   f. Other non-fermentative Gram-negative rods
   g. Fastidious and other miscellaneous Gram-negative rods
   h. Non spore-forming Gram-positive rods
   i. Spore-forming Gram-positive rods
   j. Branching and filamentous Gram-positive rods
   k. Mycobacteria

2. Differentiate common growth characteristics
   a. Blood Agar media
      i. Hemolysis (alpha/beta/gamma)
         1) Double beta
         2) Subtle or narrow zone
      b. Selective Gram Negative media (i.e., MacConkey)
         i. Fermenter vs. non-fermenter
         ii. Detection of Hydrogen Sulfide (H₂S)
         iii. Lysine decarboxylation
      c. Chocolate media
         i. Modified Thayer Martin (MTM)
      d. Campy-blood agar (BA)
         i. Cefoperazone
ii. Vancomycin
iii. Amphotericin B (CVA)
e. Modified CCDA Medium
f. Colistin-nalidixic acid (CNA) blood agar
   i. Phenylethyl alcohol (PEA)
   ii. Mannitol salt agar (MSA)
g. Anaerobic media
   i. Anaerobic blood agar
   ii. Kanamycin-vancomycin laked (KVL)
   iii. Other anaerobic media (i.e., BBE, etc.)
h. Other media
   i. Group B selective broths
   ii. Routine enrichment broths
   iii. Mueller-Hinton
   iv. Chromogenic agar

3. Select for significant uncommon organisms using selective media
   Level 1
   a. Enrichment media
   b. Buffered charcoal yeast extract (BCYE)
   c. Stool selective media
   d. Corynebacterium selective media

4. Evaluate growth on primary isolation media
   Level 3
   a. Correlation of direct gram stain results and culture results
   b. Correlation of clinical diagnosis and specimen source
   c. Variations in colony morphology
      i. Colony characteristics
         1) Size
         2) Shape
            a) Elevation
            b) Form
            c) Margin
               i) Umbilicated
               ii) Swarming, etc.
            d) Surface appearance
               i) Mucoid
               ii) Transparent
               iii) Opaque, etc.
            e) Pigmentation
            f) Changes in media
               i) Hemolysis
               ii) Pitting
               iii) Fermentation, etc.
         3) Correlation of growth on different media
         4) Normal flora vs. potential pathogens
5) Characteristic odors of selected organisms
6) Growth quantitation

E. **Organism identification**

1. Apply principles of identification **Level 2**
   a. Limitations and sources of errors
   b. Troubleshooting according to set guidelines
   c. Sensitivity and specificity
   d. Environmental requirements atmosphere, growth temperature, etc.

2. Evaluate confirmatory identification tests (including rapid tests) **Level 3**

3. Perform confirmatory identification tests (including rapid tests) **Level 2**
   a. Catalase
   b. Oxidase/DMSO modified
   c. Coagulase
   d. TSI and KIA slants
   e. Methyl Red
   f. Phenylalanine deaminase (PAD)
   g. Amino acid (ornithine, arginine and lysine) decarboxylase, i.e., lysine iron agar (LIA)
   h. Acid production from carbohydrates
      i. Fermentation/oxidation
      r. Indole
      i. Tube
      r. Spot
   r. Porphyrin (Delta aminolevulinic acid) (ALA)
   s. Pyrrolidonyl arylamidase (PYR)
   t. Salt tolerance
   u. Esculin hydrolysis
      i. Rapid
      r. Bile esculin slant
   v. Hippurate hydrolysis
   w. H2S production
   x. Nitrate reduction
   y. Citrate utilization
   z. Urease
   aa. Butyrate esterase
   bb. Voges-Proskauer
   cc. Bile solubility
   dd. Growth factor requirement (X, V and XV)

3. Perform Disk identification tests **Level 2**
   a. Novobiocin
   b. Optochin (ethylhydrocureine hydrochloride)
c. Special potency disks  
d. Bacitracin  
e. Beta lactamase  
f. Growth factors (X, V, and XV)  
g. Colistin, Kanamycin, Vancomycin

4. Choose other testing
   a. Satellitism, i.e., *Staphylococcus aureus* streak  
b. Motility  
c. Aerotolerance  
d. Colony fluorescence

5. Identify basic concepts of commercial identification systems
   a. Non-automated
      i. Miniaturized  
      ii. Rapid  
         3) Substrate based  
         4) Spot tests  
   b. Automated
      i. Nucleic acid detection  
         1) Nonamplified  
            a) Hybridization probes  
         2) Amplified, including but not limited to real time polymerase chain reaction (PCR)  
         3) Maldi-TOF  
         4) Microarray

6. Identify basic concepts of serological identification
   a. Coagglutination  
   b. latex agglutination  
   c. urine antigen detection  
   d. Toxin detection  
   e. Immunofluorescent assays (Direct-DFA/Indirect-IFA)  
   f. Enzyme linked immunoabsorbant assay (ELISA)  
   g. Serotype

7. Utilize established algorithms and databases to establish identification

F. Clinically Significant Organisms

6. Isolate organisms listed below at the following identification levels:

   **Level 1**
   Can recall it  
   Can identify it

   **Level 2**
   Can assess significance of culture findings based on identification and specimen site

   **Level 3**

a. Staphylococci
   i. *Staphylococcus aureus* (**Level 3**)  
   ii. Methicillin-resistant *Staphylococcus aureus* (MRSA) (**Level 3**)  
   iii. Vancomycin-intermediate *S. aureus* (VISA) (**Level 3**)
iv. Vancomycin-resistant *S. aureus* (VRSA) (*Level 3*)
v. *Staphylococcus epidermidis* (*Level 1*)
vi. *Staphylococcus saprophyticus* (*Level 2*)
vii. *Staphylococcus lugdunensis* (*Level 1*)
viii. Other coagulase-negative Staphylococci (*Level 2*)
b. Micrococcus species (*Level 2*)
c. Streptococci
   i. *Streptococcus pyogenes* (Group A) (*Level 3*)
   ii. *Streptococcus agalactiae* (Group B) (*Level 3*)
   iii. Other beta-hemolytic Streptococci (*Level 3*)
   iv. *Streptococcus pneumoniae* (*Level 3*)
v. Viridans group (*Level 3*)
   vi. Alpha and non-hemolytic Streptococci (*Level 2*)
d. Enterococcus, VRE,
   i. *Enterococcus faecalis* (*Level 3*)
   ii. *Enterococcus faecium* (*Level 3*)
   iii. *Vancomycin resistant Enterococcus (VRE)* (*Level 3*)
e. Group D Streptococcus i.e., *S. gallolyticus* (previously *S. bovis*) (*Level 3*)
   Nutritionally variant streptococci (NVs) (*Level 2*)/Abiotrophia (*Level 2*)
f. Aerobic Gram-positive cocci
   i. Lactobacillus spp. (*Level 1*)
   ii. *Gemella* spp. (*Level 1*)
   iii. *Stomatococcus* spp. (*Level 1*)
   iv. *Pediococcus* spp. (*Level 1*)
   v. *Aerococcus* (*Level 1*)
g. Aerobic Gram-negative cocci
   i. *Neisseria gonorrhoeae* (*Level 3*)
   ii. *Neisseria meningitidis* (*Level 3*)
   iii. *Moraxella catarrhalis* (*Level 3*)
h. Enterobacteriaceae
   i. *Escherichia coli* (*Level 3*)
      1) Enterohemorrhagic *E. coli* due to Shiga toxin
      2) Other diarrheagenic *E. coli*
   ii. *Shigella sp.* (*Level 3*)
   iii. *Edwardsiella tarda* (*Level 2*)
   iv. *Klebsiella sp.* (*Level 3*)
      1) *K. pneumoniae*
      2) *K. oxytoca*
   iv. *Enterobacter sp.* (*Level 3*)
      1) *E. aerogenes*
2) *E. cloacae*

v. *Serratia sp.* (Level 3)

vi. *Hafnia alvei* (Level 1)

vii. *Citrobacter sp.* (Level 3)

viii. *Salmonella spp.*, i.e., *Salmonella enterica biovar typhi* (Level 3)

ix. *Proteus sp.* (Level 3)

1) *P. mirabilis*

2) *P. vulgaris*

x. *Providencia sp.* (Level 1)

xi. *Morganella morganii* (Level 1)

xii. *Yersinia enterocolitica* (Level 3)

h. Other facultative Gram negative rods

i. *Vibrio spp* (Level 3)

6) *V. cholera*

7) *V. alginolyticus*

8) *V. parahaemolyticus*

9) *V. vulnificus*

ii. *Aeromonas sp.* (Level 3)

iii. *Campylobacter jejuni* (Level 3)

iv. *Helicobacter sp.* (Level 1)

i. Glucose non-fermenting Gram-negative rods

i. *Pseudomonas aeruginosa* (Level 3)

ii. *Other Pseudomonas species* (Level 3)

iii. *Stenotrophomonas maltophilia* (Level 2)

iv. *Burkholderia spp* (Level 2)

v. *Acinetobacter spp* (Level 2)

vi. *Alcaligenes* (Level 2)

vii. *Elizabethkingia meningoseptica*

viii. *Moraxella sp.* (Level 2)

j. HACEK and other fastidious Gram negative rods

i. *Aggregatibacter aphrophilus* (previously known as *Haemophilus aphrophilus/H. paraphrophilus*) (Level 1)

ii. *Aggregatibacter actinomycetemcomitans* (previously known as *Actinobacillus actinomycetemcomitans*) (Level 1)

iii. *Cardiobacterium hominis* (Level 1)

iv. *Eikinella corrodens* (Level 1)

v. *Kingella sp.* (Level 1)

k. Other delicate/fastidious Gram-negative coccobacilli

i. *Bartonella spp.* (Level 1)

ii. *Bordetella sp.* (Level 1)

iii. *Brucella sp.* (Level 1)
iv. *Francisella tularensis* (Level 1)

v. *Haemophilus influenzae* (Level 3)
   1) Serotypes b and non-b
   2) Biovar aegyptius

vi. Other *Haemophilus* sp. (Level 2)

vii. *Legionella pneumophila* (Level 1)

viii. *Pasteurella multocida* (Level 2)

ix. *Capnocytophaga* (Level 1)

x. *Steptobacillus monoliformis* (Level 1)

i. Aerobic Gram-positive rods
   i. *Gardnerella vaginalis* (Level 1)
   ii. *Corynebacterium diptheriae* (Level 1)
   iii. Other *Corynebacterium* species (Level 2)
   iv. *Listeria monocytogenes* (Level 1)
   v. *Bacillus anthracis* (Level 1)
   vi. *Bacillus cereus* (Level 2)
   vii. other *Bacillus* sp. (Level 2)
   viii. *Erysipelothrix rhusiopathiae* (Level 1)
   ix. *Nocardia* sp. (Level 1)
   x. *Rhodococcus* sp. (Level 1)
   xi. *Arcanobacterium heamolyticum* (Level 1)
   xii. *Mycobacterium* spp. (Level 2)
   xiii. *Streptomyces* (Level 1)

m. Anaerobic Gram-positive rods
   i. *Clostridium perfringens* (Level 3)
   ii. *Clostridium difficile* (Level 2)
   i. Other *Clostridia* (Level 1)
   ii. *Propionibacterium acnes* (Level 2)
   iii. *Mobiluncus* sp. (Level 1)
   iv. Actinomyces sp. (Level 2)
   v. *Lactobacillus* sp. (Level 2)

n. Anaerobic Gram-positive cocci
   i. *Peptococcus* (Level 1)
   ii. *Peptostreptococcus* sp. (Level 2)

o. Anaerobic Gram-negative rods and cocci
   i. *Bacteroides fragilis* group (Level 3)
   ii. *Bacteroides* sp. (Level 2)
   iii. *Fusobacterium* sp. (Level 2)
   iv. *Prevotella* sp. (Level 2)
   v. *Veillonella* sp. (Level 1)
   vi. *Porphyromonas* sp. (Level 2)
p. Miscellaneous bacteria and organisms
   i. Treponema pallidum (Level 1)
   ii. Borrelia spp. (Level 1)
   iii. Leptospira interrogens (Level 1)
   iv. Mycoplasma (Level 1)
   v. Ureaplasma (Level 1)
   vi. Chlamydia (Level 3)
   vii. Rickettsia spp (Level 1)
   viii. Orientia tsutsugamushi (Level 1)
   ix. Ehrlichia spp (Level 1)
   x. Anaplasma phagocytophilum (Level 1)
   xi. Coxiella burnetii (Level 1)
   xii. Spirillum sp. (Level 1)

10. Identify public health and reference laboratories for special tests
    Level 1
    a. Reference laboratory resource information
    b. Specimen handling
       i. Packaging and shipping regulations
       ii. Safety precautions
       iii. Transport conditions
    c. Requisition information
    d. Records/documentation/protocols
    e. Cost

F. Antimicrobials
1. Describe the mechanism of action of commonly used antimicrobials Level 1
2. Apply standard performance principles and quality control to antimicrobial susceptibility tests Level 2
   a. Principles
   b. Limitations and sources of errors
   c. Troubleshooting according to set guidelines
   d. Sensitivity and specificity
   e. Quality control
2. Describe and perform appropriate disk diffusion (Kirby Bauer) and antimicrobial gradient method (E-test) Level 2
   a. Media
      i. Depth
      ii. Supplements
      iii. Storage
   b. Inoculum
      i. Organism
      ii. Standardized suspension
iii. Time limit for inoculation
iv. Pattern of inoculation
v. Time limit for application of disks
vi. Disk placement
c. Incubation
  i. Time
  ii. Temperature
  iii. Atmosphere
d. Disk potency and storage
e. Reading
f. Interpretation
  i. Qualitative
  ii. Quantitative
g. Reporting
h. Special techniques
  i. Error detection and resolution according to predetermined criteria

3. Interpret Beta-lactamase detection  
**Level 2**

4. Identify and correlate organisms using Minimum inhibitory concentration (MIC) – micro-broth and automated systems  
**Level 2**
a. Inoculum
b. Selection of appropriate organism for method
c. Incubation
d. Reading
e. Interpretation
f. Reporting
g. Supplements and special techniques
h. Error detection and resolution according to predetermined criteria
  i. Minimum bactericidal concentration (MBC)

5. Perform molecular detection of resistance  
**Level 2**

6. Utilize Clinical and Laboratory Standards Institute (CLSI) guidelines  
**Level 2**

7. Perform susceptibility testing and special resistance detection methods on appropriate organisms  
**Level 2**
a. Oxacillin resistance for *Staphylococcus* spp.
b. Inducible clindamycin resistance for *Staphylococcus*, beta-hemolytic *Streptococcus* spp. and *Streptococcus pneumoniae*
c. Vancomycin resistance for *Staphylococcus* and *Enterococcus* spp.
d. High level aminoglycoside resistance for *Enterococcus* spp.
e. Penicillin resistance for *Streptococcus pneumoniae*
f. Extended spectrum beta-lactamases (ESBL) for Enterobacteriaceae
g. ampC enzymes for Gram-negative rods
h. Carbapenemase resistant Enterobacteriaceae (CRE)

8. Interpret and evaluate susceptibility testing results according to established guidelines
   Level 3
   a. Qualitative
   b. Quantitative

9. Review susceptibility data and recognize unusual antimicrobial profiles according to set guidelines Level 2

10. Recognize “predictor” antimicrobial agents used to detect specific resistance mechanisms Level 2

11. Recognize multidrug-resistant organisms (MDRO) Level 2

12. Report data according to established guidelines and utilizing cascade and selective reporting Level 2

13. Relate antimicrobial agents to mode of action and spectrum of activity Level 1

14. Explain the common mechanisms of bacterial resistance Level 1

15. Recognize antimicrobials within each major class and by generic and brand name Level 1

16. Describe the function of other professionals to select appropriate drugs for testing Level 1
   a. Antibiotic usage committee
   b. Pharmacy
   c. Infectious disease clinicians
   d. Hospital epidemiologist/infection control committee
   e. Antibiogram data

G. Results

1. Prioritize reporting of direct smears Level 3

2. Prepare (Level 2) culture reports and assure (Level 3) quality of results based on predetermined criteria
   a. Culture correlation with
      i. Direct Gram stain
      ii. Body site/specimen type
      iii. Patient history/population
      iv. Identification testing results
      v. Susceptibility testing results
      vi. Clinical significance of organisms
      vii. Other significant information
   b. Selective reporting of antimicrobials

3. Report normal flora appropriately Level 1

4. Designate preliminary or finalized status Level 1

5. Recognize (Level 2) and resolve (Level 3) issues according to predetermined criteria Level 1

6. Report cultures concisely, clearly and in a timely fashion Level 1

7. Document work performed Level 1
A. **Basic principles of Clinical Mycology**

1. Describe characteristics of fungi  
   a. Classification, Taxonomy  
      i. Scientific Classification by sexual reproductive structures  
      ii. Clinical Classification by anatomic site of infection  
         1) Systemic  
         2) Subcutaneous  
         3) Cutaneous  
         4) Superficial  
   b. Eukaryotic cells  
   c. Reproduction  
   d. Growth requirements  
   e. Morphologic structures  
      i. Yeast cells/Hyphae/pseudohyphae/mycelia  
      ii. Conidiophores/metulae/phialides/vesicles  
      iii. Conidia/blastoconidia/arthroconidia/micro and macrconidia/chlamydoconidia  
      iv. Cleistothecia/perithecia/ascocarps/asci/ascospores  
      v. Stolons/rhizoids/sporangia/columellae/apophyses/sporangiospores/zygospores  
      vi. Chlamydospores  
      vii. Cleistothecia  
      viii. Columella  

B. **Laboratory examination of fungal specimens**

1. Describe proper collection methods  
2. Discuss appropriate transportation and storage of specimen  
3. Determine acceptability of specimen  
4. Select appropriate media for culture of fungal specimens  
   a. Primary isolation media  
   b. Without antibacterial or antifungal agents  
   c. With antibacterial agents (chloramphenicol, ciprofloxacin, gentamicin, penicillin or streptomycin)  
   d. With antibacterial agents and antifungal agents (cyclohexamide)  
   e. Dermatophyte test medium (DTM)  
   f. Mycosel or mycobiotic agar  
   g. Selective and differential for yeast, e.g., CHROMagar Candida  
   h. Medial for demonstration of reproductive structures of molds  
5. Discuss the purpose of each media preparation  
   a. pH  
   b. Antibacterial agents
c. Antifungal agents

6. Inoculate media using Level 2
   a. Aspirates, tissue, bone
   b. Blood and bone marrow
   c. CSF and other body fluids
   d. Upper and lower respiratory specimens
   e. Urine
   f. Hair, skin, nails

7. Discuss the influence on incubation Level 1
   a. Temperature
   b. Atmosphere
   c. Length of incubation and examination schedule

8. Perform (Level 2) and interpret (Level 3) direct microscopic smears of fungal specimen according to set guidelines
   a. KOH
   b. India ink
   c. Gram stain
   d. Lactophenol cotton blue
   e. Calcofluor white
   f. Acid fast
   g. Giemsa

9. Differentiate common yeasts and molds from bacteria on routine mycology media Level 3

10. Describe procedures for microscopic observation of fungi Level 1
    a. Cornmeal/rice (chlamydospore agars)
    b. Scotch tape preparation with LPCB
    c. Slide cultures
    d. Tease preparations with lactophenol cotton blue

11. Correlate patient history and clinical symptoms with growth on media, colonial morphology and microscopic structures to assist in identification of fungi and assessment of clinical significance Level 2
    a. Yeasts
       i. Candida
          1) C. abicans
          2) C. glabrata
          3) C. tropicalis
          4) Other Candida sp.
       ii. Cryptococcus
            1) C. neoformans
            2) Other Cryptococcus sp.
       iii. Trichosporon sp.
       iv. Geotrichum sp.
v. Malassezia spp., i.e., *M. furfur*
vi. *Rhodotorula* sp.
vii. *Saccharomyces* sp.
b. Dimorphic moulds  
i. *Blastomyces dermatitidis*  
ii. *Coccidioides* sp., i.e., *C. immitis*  
iii. *Histoplasma capsulatum*  
iv. *Sporothrix schenckii*  
v. *Paracoccidioides braziliensis*  
vi. *Talaromyces marneffei*
c. Brightly colored/hyaline molds  
i. *Aspergillus* spp.  
   1) *A. fumigatus*  
   2) *A. flavus*  
   3) *A. niger*  
   4) Other *Aspergillus* species  
ii. *Penicillium* sp.  
iii. *Fusarium* spp.  
iv. *Scopulariopsis*  
v. *Paecilomyces*  
vi. *Pseudoallecheria boydii*  
vii. *Acremonium* spp  
viii. *Chrysosporium* spp  
ix. *Sepedonium* spp
d. Dermatophytes  
i. *Microsporum* species  
   1) *M. canis*  
   2) *M. gypseum*  
   3) *M. gudouinii*  
   4) Other *Microsporum* species  
ii. *Trichophyton* species  
   1) *T. mentagrophytes*  
   2) *T. rubrum*  
   3) *T. tonsurans*  
   4) Other *Trichophyton* species  
iii. *Epidermophyton floccosum*
e. Zygomyces  
i. *Rhizopus* spp.  
ii. *Mucor* spp.  
iii. *Absidia* spp.  
iv. *Rhizomucor* spp
v. Cunninghamella spp
vi. Syncephalastrum spp
f. other fungi
  i. Pneumocystis jiroveci

12. Describe test methodologies for fungi identification  
   a. Principles  
   b. Limitation and sources of errors  
   c. Troubleshooting according to set guidelines  
   d. Sensitivity and specificity  
   e. Rapid and traditional testing methods  
      i. Assimilation/fermentation  
      ii. Temperature tolerance  
      iii. Mold/yeast conversion  
      iv. Wood’s lamp fluorescence  
      v. In-vitro hair perforation  
      vi. Germ tube production  
      vii. Antigen detection methods  
          1) Cryptococcal antigen  
      viii. Commercial methods  
     viii. Molecular methods

13. Utilize databases and reference materials in identification of fungi
A. Taxonomy and terminology for categories of parasites

1. Describe the distinguishing characteristics of parasite categories  
   - Nematodes (roundworms)  
     i. Tissue and blood  
     ii. Intestinal  
   - Cestodes (tapeworms)  
   - Trematodes (flukes)  
   - Protozoan  
     - Amebae  
     - Flagellates  
     - Sporozoa  
       i. Plasmodium spp.  
       ii. Coccidia  
   - Ciliates  

2. Recognize characteristic structures of adults, larvae, ova, cysts, trophozoites, etc.  

B. Define the stages and structures associated with parasite identification  

1. Trophozoite  
2. Cyst  
3. Egg  
4. Larvae  
5. Rhabditiform  
6. Filariform  
7. Microfilaria  
8. Sheath  
9. Rostellum  
10. Hermaphrodite  
11. Proglottids  
12. Intermediate host  
13. Definitive host  
14. Operculum  
15. Brood capsule  
16. Hydatid cyst or sand  
17. Schizont  
18. Schuffner’s dots/Maurer’s dots  
19. Merozoites  
20. Gametocyte  
21. Undulating membrane  
22. Parabasal body
23. Chromatoid body
24. Glycogen vacuole
25. Karyosome
26. Nucleus
27. Peripheral chromatin
28. Sporogony
29. Schizogony
30. Abopercular knob
31. Scolex
32. Uterine branches
33. Vector
34. Shoulder
35. Hexacanth larva
36. Corticate/mammilate
37. Axostyle
38. Kinetoplast
39. Axoneme
40. Cercarie
41. Coracidium
42. Miracidium
43. Flame cell

C. **Specimen Collection and handling**
1. Determine specimen acceptability in parasitic identification
   
   a. Collection method
   b. Collection time/receipt time
   c. Specimen storage
   d. Number of specimens
   e. Presence of interfering or contaminating substances
   f. Preservatives for parasitic specimen
      i. Polyvinyl alcohol (PVA)
      ii. 10% Formalin
      iii. Schaudinn solution (mercury free)
      iv. Sodium acetate-acetic acid-formalin (SAF)
      v. Less toxic single tube systems
   g. Rejection criteria

C. **Examination of specimens**
1. Examine the specimen macroscopically
   
   a. Color
   b. Presence of blood or mucous
   c. Consistency (watery/Loose,semisolid,formed)
d. Worm components (proglottids, adult, scoleces, etc)

2. Describe direct microscopic examination of specimen
   a. Proper use of the microscope, objectives, and light source
   b. Use of ocular micrometer for measurement of size
      i. Calibration
   c. Use of direct wet mounts with saline and iodine preparations
   d. Systematic examination of prepared slide
   e. Detection of parasites

3. Select and perform appropriate concentration methods and stains
   a. Principles
   b. Limitations and sources of errors
   c. Trouble-shooting according to set guidelines
   d. Sensitivity and specificity
   e. Quality control
   f. Concentration methods
      i. formalin-ethyl acetate
      ii. alternate solvents sedimentation
   g. Permanent stained smears
      i. trichrome/modified trichrome
      ii. iron-hematoxylin
      iii. modified Kinyoun (acid-fast)
      iv. Calcofluor white
      v. Auromine O
   h. Preparations of reagents and stains
      i. Preparation of malarial smears
         i. Thick smears
         ii. Thin smears

4. Explain the detection and differentiation of specific parasites
   a. Immunoassays
   b. Nucleic acid assays

5. Detect and identify the following parasites at the following identification levels”
   Can recall it
   Can identify/recognize it
   Level 2
   a. Nematodes
      i. Intestinal
         1) *Ascaris lumbricoides* (Level 2)
         2) *Strongyloides stercoralis* (Level 1)
         3) Hookworm (Level 2)
            a) *Necator spp.*
            b) *Ancyclostoma spp.*
4) *Trichuris trichiura* (Level 2)
5) *Enterobius vermicularis* (Level 2)

ii. Blood and tissue
1) *Trichinella spiralis* (Level 1)
2) *Wuchereria bancrofti* (Level 1)
3) *Brugia malayi* (Level 1)
4) *Loa loa* (Level 1)
5) Mansonella (Level 1)
6) *Onchocerca volvulus* (Level 1)
7) *Dracunculus medinensis* (Level 1)

b. Cestodes
i. *Taenia solium* (Level 2)
ii. *Taenia saginata* (Level 2)
iii. *Echinococcus granulosus* (Level 1)
iv. *Diphyllobothrium latum* (Level 2)
v. *Hymenolopis nana* (Level 2)
vi. *Hymenolopis diminuta* (Level 1)

iii. flagellates
1) *Giardia lamblia/intestinalis* (Level 2)
2) *Trichomonas vaginalis* (Level 2)
3) *Dientamoeba fragilis* (Level 2)
4) *Chilomastix mesnili*

iii. *Trypanosoma* spp. **(Level 1)**

iv. *Leishmania* spp. **(Level 1)**

v. Sporozoa **(Level 2)**
   1) *Plasmodium* spp.
   2) *Babesia* spp.
   3) *Cryptosporidium parvum*
   4) *Cystoisospora belli*
   5) *Cyclospora*

e. Ciliates
   i. *Balantidium coli** *(Level 2)*

6 Correlate information in order to identify parasites according to set guidelines **(Level 3)**
   i. Diagnostic stage, i.e., characteristic structure(s) present
   ii. Knowledge of life cycle
   iii. Specimen of choice for detection
   iv. Detection methods available

7 Differentiate artifact from parasites **(Level 2)** and differentiate **(Level 3)** them from parasites
   i. White and red blood cells
   ii. Epithelial cells
   iii. Pollen granules
   iv. Vegetable fibers and cells
   v. Yeast cells
   vi. Charcot-Leyden crystals
   vii. Fungal spores (morels)
   viii. Diatoms
   ix. Hair

8 Examine specimens other than stool **(Level 1)**
   i. Cellophane tape/vaspar paddle preparation for *Enterobius vermicularis*
   ii. Wet mount/culture for *Trichomonas species*
   iii. Duodenal capsule or string technique (Entero-Test)
   iv. Thick and thin blood films
   v. Bone marrow and body fluids
   vi. Urine
   vii. Lower respiratory
   viii. Biopsy
Mycobacteriology – MLS Entry Level Curriculum

A. General Characteristics
1. Describe the general characteristics of mycobacteria
   a. Acid-fastness
   b. Growth requirements
   c. Rate of growth
   d. Atmosphere requirements
   e. Temperature

B. Specimen management
1. Identify the safety requirements for working with mycobacteria
   a. Biological safety cabinet (BSC/Biosafety level (BSL))
   b. Personal protective equipment
      i. Respirator
      ii. Gloves
      iii. Liquid impervious gowns
      iv. Centrifuges with safety carriers
      v. Germicides
   c. Equipment
   d. Negative pressure facility
   e. Annual tuberculin skin test
      i. Chest x-ray if skin test is positive
      ii. Effects of BCG vaccine
2. Discuss specimen collection and transportation procedures
   a. Pulmonary sites
      i. Sputum, expectorated and induced
      ii. Bronchial alveolar lavage (BAL), bronchoscopy, etc.
   b. Extrapulmonary sites
      i. Non-contaminated
         1) Blood and bone marrow
         2) Body fluids
         3) Tissue
      ii. Contaminated
         1) Urine
         2) Skin lesions, wound, abscesses
         3) Gastric lavage or aspirate
         4) Stool for Mycobacterium avium complex
      iii. Blood for interferon gamma release assay (QuantiFERON – TB test)
   c. Collection method/site preparation
      i. Container
ii. Collection time
iii. Number of specimens
iv. Quality
v. Optimum volume
vi. Rejection criteria

3. Describe (Level 1) and utilize (Level 2) specimen processing procedures
   i. Contaminated specimens
      1) Digestion and decontamination
         a) Liquefaction
         b) Decontamination
         c) Centrifugation
            i) Speed
            ii) Time
            iii) Equipment required
         d) Limitations and potential sources of errors
      e) Quality assurance, e.g., maintenance of a contamination rate of 3-5%
      ii. Non-contaminated specimens
          1) Centrifugation
          2) Direct inoculation

C. Smears and Stains
   1. Discuss the preparation, staining and screening of smears
      Level 1
      a. Specimen selection
         i. Smear preparation, standardization, fixation
            1) Direct
            2) Concentrated
            3) Cytocentrifugation with bleach
      b. Stains
         i. Reagent preparation
         ii. Acid-fast stain procedures
            1) Principle
            2) Acid-fast: fuchsin
               a) Ziehl-Neelsen
               b) Kinyoun
            3) Acid-fast: fluorochrome
               a) Auramine O
               b) Auramine-rhodamine
         iii. Quality control
      iv. Limitations and potential sources of errors
      v. Troubleshooting and according to set guidelines
      vi. Sensitivity and specificity
c. Microscopic evaluation
   i. Magnification
   ii. Scanning pattern
   iii. Organism morphology, e.g., serpentine cording
   iv. Specificity
   v. Sensitivity

2. Describe specimen processing
   a. Digestion
   b. Decontamination
   c. concentration

3. Describe the interpretation and reporting of smear
   a. Sources of false positives
      i. Nocardia
      ii. Rhodococcus
      iii. Cryptosporidium, Cystoisospora and Cyclospora oocysts
      iv. M. gordonae from a tap water source
      v. Other
   b. Appearance of artifacts, debris, background
   c. Reporting scheme
   d. Internal review process for quality assurance

D. Culture medium
1. Describe the culture media most appropriate for primary cultures by specimen type
   a. Egg-based
      i. Lowenstein-Jensen
   b. Agar-based
      i. Middlebrook 7H10 and 7H11
   c. Liquid based
      i. Middlebrook 7H9, 7H12 and 7H13
   d. Commercial systems
   e. Other
2. Discuss the incubation of the primary media
   a. Describe optimal temperature to isolate mycobacteria
      i. 35 degrees C vs. 37 degrees C
      ii. 25-33 degrees C
   b. Describe the optimal atmospheres of incubation
   c. Describe the optimal length of incubation
   d. Reading schedule for inoculated media

E. Identification
1. Describe the identification of isolates using established algorithms and databases
a. Acid-fastness of the organism
b. Preferred temperature of growth
c. Rate of growth
   i. Rapid grower (< 7 days)
   ii. Slow grower (> 7 days)

2. Colony morphology
   i. Pigment
      1) Photochromogen
      2) Scotochromogen
      3) Non-chromogen

F. Discuss common testing
   Level 1
1. Biochemical testing
2. Other methods for organism identification
   a. Molecular diagnostics
   b. Amplification methods for direct detection of *Mycobacterium tuberculosis*
3. Describe mycobacteria based on key criteria
   a. *Mycobacterium tuberculosis complex*
   b. *M. tuberculosis*
   c. *Mycobacterium avium-intracellularare* complex (MAC or MAI)
   d. *M. ulcerans*
   e. *M. xenopi*
   f. *M. kansasii*
   g. *M. marinum*
   h. *M. gordonae*
   i. *M. scrofulaceum*
   j. *M. chelonae*
   k. *M. abscessus*
   l. *M. leprae*
4. Correlate the presence of organisms with the most common types of clinical infections and clinical significance according to set guidelines
   a. Routes of transmission
   b. Signs and symptoms

G. Reporting
1. Describe the turnaround time and reporting of direct smear, culture, and susceptibility results
Virology – MLS Entry Level Curriculum

A. **Characteristics of viruses**
   1. Describe the basic structure/components of viral agents
      a. **Virion**
         i. Type of nucleic acid present (RNA or DNA)
         ii. Capsid
         iii. Envelope
         iv. Glycoprotein spikes
   2. Differentiate viruses from bacteria
      a. Requirement for living cells
      b. Size
      c. Structure
      d. Replication
      e. Therapy

B. **Classification of viruses**
   1. Outline the criteria for classifying or grouping viruses
      a. Nucleic acid type (RNA or DNA)
      b. Host
      c. Size and morphology
      d. Type of replication
   2. Correlate agents of infections infection with disease or pathologic manifestations and route of transmission
      a. Hepatitis viruses
      b. Simplex virus, Herpesvirus 1 and 2
      c. Cytomegalovirus (CMV)
      d. Varicella-Zoster virus (VZV)
      e. Influenza virus A
         i. H1N1
         ii. H5N1
      f. Influenza virus B
      g. Respiratory syncytial virus (RSV)
      h. Coronavirus
         i. SARS related coronavirus
      j. Middle Eastern Respiratory Syndrome coronavirus (MERS)
      k. Human Papillomavirus (HPV)
      l. Eastern and Western equine encephalitis virus
      m. Arenavirus
         i. Lassa virus
ii. Lymphocytic choriomeningitis virus
n. Human T lymphocytic virus
o. Ebola
p. Enteroviruses
  i. Poliovirus
  ii. Coxsackievirus
  iii. Enterovirus
  iv. Rhinovirus
  v. Echovirus
q. Hantavirus
r. Parvovirus B19
s. Flaviviruses
  i. West Nile virus
  ii. St. Louis Encephalitis virus
  iii. Dengue virus
  iv. Yellow fever virus
  v. Zika virus
t. Parainfluenza virus
u. Adenovirus
v. Epstein-Barr virus (EBV)
w. Marburg virus
x. Rabies virus
y. Metapneumovirus
z. Measles virus
aa. Norwalk virus
bb. Rift Valley Fever virus
cc. Rotavirus
dd. Rubella virus
e. Mumps virus
ff. Smallpox
gg. Vaccinia virus
hh. Human Immunodeficiency virus
ii. Polyomavirus

C. **Specimen collection and processing**
   1. Discuss important information for specimen collection and processing of specimens
      a. Selection of body site/Specimen type
      b. Collection methods, devices and containers
c. Safety precautions
d. Transport media
e. Temperature
f. Time

2. Utilize proper specimen storage upon receipt in laboratory

3. Utilize proper specimen shipment methods are used

4. Utilize specimen processing algorithms based on most likely virus present
   a. Rejection criteria
   b. Specimen type/body site
   c. Specimen preparation
   d. Age of patient
   e. Time of year/virus seasonality
   f. Virus suspected
   g. Immune status

D. Laboratory procedures

1. Describe laboratory procedures for detection of viral agents and particles
   a. Principles
   b. Limitations and sources of errors
   c. Troubleshooting according to set guidelines
   d. Sensitivity and specificity
   e. Quality control
   f. Direct detection methods
      i. Immunodiagnostic
         1) Direct and indirect immunofluorescent
         2) Antibody methods
         3) Enzyme immunoassay methods (EIA)(ELISA)
      ii. Molecular methods
      iii. Cell culture systems
      iv. Serology
Infection Prevention and Control – MLS Entry Level Curriculum

A. Disease transmission

1. Define terms associated with disease transmission  
   a. Epidemiology
   b. Community acquired infections
   c. Nosocomial infections
   d. Epidemic
   e. Endemic
   f. Outbreak
   g. Cluster
   h. Surveillance
   i. Morbidity
   j. Mortality

2. Describe the origin and mode of spread  
   a. Droplet
   b. Airborne
   c. Fomite
   d. Vector
   e. Reservoir
   f. Endogenous
   g. Exogenous

3. Compare and contrast  
   a. Colonization
   b. Infection
   c. Carrier state

B. Infection prevention methods

1. Relate underlying patient condition/factors to acquisition of infection  
   a. Medical devices (Catheters, respirator)
   b. Immunocompromised
   c. Immunosuppressive therapy
   d. Antimicrobial therapy
   e. Malignancy
   f. Age
   g. Occupation
   h. Surgery
   i. Prosthetic devices (pacemaker, artificial heart valve, shunt, joint)

2. Apply concepts of disease transmission to disease prevention
a. Education
   i. Health care professionals
   ii. Patients
   iii. Environmental services (housekeeping)
b. Precautions
   i. Standard Precautions
   ii. Transmission-based
      1) Direct and indirect contact
      2) Droplet
      3) Airborne
   iii. Immunizations
   iv. Treatment Level 1
      1) Antibiotics
      2) Antiviral
      3) Antifungal
      4) Antiparasitic

C. Role of clinical microbiology laboratory
   1. Culture microbial pathogens Level 2
      a. Common bacteria
      b. Multiple drug resistant organism (MDRO)
      c. Mycobacteria
      d. Fungi
      e. Unusual organisms
      f. Viruses
      g. Parasites
   2. Identify common bacteria through interpretation of culture, microscopic, or rapid testing Level 2
   3. Detect microbial organisms through microscopic or rapid testing Level 2
      a. Mycobacteria
      b. Fungi
      c. Unusual organisms
      d. Viruses
      e. Parasites
   4. Determine when to report relevant cultures/organisms to infection control personnel Level 2
   5. Assist medical laboratory scientists with surveillance of infectious diseases Level 2
      a. Environmental samples
      b. Personnel specimens
      c. Patient specimens
      d. Rapid diagnostic testing
e. Organism identification
f. Antimicrobial susceptibility testing
g. Epidemiologic analysis of microorganisms
   i. Phenotypic techniques
   ii. Genotypic techniques
6. Report communicable diseases/organisms to the appropriate public health agencies  
   Level 2
7. Monitor for bioterrorism agents and emerging infections  
   Level 2
   a. Centers for Disease Control (CDC) categories of organisms
   b. CDC laboratory response network
   c. Specimen packing and shipping
   d. Biosafety
   e. Protocols to rule in/rule out critical agents
8. Maintain adequate archival information  
   Level 2
   a. Data
      i. Health Insurance Portability and Accountability Act of 1996 (HIPAA)
   b. Organisms
      i. Patient
      ii. Personnel
      iii. Surveillance/environmental
9. Handle and dispose of biohazard materials  
   Level 2
   a. QC of autoclaves
   b. Identification of biological, pathological, and surgical infectious materials
   c. Cleaning, sterilization, disinfection
   d. Laboratory safety procedures manual
   e. Aseptic technique
Laboratory Practice – MLS Entry Level Curriculum

A. Quality management (Also covered in Laboratory Administration)
   1. Follow policies and procedures Level 2
   2. Perform (Level 2) procedures and review (Level 3) results of standard quality control
      a. Media
      b. Stains
      c. Reagents/kits
      d. Equipment
      e. Physiological tests
      f. Antimicrobial testing
      g. Serological tests
      h. Stock organisms
      i. Inventory
      j. Automated systems
      k. Immunological test
      l. Microscope calibration
   3. Recognize (Level 2) and resolve (Level 3) errors according to set guidelines
   4. Participate in data collection for a quality management plan Level 2
   5. Assist in the education and training of others Level 3
      a. Laboratory science students
      b. Healthcare personnel
      c. Co-workers
   6. Maintain knowledge and skills through continuing education

B. Laboratory Safety (Also covered in General Lab Practice)
   1. Describe (Level 1) and utilize (Level 2) accepted safety precautions to prevent laboratory acquired infections
      a. Standard Precautions
         i. Handwashing
         ii. Protective clothing/devices
      b. Engineering controls
         i. HEPA filtration
         ii. Ultraviolet germicidal irradiation
         iii. Negative pressure room
      c. Emergency action protocol
      d. Training
      e. Health care facilities
         i) Emergency care
ii) Respiratory fit testing

iii) Treatment

f. Aseptic techniques
g. Handling and disposal of sharps
h. Use of biological safety cabinets
i. Center for Disease Control and Prevention (CDC)/biological safety level (BSL) classification
   i. Classifications of BSL requirements
   ii. Correlation of specific organisms and required BSL
j. Bio-hazardous materials discard
k. Decontamination, disinfection, sterilization
l. Emergency first aid, eye wash, showers
m. Immunizations
n. Employee health services

2. Take immediate and appropriate action when an incident occurs

3. Describe the procedures for prevention of aerosolization of microbial agents (mycobacteria and other bacteria, fungi, and viruses)
   a. Aseptic techniques
   b. Containment procedures
   c. Decontamination, disinfection, sterilization
d. Centrifuge use
e. Bio-hazardous materials discard

4. Describe the collection and discard of infectious waste materials
   a. Environmental Protection Agency (EPA)/state regulations
   b. Definition of infectious waste

5. Discuss hazards of chemicals in the workplace
   a. Safety data sheets (SDS)
b. Storage, labeling and use
   i. Physical hazards
      1) Flammable
      2) Oxidizer
      3) Corrosive
   ii. Health hazards
      1) Toxicity
      2) Carcinogenicity
   iii. Environmental hazards

6. Outline fire safety guidelines
   a. Fire protocol (RACE - rescue, alarm, contain, extinguish)
b. Classes of fire extinguishers
c. Fire evacuation plan
d. Fire extinguisher protocol (PASS - pull pin, aim, squeeze, sweep base of fire)
C. **Laboratory Information System (LIS)**
   1. Describe data entry
      a. Automated/Manual
   2. Describe the reporting of data
   3. Discuss data retrieval to provide relevant information for microbiology
      a. Analysis
      b. Integration
      c. Antibiogram
   4. Describe the retrieval of information by clinics/providers
      a. Results
      b. Services provided
      c. Specimen handling
      d. Education

D. **Administrative tasks**
   1. Explain the responsibilities of laboratory management (also covered in Laboratory Administration)
      a. Personnel
         i. Safety
         ii. Training
         iii. Proficiency
         iv. Competency
      b. Physical facilities
      c. Communication
         i. Public health authorities
         ii. Infection prevention/epidemiology
         iii. Service providers/clinicians
         iv. Administration
         v. Education
         vi. HIPAA
         vii. Finance, i.e., cost containment
Deletions - Microbiology
- CAMP
- Perform confirmatory identification tests (including rapid tests)
  - Hemolysis on Horse blood
  - Beta-glucuronidase (MUG)

Additions - Microbiology
- Prions
- Staphylococcus lugdunensis
- viridans Streptococci
- Enterococcus faecalis; Enterococcus faecium; Vancomycin resistant Enterococcus (VRE)
- Group D Streptococcus ie S. gallolyticus (previously S. bovis)
- Abiotrophia
- Moraxella catarrhalis
- Edwardsiella tarda
- Vibrio alginolyticus
- Vibrio parahaemolyticus
- Vibrio vulnificus
- Aggregatibacter aphrophilus (previously known as Haemophilus aphrophilus/H. paraphrophilus)
- Aggregatibacter actinomycetemcomitans (previously known as Actinobacillus actinomycetemcomitans)
- Capnocytophaga
- Steptobacillus monoliformis
- Eggerthella
- Orientia tsutsugamushi
- Anaplasma phagocytophilum
- Coxiella burnetii
- Spirillum spp

Additions - Mycology
- Rhodotorula spp
- Saccharomyces spp
- Penicillium marneffei
- Acremonium spp
- Chrysosporium spp
- Sepedonium spp
- Rhizomucor spp
- Cunninghamamella spp
- Syncephalastrum spp

Additions - Parasitology
- Heterophyes heterophyes
Metagonimus yokagawai
Naegleria fowleri
Chilomastix mesnili
Trichinella spiralis
Wuchereria bancrofti
Brugia malayi
Loa loa
Mansonella
Onchocerca volvulus
Dracunculus medinensis

**Additions - Mycobacteria**
M. ulcerans
M. xenopi
M. kansasii
M. marinum
M. gordonae
M. scrofulaceum
M. chelonae
M. abscessus
M. leprae

**Additions - Viruses**
SARS related coronavirus
Poliovirus
Coxsackievirus
Enterovirus
Rhinovirus
Echovirus
Hantavirus
Parvovirus B19
Flaviviruses: West Nile virus, St. Louis Encephalitis virus, Dengue virus, Yellow fever virus
MERS
Rift Valley Fever virus
1. Basic Foundation Concepts
   a. Describe a brief history of the development of molecular diagnostics Level 1
   b. Discuss the impact molecular diagnostic will have on: Level 1
      i. Laboratory medicine
      ii. Diagnosis and management of diseases
      iii. Ethical implications
   c. Discuss the basic functions of DNA Level 1

2. Nucleic Acid Biochemistry
   a. Discuss/diagram RNA, DNA, and genome structure Level 1
      i. Pairing of nitrogen bases
         1. Chargaff rules
         2. Pyrimidine, purine
      ii. Complementary rule
      iii. Sugars found in DNA and RNA
   b. Explain semi-conservative DNA replication Level 1
      i. Origin or replication (eukaryote vs prokaryote)
      ii. Leading strand
      iii. Lagging strand
      iv. Primase
      v. Okazaki fragments
   c. Describe DNA Level 1
      i. Central dogma
      ii. Transcription
         1. Polarity (5’, 3’)
         2. Nucleosides, Nucleotides
         3. Template strand
      iii. Translation
         1. Codons/anticodons
         2. Ribosomes
         3. Genetic code
         4. Degeneration
         5. Wobble rule
      iv. Extrachromosomal (plasmid, mitochondrial transmission)
   d. Compare and contrast viral, bacterial, eukaryotic Level 2
      i. Complexity
      ii. Shape
      iii. Nucleic acid content

3. Genetics
   a. Describe chromosome morphology Level 1
   b. Define the various changes in chromosomal structure, such as inversion, duplication, deletion, translocation and isochromosome Level 1
   c. Explain the various changes in chromosomal number, such as: aneuploidy, monosomy, trisomy, nondisjunction and polyploidy Level 1
   d. Discuss Mendelian and non-Mendelian Genetics Level 1
   e. Define: carrier, penetrance, founder affect, incomplete dominance Level 1
   f. Determine disease carriage state using punnet squares Level 2
g. Describe inherited disease patterns, such as: autosomal dominant, autosomal recessive, X-linked Dominant, X-linked recessive Level 1
h. Provide specific examples of diseases that follow each type of inheritance pattern Level 1
i. Interpret a pedigree to determine the inheritance pattern Level 2
j. Compare and contrast single-gene disorders, polygenic disorders and chromosomal disorders Level 2

4. Molecular Methodologies
   a. Describe nucleic acid extraction/isolation/quantitation/purification techniques Level 1
      i. Purpose
      ii. Molecules that interfere
      iii. Conditions to consider when choosing method of extraction
      iv. Reagents and purpose
      v. Acceptable specimen types
      vi. Advantages and disadvantages of solid phase extraction vs. liquid phase
           Calculation of DNA and RNA concentration and yield and acceptability/contamination
   b. Discuss nucleic acid modifying enzymes Level 1
      i. Storage criteria
      ii. Nomenclature
      iii. Enzyme inactivation
      iv. Function of a restriction endonuclease and the two types of cuts
      v. Basic function of the following enzymes
         1. Endonucleases
         2. Exonucleases
         3. Ligases
         4. Polymerases
         5. Reverse transcriptases
         6. Phosphatases
         7. Kinases
   c. Discuss nucleic acid Electrophoresis Level 1
      i. Role of size, charge, and shape or conformation in migration/movement
      ii. Components, staining methods, safety consideration and waste disposal
         1. Ethidium bromide staining
         2. Other staining methods
      iii. Electrophoresis methods
         1. Agarose
         2. Polyacrylamide gel electrophoresis (PAGE)
         3. Pulse Field
         4. Capillary
   d. Compare and contrast blotting techniques
      1. Western, Northern, and Southern blotting
      2. Nucleic substance tested (DNA, RNA, protein)
      3. Consider the following variables when performing various blotting techniques
         a. Restriction fragment length polymorphism (RFLP)
         b. Stringency
         c. Hybridization
      4. Pros and Cons of each method
e. Discuss amplification Techniques
   i. polymerase chain reaction (PCR).
      1. Amplification reaction
      2. Cycle (denature, anneal, extend)
         a. Thermocycler use
      3. Stringency
      4. Fluorescent resonance energy transfer (FRET)
      5. Melt-curve analysis and validity
         a. Melting temperature (Tm), including the calculation
   6. Components/concentration
      a. Primers
      b. Primer-dimers
      c. DNA template, bases, polymerase
      d. Buffer
   7. Probe assays
   8. Master mix
   9. Amplicons
ii. Amplification assays
   1. Target amplifications
      a. Polymerase Chain Reaction (PCR)
      b. Differentiate PCR modification techniques (end-point vs real time)
         i. Real time PCR
         ii. Nested PCR
         iii. Multiplex PCR
         iv. Reverse transcription – PCR (RT-PCR)
      c. Transcription mediated amplification (TMA)
   2. Probe amplification
   3. Signal amplification
f. Explain the purpose of fluoresence in situ hybridization (FISH)

g. Explain DNA sequencing methods
   i. Sanger chain termination sequencing (level 2) and the role of ddNTPs
      1. Define:
         a. Deoxynucleosidetriphosphates (dNTP)
         b. Dideoxynucleosidetriphosphates (ddNTP)
      ii. Automatic fluorescent sequencing
      iii. Pyrosequencing
      iv. Array sequencing
      v. Next-generation sequencing (NGS)

h. Discuss microarray/Arrays
   i. General concept
   ii. Specific uses and clinical applications

5. Mutations and polymorphisms
   a. Define:
      i. Mutations
      ii. Polymorphisms
iii. Single nucleotide polymorphism (SNP)
iv. Short tandem repeats (STRs)
v. Variable numbers of tandem repeats (VNTRs)
b. Distinguish among DNA gene, chromosomal, and genome mutations Level 2
c. Evaluate a small gel sequence result (visual representation) Level 3
d. Define genotype versus phenotype Level 1

6. Laboratory Operations, Quality Control and Quality Assurance in the molecular laboratory

a. State variables of concern for pre-analytical Level 1
   i. Test request
   ii. Acceptable specimen types
   iii. Specimen collection/handling
       1. DNA vs RNA
       2. Temperatures and timing
   iv. Informed consent
b. State variables for the analytic phase Level 1
   i. Specimen extraction and storage
   ii. Lab design
   iii. Contamination monitoring
   iv. Contamination prevention
       1. Unidirectional (clean to dirty) workflow in the molecular laboratory
       2. Function of RNases/DNases
   v. QC/preventive maintenance
c. Define Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) Level 1
d. Discuss the importance of test validation Level 1
e. Recognize the complexity of reporting patient results, including laboratory test regulations, as they pertain to: Level 1
   i. Analyte specific reagent (ASR)
   ii. Research use only (RUO)
   iii. In vitro diagnostics (IVD)
   iv. Lab developed test (LDT)
   v. Personnel training and competency
f. State concerns for the post-analytical phase Level 1
   i. Reporting of results
   ii. Follow-up recommendations
   iii. Confidentiality
g. Evaluate controls and patient results for acceptability Level 3
   i.
h. Troubleshoot questionable or invalid results Level 2
   i. Specimen issues
   ii. Procedural issues
   iii. Instrumentation problems
Molecular Diagnostics
Medical Laboratory Scientist: Entry Level Curriculum

i. Compare and contrast: Level 2
   i. Clinical sensitivity
   ii. Clinical specificity
   iii. Accuracy
   iv. Precision

j. Discuss the clinical applications and impact of molecular testing on the following: Level 1
   ii. Oncology/hematopathology
   iii. Solid tumors
   iv. Forensics
   v. Infectious disease
      a. Detection monitoring
      b. Qualitative vs quantitative viral load
      c. Genotyping of virus/resistance
      d. Time results
      e. Commonly tested/examples – usually nucleic acid amplification PCR methods
   vi. Blood Bank
   vii. HLA typing
   viii. Inherited diseases
      i. Define
         1. Allele
         2. Chimerism
         3. Diploid
         4. Haploid
         5. Methylation in terms of gene expression
         6. Transformation
   k. Discuss the inheritance and mutations involved in inherited diseases, such as: Level 1
      i. Cystic fibrosis
      ii. Fragile X
      iii. Huntington’s disease
      iv. Prader-Wille/Angelmann disorder
      v. Thalassemias (alpha and beta)
      vi. Sickle cell anemia
      vii. Other inherited disorders
   ix. Epigenetics
   x. Bacteriology
      i. Antibiotic resistance
      ii. Epidemiology
   xi. HLA typing
      i. Transplantation
      ii. Parentage/kinship
   xii. Define Pharmacogenetics/genomics
      i. Cytochrome p450
   xiii. Role in evidence based medicine
xiv. Consider the various ethical implications of molecular methodologies
   i. Discrimination
   ii. Confidentiality
   iii. Informed consent
MLS Entry Level Curriculum
Phlebotomy

The Health Care System and Services
Demonstrate a knowledge and proficiency in the use of computers as related to job duties and responsibilities Level 2

Define and utilize health professions/medical terminology pertinent to phlebotomy, laboratory testing, and patient care Level 2

Patient and laboratory safety
List and discuss precautions, practices and procedures to assure patient safety Level 1
- Correct identification of patients
- Communication and its applications to patient safety
- Use of proper equipment and procedures for specimen/sample collection
- Identification and avoidance of safety risks including but limited to nerve damage.
- Preventing errors in specimen/sample collection
- Preventing errors in point-of-care testing
- Relevance of specimen/sample collection to preventing errors in testing procedures
- Identification of improper specimens/samples and the impact on testing, e.g., hemolysis, insufficient blood collected in tubes with anti-coagulant, improper draws, etc.

Identify and/or perform emergency procedures necessary for survival of patients/clients in the health care setting limited to scope of training and practice Level 2
- Cardiopulmonary resuscitation (CPR)
- First aid techniques to prevent bleeding
- Managing adverse reactions

Demonstrate an understanding of safety hazards and precautions and identify symbols Level 1
- Biological hazard
- Electrical safety
- Chemical safety
- Radiation safety
- Fire safety
- Mechanical safety
- Biosafety
- Biosecurity

Discuss and apply the Occupational Safety and Health Administration (OSHA) Standards and compliance with OSHA in phlebotomy and clinical laboratory practice Level 2

Discuss institutional safety procedures and practices Level 1
- Biological and physical safety of oneself and others in the workplace
- Proper labeling of biohazardous specimens/samples
- Handling biological specimens/samples routinely
- Handling biological specimens/samples collection in cases of bioterrorism and other emergency response situations
- Hazardous materials
- Natural disasters including weather emergencies
- Fire and electrical safety
- Cleaning protocols including cleaning phlebotomy trays and equipment, cleaning up of specimen/sample spills, and other biohazardous spills
- Waste disposal

Comply with federal and state mandates and regulations and organizational requirements regarding safety practices  

Develop and evaluate safety equipment for use in phlebotomy and related services  

Select and evaluate safety equipment for use in phlebotomy and related services  

**Infection Prevention**

List and explain the principles of infection control  
- sources of infection
- modes of disease transmission
- hosts
- susceptibility to infection
- healthcare-associated infections (HAI)

State the elements of the chain of infection and mechanisms to break the chain  

Discuss and demonstrate sterile techniques related to the scope of practice  

Discuss and apply standard precautions, workplace practices, and engineering controls and the application to phlebotomy and related services:  
- Use of isolation procedures
- Use of personal protective equipment – gloves, gowns, masks, and face shields
- Hand washing and hand antisepsis
- Sterile technique
- Environmental controls including use of approved surface disinfectants
- Needle and other sharps disposal
- Other

Discuss and apply the isolation procedure and personal protective equipment requirements in accordance with standard precautions and identify example disease conditions associated with each isolation procedure  
- Airborne or droplet precaution (respiratory isolation)
- Contact precautions
- Protective precautions
- Body substance isolation

Relate the types of isolation associated with specific inpatient or clinical treatment units  
- Burn unit
- Dialysis
- Intensive care unit
- Nursery
- Oncology Unit
- Infectious diseases/ Select Agents
Discuss and evaluate protocols for exposure to blood and other body fluids including accidental sticks with contaminated needles Level 3

Discuss and evaluate proper hand washing procedure and hand asepsis Level 3

Develop and evaluate a system including protocols for ensuring proper infection control in phlebotomy and related services Level 3

Human Anatomy and Physiology

Describe terminology related to direction, anatomic positions, body planes and body cavities Level 1

Identify body systems by discussing:
   o Major organs
   o Components and structures
   o Primary functions
   o Common disorders and clinical laboratory tests/results

State specimen requirements and laboratory commonly performed for evaluation of each body system Level 1

Discuss the circulatory system Level 1
   o Characteristics of blood and its components- cellular and non-cellular
   o Blood vessels and sites used for arterial, capillary and venipuncture
   o Properties of arterial blood, capillary blood, and venous blood, and differences related to collection, handling, and appropriate use for laboratory testing
   o Process of coagulation and fibrinolysis as it relates to phlebotomy

Discuss the proximity of nerves to arteries and veins and the impact on phlebotomy Level 2

Discuss the vascular system in the skin and how it applies to phlebotomy and phlebotomy practice Level 2
   o Sites for skin puncture for capillary blood collection in infants, children, and adults
   o Limitations and precautions related to skin puncture and capillary blood collection

Specimens/samples

Define the term specimen/sample Level 1

Identify types of specimens/samples tested within the clinical laboratory Level 1

Discuss requirements that ensure the integrity of each type of specimen/sample type Level 1

Discuss specimen/sample collection including order of draw, preservation, processing and analysis of the integrity of each specimen/sample Level 1

State the components of blood Level 1

Explain the differences between serum and plasma Level 1

State and discuss pre-analytical factors that affect basal state of specimens/samples
   o Age
   o Altitude
   o Dehydration
   o Diet
   o Diurnal variation
   o Hemoconcentration
   o Hemolysis
   o Exercise
   o Intravenous therapy
- Lipemia
- Obesity
- Posture
- Smoking
- Stress
- Tourniquet applications
- Use of improper collection devices

Describe the procedures and discuss the rationale for handling urine specimens Level 1
- Collection
- Preservation
- Transporting
- Handling
- Processing

State factors that compromise the integrity of specimens/samples as related to the accuracy of clinical laboratory testing- Level 1
- Timing of collection, transport and testing
- Order of draw during specimen/sample collection
- Light
- Temperature
- Medications/drugs

Evaluate specimens/samples and determine the integrity and appropriateness for specific tests requested Level 3

State the types of additives used for blood collection in phlebotomy Level 1
- EDTA (citrate, potassium and disodium forms)
- Heparin
- Sodium fluoride
- Oxalate
- Antiglycolytic agents
- Clot activators
- Thixotropic gel, polymer gel
- Preservatives

Discuss the modes of action and appropriate use of each additive used for blood Collection Level 1

Match the blood collection tube stopper colors with the additive routinely associated with each colored stopper (e.g., tubes with lavender) Level 1

State, select, and evaluate appropriate equipment and supplies to be used for skin puncture and venipuncture for a variety of patient types Level 3

List specimens/samples used for commonly ordered clinical tests Level 1
State the laboratory section in which these tests are generally performed Level 1
Equipment and Supplies
Name, select and evaluate equipment and supplies used for phlebotomy and discuss proper use of each-

Level 3
- Evacuated tube system
- Syringes
- Winged and non-winged infusion sets
- Micro collection containers
- Skin puncture devices
- Arterial blood collection equipment
- Blood culture collection equipment
- Micro pipette dilution systems
- Tourniquets
- Antiseptics
- Disinfectants
- Puncture resistant containers
- Phlebotomy trays and carts
- General supplies (gauze, bandages, etc)
- Newborn screening testing kits
- POCT tests kits

Name, select and evaluate appropriate protective wear to be used during blood collection, transport, and handling- Level 3

Use equipment and supplies appropriately such that specimens/samples of quality and high integrity are obtained and efficient services of high quality are realized Level 2

Appropriately store equipment and supplies Level 2

Appropriately dispose of used/contaminated equipment and supplies Level 2

Specimen/sample collection
Instruct the patient on specimen/sample collection Level 2

Evaluate patient readiness for quality specimen/sample collection including adherence to diet, medication, etc. by interviewing/communicating with patients Level 3

Prepare and organize equipment and supplies prior to performing phlebotomy and related services Level 2

Name and select the appropriate collection site for arterial puncture, skin puncture, and venipuncture after considering factors that affect site selection- Level 2
- Intravenous fluid lines
- Transfusion
- Presence of burns
- Broken skin
- Scars
Collect blood via appropriate collection site and standard venipuncture techniques - Level 2
- Syringe system
- Winged and non-winged infusion set system
- Evacuated tube system using correct order of draw

Collect blood via appropriate collection site using standard skin puncture techniques on various patient types- Level 2
- Adults
- Infants
- Children

Evaluate specimen/sample integrity by proper patient preparation for tests ordered- Level 3
- Accurate patient identification
- Use of proper collection site and supplies, devices and procedures including order of draw
- Accurate labeling, transport and handling of specimens/samples collected

Discuss and appropriately use special precautions when collecting blood specimens/samples- Level 2
- Decontaminating the skin for routine collection
- Aseptic technique for blood cultures
- Warming devices
- Collecting appropriate Sample size
- Suitability of site for collection
- Implementing, monitoring, and evaluating quality assurance methods relevant to the scope of practice

Discuss the purpose of performing arterial punctures Level 2

Discuss blood donor screening, donor blood collection procedures, and precautions, blood products, expiration dates, and storage requirements Level 2 (Cross Reference in Immunohematology)

Discuss patient factors and adverse complications that affect phlebotomy specimen/sample collection Level 1
- Vein damage
- Collapsed veins
- Scar tissue
- Infections
- Difficult veins
- Pain
- Petechiae
- Excessive bleeding
- Syncope
- Seizures
- Nausea
- Vomiting
- Insulin shock
- Tatoos
Discuss methods to prevent or address technical and physiological complications in phlebotomy Level 1

Define and discuss the prevention of phlebotomy complications Level 1
  - Hematoma
  - Hemoconcentration
  - Hemolysis

Describe and demonstrate appropriate technique in preparation of acceptable peripheral blood smears Level 2

Label specimens/samples collected with appropriate information as defined by standard protocol Level 2

Identify and label biohazard specimens/samples Level 1

Prepare specimens/samples for transport or mailing to reference laboratories or other off site laboratories for testing using appropriate standard protocol Level 2

Describe and demonstrate proper disposal of contaminated equipment, supplies, and discard specimens/samples Level 2

Point of Care Testing (POCT)
State tests commonly performed at the patients' bed side or chair side- point of care Level 1
Name practitioners who are qualified to perform point of care tests Level 1
Discuss qualifications of practitioners who may perform point of care tests Level 1
Discuss the purpose of each POCT test Level 1
  - Sample/specimen requirements
  - Precautions
  - Limitations
  - Sources of error
  - Reference values
  - Quality assurance

State critical values and follow established criteria for reporting such values Level 1

Quality Assurance/Quality Control
Define and distinguish among the terms quality control, quality assurance and quality improvement Level 3
Discuss quality assurance in phlebotomy and related services Level 1
  - Requisitioning
  - Patient preparation
  - Phlebotomy procedures
  - Aspects of post phlebotomy care
  - Specimen labeling, transport, handling and procurement
  - Point of Care testing

Implement and evaluate a quality assurance system for phlebotomy Level 3

Discuss methods of improving phlebotomy services and related patient outcomes Level 1
Discuss and demonstrate proper documentation of procedure and quality assurance using established standards Level 2
- Specimen logs
- Tracking specimens manually and with the computer system

Evaluate specimens/samples for acceptability for tests requested Level 3
- Labeling discrepancies or absence of labels
- Hemolysis
- Specimen collection using the Wrong additive
- Use of outdated supplies
- Improper storage or transport

Discuss the volume of blood that can be taken from a patient with regard to age and standard practice- Level 1
Discuss standard practices related to the number of time a patient can be punctured by the same phlebotomist- Level 1

**Human communication definitions and application to practice**

Discuss effective human communication in phlebotomy and related services- Level 1
- Definitions
- Theories
- Key components

Discuss and demonstrate the application of communication theories in practice as a means of assuming the role of listener, speaker, and ultimately, effective communicator as a phlebotomist and patient care provider- Level 2
Demonstrate effective communication in providing patients with instructions for preparing for phlebotomy procedures- Level 2
- Fasting specimens/samples
- Glucose tolerance tests
- Urine collection
- Occult blood test

Demonstrate proper communication skills in interviewing a patient/client as related to phlebotomy and phlebotomy services- Level 2

Demonstrate proper greeting of patients/clients, visitors, peers, and other health care professionals- Level 2
Discuss and demonstrate effective communications with diverse clients encountered including pediatric and geriatric patients- Level 2
Describe factors that influence effective communications between patient/client and phlebotomists, medical laboratory technician (MLT) or medical laboratory scientist (MLS), the health care professional and their colleagues/other health care professionals, the health care professional, and patients’ families and guests- Level 2
- Cultural sensitivity
- Language barriers
- Technical jargon
- Disabilities
- Age
- Stress
- Medication
- Other
Professionalism, legal, and Ethical aspects

Discuss professionalism and behaviors associated with professionals practicing phlebotomy- Level 1
Demonstrate professional appearance by proper grooming and wearing professional attire- Level 2
Discuss basic theories of ethics and application to persons practicing phlebotomy- Level 1
Discuss the Patients' Bill of Rights and its application to phlebotomy and related services- Level 1
Discuss the importance of patient confidentiality and demonstrate maintenance of patient confidentiality and how it related to HIPPA- Level 1
Discuss the legal and ethical implications associated with breach of patient confidentiality- Level 1
Discuss and apply laws that impact upon phlebotomy and related services- Level 2
   o Clinical Laboratory Improvement Amendments of 1988
   o Occupational Safety and Health Administration regulations
   o Health Insurance Portability & Accountability Act (HIPPA)
   o Patient Self-Determination Act of 1990
   o Affordable Care Act (2010)
   o Other
Discuss and apply the ethical and legal responsibilities of the Patient’s Bill of Rights especially as they relate to phlebotomy and phlebotomy service- Level 2
   o HIPPA
   o The Patient Self-Determination Act of 1990
   o Confidentiality
   o Right to refuse treatment
   o Informed consent
   o Privacy
   o Other
Discuss the United States legal system as it relates to Phlebotomists, MLTs, MLSs participating in duties related to phlebotomy- Level 1
Discuss the importance of standard of care and legal implications associated with standards of care- Level 1
Discuss the importance of labeling specimens/samples and the legal ramifications associated with improper specimen labeling- Level 1
Discuss the legal ramifications of testing specimens/samples that lack integrity- Level 1
Discuss the interrelationship of ethics, morals, professional and personal values, and legal aspects of care in performing phlebotomy- Level 1
Discuss stress and the effects of stress on professionals performing phlebotomy and related services- Level 1
State methods of handling stress or eliminating stress in the workplace- Level 1
Discuss measures that can be taken to avoid or reduce risks and liability in performing phlebotomy and related duties- Level 1
The Health Care System and Services
   Identify components of the health care delivery system and the services each provides

Point of Care Testing (POCT)
   bleeding time

Patient and laboratory safety
   Discuss and evaluate safety equipment for use in phlebotomy and related services

Infection control
   Relate the types of isolation associated with specific inpatient or clinical treatment units - Oncology unit
   Develop and evaluate a system including protocols for ensuring proper infection control in phlebotomy and related services

Specimens/Samples
   Match the blood collection tube stopper colors with the additive routinely associated with each colored stopper (e.g., tubes with lavender)

Equipment and Processing for phlebotomy and processing
   Select and evaluate equipment and supplies used for phlebotomy and discuss proper use of each
      • Winged and non-winged blood collection sets
      • Triple Packaging System/Transfer devices
      • Dried Blood Spot and filter paper collections

Specimen/Sample collection
   Discuss precautions when collecting blood specimens/samples
   Discuss technical complications associated with blood collection and methods of correction for each - include needle insertion and loss of vacuum in evacuated tubes
   State and discuss patient factors and adverse complications that affect phlebotomy specimen/sample collection - mastectomy, stroke, double IV
Renal Anatomy and the Urinary System

Describe the anatomy of the kidney Level 1
Shape
Size
Placement in the abdominal cavity

Describe the function of each structure Level 1
Cortex
Medulla
Pyramids
Papilla
Calyces
Pelvis

Diagram each portion of the nephron Level 1
Bowman’s capsule
Proximal convoluted tubule
Ascending and descending limbs of Loop of Henle
Distal convoluted tubule (macula densa)
Collecting duct

Describe the function of each portion of the nephron Level 1

Explain the function of each component of the glomerulus Level 1
Capillary endothelium
Basement membrane
Podocytes (epithelium)

Explain role of renal blood circulation related to renal function Level 1

Describe the renal blood circulation Level 1
Afferent and efferent arterioles
Glomerulus
Peritubular capillaries
Vasa recta

Describe the ureters Level 1
Anatomical structure and location
Epithelium
Mechanism of action

Describe the bladder Level 1
Anatomical structure
Epithelium
Mechanism of action

Describe the urethra for male and female Level 1
Anatomical structure
Epithelium
Mechanism of action

Renal Physiology
Describe the process of glomerular filtration Level 1
Hydrostatic and oncotic forces
Glomerular filtration barrier (GFB)
Capillary endothelium
Basement membrane
Podocyte filtration diaphragms
“Shield of negativity”

Describe how glomerular filtration rate is calculated Level 1
Creatinine clearance
eGFR

Describe the process of urine formation Level 1
Tubular reabsorption and secretion
Active and passive transport
List the solutes that are reabsorbed by the nephron Level 1

List the solutes that are secreted by the nephron Level 1

Identify the nephron location and mechanism of reabsorption or secretion for each solute Level 1

Explain changes in solute composition as ultrafiltrate passes through the nephron Level 1

Explain the changes in osmolality as the ultrafiltrate passes through the nephron Level 1

Explain tubular transport capacity (Tm) in relation to renal threshold level Level 1

Describe secretory mechanisms that regulate acid-base balance Level 1

Hydrogen ion secretion to recover bicarbonate
Hydrogen ion secretion to form acids
Hydrogen ion secretion to form ammonium ions

Discuss the mechanisms that maintain hypertonicity/osmotic gradient of renal medulla physiology Level 1

Countercurrent multiplier mechanism
Countercurrent exchange mechanism
Urea cycle
Role in urine formation and concentration

Explain changes in urine volume and solute composition Level 1

Volume and composition of normal urine
Role of ADH/vasopressin in water reabsorption

Describe the renin-angiotensin-aldosterone system Level 1

Describe physiologic factors involved in determining the volume of urine excreted Level 1

Anuria
Oliguria
Polyuria

Renal Disease
Describe the pathogenesis and clinical features associated with glomerular disease/damage Level 1
State the clinical features of nephrotic syndrome and state diseases that are associated with this syndrome. Level 1

Compare and contrast typical urinalysis findings in glomerular diseases. Level 2

Acute glomerulonephritis
Chronic glomerulonephritis
Nephrotic syndrome

Compare and contrast the mechanism of tubular dysfunction and typical urinalysis findings. Level 2

Acute tubular necrosis (ATN)
Cystinosis and cystinuria
Renal glycosuria
Renal tubular acidosis (RTA)

Describe the clinical features of Fanconi Syndrome and identify diseases associated with this syndrome. Level 1

Compare and contrast etiology, clinical features and typical urinalysis findings in tubulointerstitial disease and urinary tract infections. Level 2

Acute pyelonephritis
Acute interstitial nephritis (AIN)
Lower urinary tract infections (e.g. cystitis)

Explain the presence of non-bacterial organisms (e.g., yeast, trichomonads, giardia, etc.) found in urine despite no evidence of urinary tract infection or involvement. Level 1

Describe the etiology of renal vascular disease. Level 1

Discuss effect of renal vascular disease on renal function. Level 2

Compare and contrast acute and chronic renal failure. Level 2

Etiology
Clinical features
Typical urinalysis results
Renal function tests

Define and describe formation of renal calculi. Level 1

Discuss factors that influence calculi formation. Level 1
Extrarenal Diseases
Describe physiologic mechanisms, clinical features and typical urinalysis findings of amino acid disorders  Level 1
- Cystinuria and cystinosis
- Alkaptonuria
- Maple Syrup Urine Disease
- Phenylketonuria
- Tyrosinuria and melanuria

Describe physiologic mechanisms, clinical symptoms and typical urinalysis findings of carbohydrate disorders  Level 1
- Glycosuria
- Diabetes Mellitus
- Galactosuria

Describe physiologic mechanisms, clinical features and typical urinalysis findings of metabolic disorders  Level 1
- Diabetes Insipidus
- Porphyrin disorders

Urinalysis
Instruct others in proper collection of urine specimen types  Level 2
Describe urine specimen collection techniques/procedures  Level 1
- Random void
- Midstream clean void
- Catheterization
- Suprapubic aspiration
- Pediatric collection bags
- Timed collection

Describe characteristics of urine specimen types  Level 1
- Random void
- First morning void
- Timed
Evaluate acceptability of urine specimens  Level 3

Labeling and patient information

Sufficient volume

Determine if time of collection, handling and transport conditions are appropriate  Level 3

Time elapsed since specimen collection

Timed test intervals

Storage (light, temperature, preservatives)

Visual evidence of contamination

Collection technique and specimen container is appropriate

Storage parameters for testing
   Refrigerate or freeze
   Room temperature
   Light protection
   Preservative requirements

Communicate to health care provider’s criteria for specimen rejection  Level 2

Document unacceptable specimens and action taken  Level 2

Verify acceptability of work area, equipment and supplies  Level 2

Determine and record temperatures in work area  Level 2

Room

Refrigerator

Freezer

Examine reagents for correct storage conditions  Level 2

Tightly sealed in properly labeled container

Temperature

Protected from light if necessary

Expiration date not exceeded

Prepare calibration and quality control materials  Level 2

Reagent strip controls
Refactometer calibrators and controls (If applicable)
Microscopic controls
Other chemical test controls

Perform and record calibration checks, quality control checks and equipment maintenance
Level 2

Refactometer (If applicable)
Centrifuge
Microscope
Osmometer
Automated instrument

Recognize, take corrective action and document when calibration or quality control check fails or equipment malfunctions Level 2

Evaluate quality control values to determine analytical errors and implement corrective action Level 3

Perform and record troubleshooting on equipment Level 2

Discuss evaluation and selection of methodology Level 3

Prepare specimens for analysis Level 2

Mix specimen
Aliquot for macroscopic and microscopic
Prepare dilutions as necessary
Centrifuge and remove supernatant
Resuspend sediment and stain if necessary
Prepare sediment for microscopic analysis (stain or standardized slide)

Ensure appropriate conditions for macroscopic evaluation Level 2

Adequate room illumination
Homogenous specimen
Temperature

Observe and record specimen color using established terminology Level 2

Correlate color with specimen concentration Level 2
Correlate color with patient medication Level 2
Correlate color and substances that produce them with clinical significance  Level 2
Observe and record specimen clarity using established terminology  Level 2
Correlate clarity with microscopic examination  Level 2
State substances that affect urine clarity and indicate those that are clinically significant  Level 1
Determine specimen concentration  Level 2
Perform specific gravity measurements  Level 2
  Refractometer
  Reagent strip
  Automated technology
Perform osmolality measurements  Level 2
Compare and contrast principles employed in each method of concentration measurement  Level 2
  Osmolality
  Refractometry
  Reagent strip specific gravity
Correlate urine concentration with clinical significance  Level 2
Observe and comment on abnormal urine odor, if applicable  Level 2
Distinguish between normal urine odor and that associated with old, unpreserved urine  Level 2
Describe abnormal urine odor and clinical significance  Level 2
Perform (manually or using instrument) and record qualitative/semi-quantitative reagent strip chemical tests  Level 2
Dip and remove strips in urine appropriately and correctly, time and read, and interpret reactions  Level 2
State limitations of various chemical techniques (false positive/negative)  Level 1
Apply criteria for results that require confirmatory testing and/or dilutions
Compare and contrast principles and limitations of various chemical tests on urine  Level 2
  pH
  Blood and myoglobin
Leukocyte esterase
Nitrite
Protein
Carbohydrates
Ketones
Bilirubin
Urobilinogen
Ascorbic acid
Albuminuria (microalbumin) by reagent strip
Creatinine by reagent strip

Discuss principles and limitations of confirmatory and qualitative metabolic screening tests
Level 1
Identify qualitative results as positive or negative for substance of interest  Level 2
Identify substances detected and correlate with possible metabolic disease  Level 2

Branched chain amino acids
Cystine
Homocystine
Homogentisic acid
Melanin
Phenylpyruvate and metabolites
Porphobilinogen
Tyrosine

Use established terminology to report chemical examination results  Level 2
Correlate chemical examination results for acceptability and clinical significance Level 2
Detect errors, discrepant and/or contradictory results and action to be taken before reporting results  Level 2

Preanalytical errors
  improper timing
  improper preservative
exposure to light
mislabeled specimens

Analytical errors
interfering substances present in urine
deteriorating reagents
instrument malfunction

Post-analytical errors

Correlate results of macroscopic examination with microscopic examination  Level 2
Apply protocol for initiation of microscopic examination based on macroscopic examination  Level 2
Explain purpose of macroscopic tests to health care personnel  Level 2

Prepare microscope for optimal viewing  Level 2  (See microscope section in MLS General Practice)

Clean ocular and objective lenses
Adjust light source for proper illumination
Place filters in light path
Protect microscope from dust

Select type of microscopy and adjust for optimum viewing (Koehler illumination)  Level 2
Optimize condenser position for height and centration
Adjust field iris and condenser aperture diaphragms

Describe and utilize various microscopic techniques  Level 2
Brightfield
Phase contrast (if available)
Polarizing (if available)

Compare and contrast viewing differences and advantages for each type of microscopy  Level 2

Check and perform phase ring alignment for phase microscopy  Level 2
Place polarizing filters in light path for polarizing microscopy  Level 2
Place, focus and scan mounted specimen on microscope
Secure microscope slide on mechanical stage
Check and perform interpupillary and diopter adjustments
Use course and fine adjustments
Use mechanical stage adjustments to scan specimen

Distinguish and quantitate cellular elements

Red blood cells (typical, ghost and crenated forms) using high power magnification (400x)
White blood cells using high power magnification (400X)
  Typical white blood cells (neutrophils, lymphs, macrophages)
  Atypical white blood cells (degenerative forms)

Special stains (eosinophils, lymphocytes, etc.)
Epithelial cells – Squamous (100x), transitional & renal tubular (400X)
Oval Fat Bodies

Abnormal and/or atypical cells

Distinguish, quantitate, and determine the type of casts

Hyaline
Waxy
Cellular inclusions (RBC, WBC, renal epithelial, mixed)
Inclusions (finely and coarsely granular, fatty, crystals, hemosiderin)
Pigmented (hemoglobin, bilirubin)

Distinguish acidic, neutral, and alkaline crystals

Associate with pathology/disease state
Derived iatrogenically

Distinguish miscellaneous formed elements

Bacteria
Fat globules
Hemosiderin
Mucus
Parasites
Spermatozoa
Yeast
Contaminants (starch, fibers, fecal material, clue cells, etc)

Record microscopic examination results using established protocol and terminology 
Level 2
Correlate microscopic with macroscopic and chemical examination Level 2
Correlate microscopic results with stated/possible conditions Level 2
Use protocol to identify specimens that require confirmatory testing before reporting results 
Level 2
Check for pre-analytical and post-analytical errors
Perform additional testing to resolve conflicting results
Explain purpose of microscopic tests to health care personnel Level 2
Describe viewing differences and advantages for each type of microscopy Level 2
Interpret and report results Level 2
Determine acceptability of quality control results and take necessary corrective action
Determine acceptability of patient specimens Level 3
Evaluate results for completeness
Intercept questionable and/or contradictory results and verify appropriate action is taken and documented
Ensure results are recorded in established format and terminology Level 2
Utilize reference intervals to determine clinical significance Level 2
Correlate results with stated/possible condition Level 2
Evaluate and correlate results with other tests results on same patient Level 3
Compare current results with previous results on same patient Level 2
Utilize protocol for identifying and reporting "critical values" Level 2
Utilize protocol to communicate results via computer, verbal or written Level 2
Respond to inquiries from health care personnel concerning test results, reference intervals, specimens Level 2

Renal Function Tests
Discuss the advantages and disadvantages of substances for determination of renal clearance 
Level 2
Creatinine
Inulin
Cystatin C
Discuss factors that can influence creatinine clearance results (timing, complete collection, body size) Level 1
Use protocol for performing creatinine clearance tests Level 2
Calculate creatinine clearance results using body surface area normalization Level 2
Differentiate eGFR and GFR Level 2
Recognize and identify factors that can influence eGFR results (age, muscle mass, pregnancy, ethnicity, race) Level 2
Interpret and report results Level 2
Evaluate acceptability of quality control results and take necessary corrective action
Evaluate acceptability of patient specimens Level 3
Evaluate results for completeness
Intercept questionable and/or contradictory results and verify appropriate action is taken and documented
Ensure results are recorded in established format and terminology Level 2
Utilize reference intervals to determine clinical significance Level 2
Correlate results with stated/possible condition Level 2
Correlate results with other tests results on same patient Level 2
Compare current results with previous results on same patient Level 2
Utilize protocol to communicate results via computer, verbal or written Level 2
Respond to inquiries from health care personnel concerning test results, reference intervals, specimens Level 2
Explain purpose of each renal function test to health care personnel Level 2
Renal Calculi
List and discuss factors that can influence calculi formation (increase in chemical salts, change in pH, urinary stasis, foreign body seed) Level 1
Describe the chemical composition of most renal calculi Level 1
Recognize modes of prevention and treatment Level 1
Body Fluids

Explain basic concepts relating to the clinical significance of body fluids   Level 1
Discuss types of body fluids (production, source, function) used in analysis  Level 1
  Cerebral spinal fluid (CSF)
  Pleural
  Peritoneal
  Pericardial
  BAL
  Synovial
  Amniotic
  Seminal
Define terminology associated with body fluid analysis  Level 1
  Paracentesis
  Thoracentesis
  Arthrocentesis
  Ascites
  Effusion (transudate/ exudate)
  Xanthochromia
  Chylos
  Pseudochylous
  Traumatic tap
Perform processing of specimens according to established laboratory protocol   Level 2
  Storage conditions
  Specimen transport
Perform body fluid analysis according to laboratory protocol for CSF, Serous, Synovial, BAL  Level 2
  Physical exam
  Color/ clarity
  Chemical exam
  Glucose
  Protein
  Oligoclonal bands and IgG Index (CSF)
Hematologic exam
  Cell counts
  Cytospin differential
  Crystal identification (synovial)
Microbiologic exam
  Gram stain
  Culture
Viscosity, if applicable (synovial)
Perform body fluid analysis according to laboratory protocol for amniotic fluid  Level 2
  Physical exam – color, turbidity
  Chemical
  fetal lung maturity
  lecithin/sphingomyelin (L/S) ratio
phosphatidylglycerol/phosphatidylinositol
lamellar body counts

Perform body fluid analysis according to laboratory protocol for seminal fluid Level 2

Physical
  appearance
  Volume
  Viscosity
Microscopic
  Motility
  Morphology
  Viability
  Agglutination
  Count
  Cells
Chemical (pH/fructose/zinc/citric acid/acid phosphatase/alpha-glucosidase)

Perform body fluid analysis according to laboratory protocol for fecal samples

Fat
Blood
White cell count

Evaluate acceptability of body fluid results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 2
Correlate patient results with disease state or disorder Level 2
MLS- Urinalysis and Body Fluids

**Deleted items**
- Explain the function of the mesangium of the glomerulus
- Diagram renal blood circulation
- Identify characteristics of fasting urine specimen types
- Assemble worksheets and other documenting materials
- Observe and record temperatures of heating blocks and water baths
- Dispense standardized volume of sediment to glass microscope slide and apply appropriate coverslip
- Perform and record confirmatory tests - Sulfosalicylic acid for protein & Watson-Schwartz for urobilinogen/porphobilinogen, clinitest, acetest, icotest
- For qualitative metabolic screening tests Select most appropriate chemical method for clinical situation
- For qualitative metabolic screening tests - Apply criteria for results that require confirmatory testing and/or dilutions
- Qualitative metabolic screening tests: Hoesch test for porphobilinogen, Watson-Schwartz for urobilinogen/porphobilinogen, Ferric chloride test for ketones, Ammoniacal silver nitrate test for homogentisic acid, Nitroprusside test for ketones
- Describe and utilize various microscopic techniques - Interference contrast microscopy
- Maintain daily and cumulative QC documentation
- Retain result documentation as required for accreditation
- Participate in continuing education programs; Enhance pertinent knowledge; Annually document competency (not needed for entry level)
- Renal calculi – locate chemical tests to determine chemical composition
- Quality Management in the Urinalysis Laboratory (covered in management section)

**Body Fluids**

- Amniotic – bilirubin (Δ 450), microviscosity
**Added items**

- Describe the process of glomerular filtration – including shield of negativity
- State the clinical features of nephrotic syndrome and state diseases that are associated with this syndrome
- Describe Specimen Collection technique - Timed collection
- Specimen preparation - mix specimen
- Observe and comment on abnormal urine odor, if applicable
- Distinguish between normal urine odor and that associated with old, unpreserved urine
- Dip and remove strips in urine appropriately and correctly, time and read, and interpret reactions
- Apply criteria for results that require confirmatory testing and/or dilutions
- Albuminuria by reagent strip
- Creatinine by reagent strip
- Discuss the advantage and disadvantages of Cystatin C for determination of renal clearance
- Differentiate eGFR and GFR
- Recognize and identify factors that can influence eGFR results (age, muscle mass, pregnancy, ethnicity, race)
- Describe the chemical composition of most renal calculi

**Body Fluids**

BAL
MLT Entry Level Curriculum - Immunohematology

**Whole blood donation -- principles of donor selection**
Review donor information (testing and interview responses) and determine if the donor is suitable for his/her category of donor
- Routine allogeneic
- Double RBC
- Therapeutic
- Autologous
- Apheresis (platelet, plasma)

Maintain donor records

Respond to questions regarding donor suitability – consulting with medical director as appropriate

**Blood collection**
List the different anticoagulant/preservative solution used in blood collection/storage bags

Describe the process for correcting the amount of solution according to body weight of donor

Perform the appropriate pre-donation testing (e.g., platelet count for plateletpheresis)
- Platelet count for plateletpheresis

Maintain produce sterility and integrity

**Donor reactions**
Describe the signs and symptoms of adverse donor reactions

**Processing donor blood**
Discuss the required standard of care tests and deferral criteria for infectious disease
- Hepatitis B and C antibody and NAT
- Syphilis
- HIV 1/2 (antibody and NAT)
- HTLV I/II
- CMV (as necessary)
- Chaga’s disease
- Bacterial testing of platelets

Determine ABO group and Rh type and record results
Determine reportability of results Level 2
Perform antibody screen and if positive identify Level 2
Store according to product requirements Level 1

**Autologous donors**
Discuss advantages and disadvantages of autologous and allogeneic donation and transfusion Level 1
Discuss and compare criteria for collection with that of random allogeneic donor Level 2
Test and label blood as required for autologous units Level 2
Dispose of unused autologous units as indicated Level 1

**Preparation of cellular and plasma components from donor units**
Describe the processes for separating units of whole blood and preparing components Level 1
- Packed red blood cells (PRBC)
- Leukocyte-poor PRB
- Washed PRBC
- Frozen, deglycerolized PRBC
- Irradiated PRBC
- Platelet concentrate
Discuss the preparation of single donor platelets by plateletpheresis Level 1
Store each component within required parameters Level 1
Prepare components according to protocol Level 2
- Fresh frozen plasma (FFP)
- Cryoprecipitate (CRYO) from fresh frozen plasma
- Single donor plasma from whole blood
Discuss the principle of pathogen inactivation for platelets and plasma products Level 1
Label units/component with required information Level 2
- Name of component
- Expiration date
- Amount of product
- Storage temperature
- Results of tests
List quality control standards for methods used in component preparation Level 1
Test components to determine if they meet the QC requirements

Document and review QC results

**Storage of blood components**
List the biochemical changes that take place in stored blood units and relate to the specific anticoagulant used, time and temperature of storage

Monitor equipment
- Document temperatures for refrigerators and freezers at required intervals
- Check temperature sensors at required intervals
- Document corrective action when temperatures vary beyond limits

Package and ship components
- Select units for shipping to fill routine and emergency orders
- Prepare transfer records
- Package components for shipping to maintain required conditions
- Maintain inventory

**Blood group serology**
Evaluate suitability of specimen
- List rejection criteria
- Ascertain that specimen has been correctly collected and labeled
- Discuss possible sources of error in testing that may result

Discuss how specific factors may affect reactions
- Incubation time / temperature
- Class of antibody
- Antigen/antibody ratio
- Centrifugation time/speed
- Suspending media (e.g., pH, saline, high protein, low ionic strength)

Prepare suspension of red blood cells using required equipment and reagents
- Choose appropriate reaction tubes and prepare saline cell concentrations
- Dispense cells and reagents without contamination
- Balance and use a serological centrifuge
- Wash cells manually and using a cell washee

Perform testing (e.g., tube, gel and solid phase) and record results
- Shake out tube tests without dispersing true agglutination
- Read and grade hemolysis and agglutination
- Interpret positive and negative reactions when an acceptable procedure has been followed
- Identify any factors that may have affected reactions and/or interpretation of reactions
**Antiglobulin tests**
Discuss the principle of the direct antiglobulin test Level 1

Discuss the principle of the indirect antiglobulin test (antibody screen) Level 1

Describe the principle and purpose of IgG sensitized cells Level 1

Use and interpret appropriate controls including autocontrol Level 2

Perform the antiglobulin test according to protocol and interpret results Level 2

Choose polyspecific and monospecific antiserum for the appropriate test specimen Level 2

Investigate and false positive and/or false negative results and determine methods for resolution Level 2

**Special methods**
Describe criteria and/or situations for use of specific elution techniques Level 1
Lui freeze-thaw
Chemical

Describe the principle of selected special methods (e.g., enzymes, pre-warmed, neutralization, elution) Level 1

Perform special methods (e.g., enzyme, pre-warmed, neutralization, elution) and record results Level 2

Select appropriate cells, reagents, controls and/or cell preparation methods for special techniques Level 1

Interpret results of special tests Level 2

Perform antigen typing (e.g. using tube, gel, and/or solid phase) Level 2

Perform (tube, gel and solid phase) testing for antibody screening & identification and document results Level 2

Apply knowledge of limitations of test procedure to test results and interpretation Level 2
Principles for recognition or differentiation of blood group antigens and antibodies

For the more common blood group systems list and compare characteristics of red cell antigens with their specific antibody
- Enzyme enhancement or inhibition
- Dosage
- Complement binding
- Other optimal conditions or reaction (e.g., pH, temperature, enhancement media)

Identify and use a source of information to identify characteristics reactions of rare unexpected antibodies

Apply characteristics of blood group antigens to interpret an antibody screen and correlate clinical significance of antibodies identified, and safety of blood components for transfusion
- Specificity and immunogenicity
- Variable expression of antigens
- Dosage
- Number and location of antigen sites
- Modes of inheritance
- Antigen development including changes from newborn through adult to aged
- Disease-related antigen changes
- RBC blood group antigens present on other tissue

Discuss properties of antibodies directed toward blood cell antigens that are used in evaluating antibody screens
- Primary vs. secondary response
- Non-red cell vs. red cell stimulation
- Expected (e.g., A, B, H) vs. unexpected
- Avidity
- Titer
- Effects of patient age, specimen age, disease
- Clinical significance
- Immunoglobulin class
- Phase of reactivity (in vivo vs. in vitro)

Identify properties related to immunoglobulin class
- Form of stimulation
- Clinical significance
Describe the effect of complement on hemagglutination reactions
   Aid in enhancing anti-Jk reactions
   Interference in immediate spin crossmatches

**Pre-transfusion testing**
Determine acceptability of recipient specimen based on specified criteria

Check records for previous ABO group and Rh type antibody problems,
   and transfusion history of patient

Perform required tests on recipient blood sample and document results
   ABO forward and reverse typing
   Rh typing including weak D when appropriate
   Antibody screen and identification
   Perform typing for special antigens as necessary employing negative
      and weakly-reacting positive control cells
   Perform antigen typing

Identify discrepancies of ABO typing results and perform
tests to resolve using appropriate methods (e.g., lectins,
   saline replacement, and reverse grouping with A2 and O cells)

Correlate results with potential causes of discrepant ABO results
   Subgroups of A and B
   Missing antibody in newborn, elderly or immunosuppressed
   Unexpected alloantibody
   Autoantibody
   rouleaux
   Transplantation of non-ABO–identical bone marrow/stem cells

Perform antibody screening and identification for antibodies that can be
   resolved using routine procedure
   Perform and interpret antibody screening including antiglobulin phase
   Perform and identify using routine antibody identification panels on
      serum or eluate

Confirm antibody identification
   Perform and interpret antigen typing of patient cells
   Select perform and interpret a cell panel using a 95% probability level
      of cells (3 cells positive and 3 cells negative) for the antigen
      against which a suspected antibody is directed

Evaluate clinical and/or laboratory data to determine when each specific
technique is appropriate
Alter reaction conditions to include appropriate controls and interpretation of results
  - Increased serum volume
  - pH adjustment
  - Neutralization techniques
  - Pre-warm technique
  - Saline replacement technique
  - Special antigen typings

**Compatibility of recipient and donor**
Discuss the need for compatibility testing depending on component required and nature of request
  - Type and screen with negative screen results vs. positive screen results
  - Routine transfusion
  - Emergency transfusion
  - Massive transfusion
  - Intrauterine and neonatal transfusion

List the blood types that are compatible with each ABO blood group

select the appropriate blood for compatibility when
  - group specific blood is available,
  - is not available,
  - if the patient has been recently transfused with non-group specific blood

Prepare donor sample from attached sealed segment or segment with number matching it to donor sample

Perform crossmatch and document results
  - Immediate spin to detect ABO incompatibility
  - routine antiglobulin crossmatch
  - computer crossmatch

Release compatible units for transfusion and complete appropriate records

Retain specimen from donor and recipient for appropriate length of time

Select blood for compatibility testing that is negative for the antigen against which clinically significant recipient antibody(ies) is/have been detected
Correlate results of compatibility testing with causes for incompatible results

- Atypical antibody(ies)
- Rouleaux
- Autoantibody(ies)
- Positive DAT on donor cells

Apply appropriate labels/tags to units including cases of incompatibility, emergency release of non-crossmatched units, least incompatible, etc.

**Testing for disease states associated with the direct antiglobulin test**

**Level 1**

- Explain the principle of the direct antiglobulin test (DAT)
- Perform DAT including use of IgG sensitized cells and record results
- Determine reportability of results
- Investigate patient history and test results for consistency with a positive DAT

**Hemolytic disease of the fetus and newborn**

**Level 1**

- Describe the immune process which causes hemolytic disease of the fetus and newborn (HDFN)
- List the common antibodies responsible for HDFN and compare their characteristics with antibodies that do not cause HDFN
- Perform prenatal testing and record results
  - ABO & Rh typing
  - Antibody screen on maternal sample
  - Identify antibody if screen is positive
- Perform testing on fetal blood samples and report results
- Procure safe blood for intrauterine transfusion
  - Select fresh blood of appropriate ABO and Rh type
  - Select or prepare leukocyte-reduced, irradiated, washed, hemoglobin S negative and CMV negative units as necessary
- Perform and record compatibility testing using maternal serum, eluate or fetal serum (when available) through umbilical cord sampling
- Determine if results can be reported or if follow-up testing is required
Perform neonatal testing and record results
  ABO (forward typing only) and Rh typing
direct antiglobulin test
elution and antibody identification where indicated
ABO and Rh typi and antibody screen
on maternal postnatal specimen
Identify antibody(ies) if present

Perform testing for exchange transfusion
  Select blood for transfusion that is appropriate to the clinical needs
  of the recipient
  Perform and interpret compatibility test using appropriate samples

Perform testing to determine necessity of administration of RhIg
  to prevent of HDFN
    Review patient history for evidence of antenatal administration of RhIg
    Perform D and weak D tests on maternal and newborn samples
    Perform antibody screen on maternal serum

Determine appropriate dosage of RhIg
  Perform test to identify and quantitate fetal maternal hemorrhage
  Rosette
  Kleihauer-Betke

Calculate dosage of RhIg based on test results

Issue product and complete records

Issuing of blood and blood components
Discuss the clinical necessity, and effects of transfusion

Prepare blood and blood components for transfusion
  Maintain adequate supply of appropriate blood and blood components
  Inspect blood and components for date of expiration and evidence
  of contamination or deterioration
  Perform confirmatory verification of ABO group and Rh type on
donor units as specified
  Verify patient identification and perform comparison checks on ABO
  and Rh of patient and complete records

Discuss bacterial testing for platelet units
Prepare products for transfusion
- Wash cells
- Irradiate product according to protocol
- Pool platelets or cryoprecipitate
- Thaw fresh frozen plasma and cryoprecipitate
- Prepare red blood cells to specified hematocrit or small volume for pediatric patients

Control return of unused blood or components
- Note time and estimate conditions under which blood components were maintained when out of the laboratory
- Inspect for evidence of improper storage
- Determine whether blood components can be reissued, complete appropriate records and store as required
- Appropriately dispose of blood components that cannot be reissued and complete paperwork

**Investigation of suspected adverse outcome to transfusion**
Perform required preliminary investigation to determine whether a hemolytic reaction has occurred
- Obtain and review completed transfusion report
- Check identification of pre-transfusion sample of donor and patient and of blood container
- Confirm correctness of interpretation of pre-transfusion test results
- Compare plasma of pre-transfusion and post-transfusion specimens for evidence of hemoglobin
- Perform and interpret a direct antiglobulin test (DAT) and ABO/Rh typing on post-transfusion sample and compare with pre-transfusion sample

Perform additional testing where appropriate to determine if a hemolytic reaction is the result of an alloantibody
- Repeat ABO, Rh, compatibility testing and antibody screening on patient pre-transfusion and post-transfusion samples and donor unit
- Identify unexpected alloantibody found in patient serum
- Type donor cells for antigen corresponding to the recipient antibody identified
- When DAT on patient cells is positive with anti-IgG prepare and test a red cell eluate for unexpected alloantibody
- Separate transfused from autologous cells by capillary centrifugation and perform appropriate testing on separated cells
**Human leukocyte antigens (HLA)**
Describe the genetic origin, biological functions, and cell distribution of the major human leukocyte antigens Level 1

Discuss the clinical importance for identifying HLA antigens or antibodies and matching HLA antigens Level 1
Disease association
Transplantation
Platelet transfusion

**Quality assurance**
Follow good manufacturing practices for environment within the facility Level 1
  - Adequate space
  - Ventilation
  - Sanitation and trash disposal
  - Temperature control
  - Water systems

Maintain/follow a Standard Operating Procedure (SOP) manual for all procedures Level 2

Participate in laboratory quality assessment Level 2

Discuss competency assessment Level 1

Discuss process improvement indicators Level 1

Participate in personnel QA Level 2
  - Provide and/or participate in continuing education programs
  - Participate in proficiency testing

Perform calibration and preventive maintenance at required intervals, trouble shooting and complete appropriate records Level 2
  - Centrifuge
  - Refrigerators/freezers/platelet chambers
  - Timers
  - Automated cell washers
  - Automated blood grouping or antibody screening instrumentation

Perform and record appropriate quality control (QC) on reagents Level 2
  - Typing sera and cells
  - Antibody screening and panel cells
  - Antiglobulin sera and IgG sensitized control cells
Perform positive and negative control testing as required in tandem with patient tests when tests are not performed daily
  Lectins
  Special antigen typing

Monitor results of quality control procedures for reagents

List the criteria for adequate recovery of prepared component

Test an appropriate percentage of blood units or components and interpret results for acceptability
  Packed red blood cells for volume and hematocrit
  Number of platelets and volume
  Number of units of Factor VII in cryoprecipitate

Maintain inventory records
  Have the records available for: ABO, Rh testing performed in the last 12 months and difficulties encountered in transfusion testing according to state and federal requirements
  Store and retrieve testing results and other information from a database

Record errors or adverse outcomes in patients and notify supervisor

**Agencies regulating blood banks**
Identify major regulatory agencies
MLT – ELC Immunohematology

Deletions & Additions

DELETIONS

Whole blood donation -- principles of donor selection
higher levels such as, Select, Identify, Perform, etc.

Blood collection
higher levels such as, Select, Identify, Perform, etc.

Donor reactions
higher levels such as, Use

Processing donor blood
higher level of, Perform tests

Autologous donors
some higher levels such as, Select, Adapt, Collect

Preparation of cellular and plasma components from donor units
some higher levels such as, Prepare (some)

Hemolytic disease of the fetus and newborn
Predict risk…..

Additions

Whole blood donation -- principles of donor selection
Modified to reflect level 1 knowledge, since actual collections are performed by blood donor facilities
Added Resolve questions……

Blood collection
Updates – Modified to reflect level 1 knowledge, since actual collections are performed by blood donor facilities

Donor reactions
Updates – Modified to reflect level 1 knowledge, since actual collections are performed by blood donor facilities

Processing donor blood
Updates – Modified to reflect level 1 knowledge, since actual collections are performed by blood donor facilities
Added more currents tests
Autologous donors
Updates – Modified to reflect level 1 knowledge, since actual collections are performed by blood donor facilities

Preparation of cellular and plasma components from donor units
Updates – Modified to reflect level 1 knowledge, since actual collections are performed by blood donor facilities
  Added Prepare (several)
  Added QC

Blood group serology
Updates – Re-ordered sequence of subtopics
  Changed Drop to Dispense
  Added Perform and Interpret

Antiglobulin tests
Updates – added this section and reorganized appropriate test/concepts under it, etc

Special methods
Updates – added this section and reorganized appropriate test/concepts under it, etc

Pre-transfusion testing
Updates – Added Determine…, Analyze…

Hemolytic disease of the fetus and newborn
Updates – Added Perform testing…

Human leukocyte antigens (HLA)
Changed heading from Major to Human
MLT Entry Level Curriculum – Immunology

Basic Concepts

Define innate immunity Level 1
Define adaptive immunity Level 1
          Passive immunity
          Active immunity

State major components and function of innate immune system Level 1
          Physical barrier
          Phagocytic cells
          pH
          Lytic components
          Inflammatory response
          Soluble mediators (cytokines, complement, acute phase reactants)

Describe the cellular & organ components of the immune system & their origins Level 1
          Lymphoid organs (primary & secondary)
          Cells (B, T, macrophage)

Contrast primary & secondary immune responses Level 1

Discuss and differentiate the features of an antigen molecule that determine immunogenicity Level 2
          Molecular size & complexity
          Foreignness
          Epitopes
          Dosage, timing & route of administration
          Cross-reactivity

Discuss and compare the structure, function, properties and formation of an antibody molecule Level 2
          Classes, subclasses
          Light & heavy chain regions
          Fragments (Fab, Fc)

Define the following and discuss their importance in immune process Level 1
          isotype
          allotype
          idiotype
Cell-mediated Immunity

Describe T cell development

Differentiate the functions of subsets of T cells
- CD8+ (cytotoxic)
- CD4+ (Th1, Th2, Th17)
- Treg

Response to intracellular vs. extracellular pathogens

Describe and compare the process of antigen recognition/presentation for T-cell subsets
- Role of activation & antigen presenting cells
- MHC molecules involved and restricted recognition
- Co-receptors, signaling, cytokines stimulated or responded to
- Cells stimulated

Discuss and differentiate the effector functions of each T-cell subset
- Lysis
- Apoptosis
- Inflammation
- B cell activation

Discuss the characteristics, role, and function of
- Natural Killer cells
- Lack of MHC restriction
- Lack of CD markers
- Cytokines stimulated

Humoral Immunity

Discuss the interaction of cells in the generation of antibody
- CD4+
- APC

Define isotype switching and describe how it occurs

List and describe characteristics of B cell memory
- Numbers of cells
- Titer of antibody
- Affinity of antibody

Compare antigen independent and antigen dependent B cell differentiation
- Affinity maturation
- Class switching

Describe the process of mature B cell activation
- Stimulatory molecules
- Membrane bound Ig → secreted immunoglobulin
- Plasma cell
Cytokines
Discuss and compare the characteristics and function of the major cytokines involved in innate immunity (e.g., IL-1, IL-6, TNF-α) Level 2

Discuss and compare the characteristics and function of the major cytokines involved in adaptive immunity (e.g., IL-2, IL-4, IL-5, IL-10, INFγ)
Cells that produce
Functions /cells affected

Discuss and compare the functions of soluble mediators affecting PMNs and macrophages Level 2
Chemotactic factor
Migration inhibitory factor
GM-CSF

Immunological Techniques Used in the Clinical Immunology Laboratory
Discuss and describe basic immunoassay principles to include characteristics such as complexity, methodology, phases, tags:
Visible (e.g., precipitation, agglutination, diffusion, flocculation, etc)
Competitive Binding:
(e.g., Radioimmunoassay, Enzyme immunoassay, Chemiluminescent assays)
Non-Competitive Binding (Sandwich assays):
(e.g., Enzyme immunoassay, Chemiluminescent assays)

Discuss basic DNA techniques
(cross reference to molecular ) Level 1

Discuss basic concepts of flow cytometry
(cross-reference to hematology) Level 1

Describe the operation of a flow cell cytometry instrument
(cross-referenced to hematology) Level 1

Prepare appropriate materials, reagents, and equipment for the performance of routine test procedures Level 2

Perform procedures according to established laboratory protocol Level 2

Determine acceptability of results and report according to laboratory protocol Level 2
Identify sources of error in test procedures according to laboratory protocol Level 2

Perform, document, and evaluate quality control Level 2

Perform and document routine preventive maintenance Level 2

Autoimmune diseases
Define tolerance Level 1

Describe proposed mechanisms for autoimmunity Level 1

Discuss characteristics of organ-specific and systemic autoimmune diseases Level 1

Describe the clinical symptoms and laboratory findings for classic autoimmune diseases Level 1
  collagen vascular (e.g., Systemic Lupus Erythematosus, Rheumatoid arthritis)
  Thyroid (e.g., Graves’ disease, Hashimoto’s thyroiditis)
  Addison’s Disease
  Type I Diabetes mellitus
  Celiac disease

Tumor Associated Antigens
Describe purpose and function of the immunosurveillance system for tumor recognition Level 1

List and describe antigens that are associated with human tumors Level 1
  Carcinoembryonic antigen (CEA)
  Alpha-fetoprotein (AFP)
  Prostate-specific antigen (PSA)
  Beta-2-microglobulin
  HCG
  Others, as applicable (e.g., CA 125, CA 19-9)

Immunodeficiency Disorders
Discuss the characteristics of congenital/genetic B cell immunodeficiencies Level 1
  X-linked hypogammaglobulinemia
    (Bruton’s agammaglobulinemia)
  Selective immunoglobulin deficiencies (e.g., IgA)

Discuss the characteristics of congenital/genetic T cell immunodeficiencies Level 1
  Thymic aplasia (DiGeorge’s syndrome)
Discuss the characteristics of combined B cell and T cell immunodeficiencies

Severe combined immunodeficiency disease (SCID)
Wiskott-Aldrich syndrome

**Complement System Deficiencies**

Describe the characteristics of common complement component deficiencies

**Phagocyte Deficiencies**

Describe the clinical symptoms and laboratory findings

Chronic granulomatous disease (CGD)
Chédiak-Higashi syndrome
Job’s syndrome

**Acquired Immunodeficiencies**

Describe the clinical and laboratory findings in a patient with acquired B cell deficiency including 2° infections

HIV/AIDS

**Infectious Diseases**

(cross-referenced to microbiology)

Describe the clinical and laboratory findings in various infectious diseases

Epstein-Barr infection (infectious mononucleosis)
Hepatitis (e.g., A, B, C)
Group A streptococcal infection
Syphilis
Rubella
CMV

Prepare appropriate materials, reagents, and equipment for the performance of test procedures

Perform procedures according to established laboratory protocol and report results

Determine acceptability of results

Identify sources of error in test procedures according to laboratory protocol

Perform, document, and evaluate quality control
Hypersensitivity

List the types of hypersensitivity and give examples of representative conditions

Types I-IV

Discuss the immunological mechanisms unique to each type of hypersensitivity
MLT Entry level curriculum
Immunology

Deletions & Additions

**Deletions**

**Humoral Immunity**
Deleted – Gene re-arrangement

**Immunodeficiency Disorders**
Deleted – Chronic mucocutaneous candidiasis
  Ataxia telangiectasia

**Additions**

**Infectious Diseases**
Updates – Changed name from “Viral Infections” to be more inclusive of others such as bacterial
  Added cross-reference to microbiology for this section
  Added other infectious diseases – Strep, MMR, Syphilis, Rubella, CMV
  Perform – modified to match “Immunological Techniques” section

**Hypersensitivity**
Same
Health care reform environment

Describe the forces affecting changes in the health care environment Level 1
State changes occurring in laboratories related to health care changes Level 1

Federal regulations, government organizations/agencies and national organizations

Describe the forces affecting changes in the health care environment Level 1
Identify and define the functions and impact on laboratory practice of the following: Level 1

- Health and Human Services (HHS)—Lab Reimbursement/Fee Schedule
- Center for Medicare and Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Federal Drug Administration (FDA)
- Department of Transportation (DOT)
- Occupational Safety and Health Administration (OSHA)
- Bureau of Biologics (BOB)
- Clinical Laboratory Standards Institute (CLSI)
- Office of Inspector General (OIG)
- Clinical Lab Improvement Amendments (CLIA) regulations and accreditation requirements
- International Standards Organization (ISO)

Identify the governmental laws and regulations that affect the laboratory and describe their impact Level 1

- Hill-Burton Act
- Medicare Act
- Clinical Laboratory Act (CLIA) ‘67
- Balanced Budget Act 1997 (BBA)
- CLIA ‘88
- Health Insurance Portability and Accountability Act (HIPPA)
- Federal and state bioterrorism statutes
Identify the following organizations and agencies and describe their roles in laboratory accreditation

- The Joint Commission (TJC)
- College of American Pathologists (CAP)
- State Health Departments
- Commission on Office Laboratory Accreditation (COLA)
- Substance Abuse and Mental Health Service Administration (SAMHSA)
- American Association of Blood Banks (AABB)

**General Management Theory**

- Define management, leadership, and administration
- Recognize the features of a good decision and explain the steps to make a sound decision
- Identify the positive influences as well as the major barriers to effective communications

**Financial Management**

- State the principles of third party payment using insurance coding and reimbursement parameters
- Explain the difference between operational and capital budgets
- Explain the difference between supply expenses and other budget items
- Explain the process of material management and inventory control
- Record inventory levels

**Information Systems**

- Demonstrate general information technology literacy
- Use software
- Use Laboratory Information Systems
- Use RFID Technology
- Use internet applications
- State the characteristics and activities of an information system
- Recognize the features and purpose of networks
Define information technology terms and explain the use of information technology in the laboratory Level 1
Use medical informatics Level 2
Explain use of bar codes Level 1
Define the goals and objectives of a laboratory information system Level 1
State IT system security Level 1
Use email and required privacy rule(s), encryption Level 3
Identify required mobile device security Level 1
Discuss electronic health records (EHR) and explain the laboratory role Level 1

**Human Resources**
Identify by name and function the professional organizations associated with the medical laboratory profession Level 1
   - American Association of Blood Banks (AABB)
   - American Association of Clinical Chemists (AACC)
   - American Medical Technologists (AMT)
   - American Society for Clinical Laboratory Science (ASCLS)
   - American Society for Clinical Pathology (ASCP)
   - American Society for Microbiology (ASM)
   - Clinical Laboratory Managers Association (CLMA)
List, define, compare and contrast associated credentialing mechanisms Level 2
   - Certification
   - Licensure
   - Accreditation
List and compare the certification levels offered and the appropriate initials offered for two, four year, and doctorally educated laboratorians and the level at which each certification level functions in a clinical laboratory Level 1
   - Board of Certification (BOC)
   - American Medical Technology (AMT)
   - American Association of Bioanalysis (AAB)
Prepare a resume or curriculum vitae Level 2
Recognize situations of unethical professional performance Level 2
State appropriate action to correct unethical or unprofessional situations  Level 1
Describe CLIA personnel qualifications and responsibilities  Level 1
  Laboratory director
  Technical consultant
  Clinical consultant
  General supervisor
  Testing personnel
Review career ladders  Level 1

Operations Management
Describe elements of a Continuous Quality Improvement (CQI) plan  Level 1
Apply Clinical and Laboratory Standards Institute (CLSI) standards for technical procedures  Level 3
Describe standards for quality assessment  Level 1
State the purpose of a proficiency testing (PT) program  Level 1
State personnel standards including required competency assessment  Level 3

General healthcare
Explain medical laboratory science’s impact on other healthcare providers and patients  Level 1
Discuss the use of clinical laboratory data in the diagnosis and treatment of patients  Level 1
Explain model hospital/facility organization  Level 1
  Typical hierarchy
  Typical committee structure, laboratory role
Describe how laboratory services impacts the delivery of care  Level 1

Professionalism: Performance standards, roles, philosophy, communication, & ethics
Exemplify concepts and practice of professional standards  Level 3
Discuss and apply confidentiality and legal requirements  Level 3
Demonstrate ethical and professional standards  Level 2
Explain and promote professionalism and professional development impact on laboratory operations  Level 2
Explain impact of professionalism on profession and healthcare delivery  Level 2
Communicate to other healthcare professionals in an effective manner  Level 2
**Personnel Safety**

- Apply OSHA standards Level 3
- Apply ergonomic practices to laboratory tasks Level 3
- Follow policies and procedures to address bioterrorism or other public health issues Level 1
- Follow a disaster preparedness program Level 1

**Patient Safety and Testing**

- Define patient safety and health care quality using the Institute of Medicine (IOM) definitions Level 1
- Describe the total testing process including pre-analytic, analytic, and post-analytic processes Level 1
- Describe components of health care quality as defined by IOM Level 1

Safe: Avoiding injuries to patients from the care that is intended to help them

Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit by avoiding underuse and overuse

Patient-centered: Providing care that is respectful of and responsive to individual preferences, needs, and value and ensuring that patient values guide all clinical decisions

Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care

Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy

Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

Follow protocols for communicating current standards of laboratory practice for laboratory testing related to specific diagnosis or condition Level 2

Explain to other the how and why of laboratory testing process Level 2

Identify and use methods to evaluate the impact of patient turnaround time on other aspects of healthcare delivery Level 2
Document Changes

Addition:

Describe the forces affecting changes in the health care environment

Editorial note:

Removed Healthcare Finance Administration and added Center for Medicare and Medicaid Services AND NCCLS changed to CLSI AND changed JCHAO to TJC to reflect current names

Additions:

ISO added to both as an agency students must know about

The following acts were added for students to know about: Balanced budget act, HIPPA, Federal and State bioterrorism statutes

Deletion:

TERFA was removed as an agency students needed to know about

Editorial Change:

Students need to know about accreditation process as a whole and not simply CAP. Furthermore, they should be able to identify the component a site survey may wish to view.

Deletions with no replacements:

- Explain the differences between management of health care organizations and other businesses
- List and explain the major managerial “functions”

Additions:

- Recognize the features of a good decision and explain the steps to make a sound decision (Level 2)
  - Identify the role human behavior plays and its influence in the decision-making process (Level 1)
  - Identify the decision-making techniques to resolve the problems and decisions faced by the laboratory (Level 1)
  - Identify the sources of conflict and resistance to change and discuss the change process and incorporation of the change process in the overall operations of the laboratory (Level 1)

- Define leadership within the functions of management (Level 3)
  - Recognize the factors that determine leadership success (Level 1)
  - List and compare the concepts and advantages of major leadership models (Level 2)
  - Explain leadership principles to the management of organizations (Level 2)
Explain the differences between management of health care organizations and other businesses (Level 2)

List and explain the major managerial “functions” (Level 2)

- Financial management
- Human resource management
- Test system management
- Operations management
- Information systems/informatics management

Addition:
Students should understand Quality Management Systems instead of continuous quality improvement.

Describe current and future reimbursement for clinical laboratory services from government agencies, insurers, and managed care groups, e.g., third party payment (Level 1)

Define medical necessity, advanced beneficiary notices, Medicare secondary payor documents, and diagnosis coding impact on laboratory reimbursement (Level 2)


Define National Coverage Determination (NCD) and Local Coverage Determination (LCD) lists (Level 2)

Explain the difference between operational and capital budgets (Level 2)

Explain the difference between supply expenses and other budget items (Level 2)

Explain the process of material management and inventory control (Level 1)

Record inventory levels (Level 1)

Deletions:

Define computer terms and explain their use in the laboratory Level 1

Laboratory information systems (LIS)

Central processing unit (CPU)

Medical informatics

Bar codes

Removed interviewing from ELC for management since that skill is not entry level

Additions:

Describe the key elements of a performance appraisal system (Level 1)
Explain the role of human resource management in the operation and functions of the management process (Level 2)

Describe CLIA personnel qualifications and responsibilities (Level 1)

Laboratory director

Technical consultant

Clinical consultant

General supervisor

Testing personnel

State principles of delegation and, given criteria, determine what and to whom to delegate (Level 1)

State various techniques to motivate employees (Level 1)

Identify incentives for professional development (Level 1)

Describe workflow productivity (Level 2)

Review career ladders (Level 1)

Operations Management

Write effective policies and procedures (Level 2)

Describe elements of a Continuous Quality Improvement (CQI) plan (Level 1)

Apply Clinical and Laboratory Standards Institute (CLSI) standards for technical procedures (Level 3)

Maintain an effective quality systems assessment program (Level 3)

Define Use Six Sigma (Level 2)

Use Lean Six Sigma (Level 2)

Use other quality models (Level 2)

Describe standards for quality assessment (Level 1)

Use an effective quality control system (Level 3)

State the purpose of a proficiency testing (PT) program (Level 1)

State personnel standards including required competency assessment (Level 3)

Utilize method evaluation and validation (Level 2)

Utilize process improvement and problem identification (Level 2)

Explain data gathering, data process, and use of information systems for data comparisons, storage, transformation, and retrieval (Level 2)
General healthcare

Explain medical laboratory science’s impact on other healthcare providers and patients (Level 2)
Discuss the use of clinical laboratory data in the diagnosis and treatment of patients (Level 2)
Explain model hospital/facility organization (Level 2)
Discuss typical hierarchy (Level 2)
Discuss typical committee structure, laboratory role (Level 2)
Discuss clinical pathway development, laboratory role (Level 2)
Discuss expanded or other roles for administrative MLS (Level 2)
   a) Technical consultant
   b) Infection control professional
   c) Information technology professional
   d) Marketing or client relations
   e) Compliance officer

Describe how laboratory services impacts the delivery of care (Level 1)

Apply CLIA pre-analytical, analytical, and post-analytical aspects (Level 3)

Professionalism: Performance standards, roles, philosophy, communication, and ethics
Exemplify concepts and practice of professional standards (Level 3)
Discuss and apply confidentiality and legal requirements (Level 3)
Demonstrate ethical and professional standards (Level 2)

Explain and promote professionalism and professional development impact on laboratory operations (Level 2)

Explain impact of professionalism on profession and healthcare delivery (Level 2)

Communicate to other healthcare professionals in an effective manner (Level 2)

Safety
Implement a laboratory safety program (Level 2)
Use Globally Harmonized System (GHS) of classification and labeling of chemicals (Level 2)
Apply OSHA standards (Level 3)
Apply ergonomic practices to laboratory tasks (Level 3)
Follow policies and procedures to address bioterrorism or other public health issues (Level 2)

Follow a disaster preparedness program (Level 2)

Patient safety and testing

Define patient safety and health care quality using the Institute of Medicine (IOM) definitions (Level 1)

Describe the total testing process including pre-analytic, analytic, and post-analytic processes (Level 1)

Describe components of health care quality as defined by IOM (Level 1)

Safe: Avoiding injuries to patients from the care that is intended to help them

Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit by avoiding underuse and overuse

Patient-centered: Providing care that is respectful of and responsive to individual preferences, needs, and value and ensuring that patient values guide all clinical decisions

Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care

Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy

Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

Identify methods to measure the effectiveness of laboratory testing (Level 2)

Testing performed for screening purposes

Testing performed to monitor progress of chronic diseases

Testing performed to monitor rates of disease diagnosis using measurements of positive and negative predictive values

Follow an effective patient safety program (Level 3)

Describe and apply changes in public health policy and oversight of healthcare delivery system that fosters and improves patient safety (Level 3)

Use facts and trends in sentinel event investigation (Level 2)

Explain overuse, underuse, and misuse of laboratory testing (Level 2)

Identify appropriate laboratory tests to order using evidence-based methods (Level 1)

Testing performed to screen for conditions and diseases

Testing performed for diagnosis of conditions and diseases

Testing performed to monitor prognosis after diagnoses of conditions and diseases

Testing performed to monitor therapy implemented to treat conditions and diseases
Identify appropriate protocols to monitor utilization of blood products in transfusion services (Level 1)

Follow protocols for communicating current standards of laboratory practice for laboratory testing related to specific diagnosis or condition (Level 2)

Identify methods to provide patient-centered laboratory services (Level 1)

Pre-analytic phase of laboratory total testing process

Cultural differences

Patient preferences

Explain to other the how and why of laboratory testing process (Level 3)

Identify and use methods to evaluate the impact of patient turnaround time on other aspects of healthcare delivery (Level 2)

Identify and use methods to quantify inefficiencies in the pre-analytic, analytic, and post-analytic phases of the total testing process, i.e., quantify savings due to improvement of efficiencies (Level 2)

Technical consultant

List the CLIA qualifications for a technical consultant (TC) (Level 1)

List the CLIA TC responsibilities (Level 1)
MLT Entry Level Curriculum – Clinical Chemistry

Mathematics and Chemical Calculations

Perform basic calculations Level 2
Exponents
Molarity
Percentage
Ratios and proportions
Unit conversions (concentration relationships)
Percent to molarity, molarity to percent
Standard solutions
Define Dilutions (Serial and Ratio) Level 1
Calculate and Perform Dilutions (Serial and Ratio) Level 2
Define units of systems of measurement Level 1
Metric
International system of units (SI units)
Define conversions between and among systems of measurement Level 1
Metric to SI
SI to metric
Perform temperature conversions Level 2
Fahrenheit to Celsius
Celsius to Fahrenheit
Define statistical data for quality control and statistical analyses Level 1
Calculate and utilize statistical data for quality control and statistical analyses Level 2
Refer to General Lab Document page 5
Mean, Median, Mode
Standard deviation
Coefficient of variation
Confidence limits

Instrumentation: Spectrometry

Identify basic concepts of spectrophotometry Level 1
Principles of light absorption
Wavelength
Spectrum
Beer’s law
Complementary spectra
Identify spectrophotometer components Level 1
Light source
Monochromator
Cuvets
Light detectors
Read-out systems
Describe the operation of a spectrophotometer Level 1
Function controls
Standard curves
Explain maintenance/quality assurance of instrumentation Level 1
Stray light
Sensitivity
Linearity
Wavelength calibration

Perform test procedures on standards, controls, and unknowns Level 2
Calculate, if necessary, and record quality control (QC) data
Evaluate quality control data (QC)
Accept/reject results
Take appropriate corrective action, if necessary
Report results, if acceptable

Perform routine maintenance checks on all spectrophotometers Level 2
Correlate test results with other laboratory test and patient diagnosis Level 2

**Instrumentation: Turbidimetry and Nephelometry**
State basic concepts of turbidimetry and nephelometry Level 1
Principles of absorption and light scatter
Reflectance

**Instrumentation: Atomic Absorption Spectrophotometry**
State basic concepts of atomic absorption spectrophotometry Level 1
Principles of light absorption
Generation of atoms from molecules

**Instrumentation: Fluorometry**
State basic concepts of fluorometry Level 1
Principles of light absorption and emission by molecules
Absorption and emission spectrum

**Instrumentation: Luminescence**
State basic concepts of luminescence Level 1

**Instrumentation: Osmometry**
Describe unique components relative to Osmometry Level 1
Principles of osmolality (colligative properties)
Definition
Calculations

**Instrumentation: Electrochemistry**
Explain basic concepts of electrochemistry Level 1
Principles of electrochemistry
Potentiometry
Electrodes
Describe the basic components of electrochemistry Level 1
Reference electrode
Indicator electrode
Salt bridge
Describe the basic concepts of ion-selective electrodes Level 1
Glass
Solid state
Liquid membrane
State the difference between a direct and indirect ISE Level 1
Correct malfunction according to manufacturer’s protocol Level 2
Perform test procedures on standards, controls, and unknowns Level 2
Evaluate quality control data (QC)
Accept/reject results
Take appropriate corrective action, if necessary
Report results, if acceptable
Correlate test results with other laboratory tests and patient diagnosis Level 2

**Instrumentation: Blood Gas Analyzers**

State basic concepts of blood gas analyzers Level 1
Describe basic components of blood gas analyzers Level 1
- pCO2 electrode
- pO2 electrode
- pH electrode
- ISE electrode (if applicable; see electrochemistry section)
- Cooximetry
- Sample chamber
Describe operation of blood gas analyzers Level 1
- Function controls
- Sample handling
Perform routine maintenance/quality assurance of blood gas analyzers (if available) Level 2
- Standard gases
- Electrode and membrane care
- Interference
Perform test procedures on standards, controls, and unknowns Level 2
- Evaluate quality control data (QC)
- Accept/reject results
- Take appropriate corrective action, if necessary
- Report results, if acceptable
Correlate test results with other laboratory tests and patient diagnosis Level 2

**Instrumentation: Balances**

Describe basic mechanisms and types of balances Level 1
Define balancing terminology Level 1
- Capacity
- Sensitivity
- Precision
- Readability
- Tare
Operate balances Level 2
- Leveling
- Handling weights
- Pan and/or beam arrest
Weighing paper or boats
Cleanliness
Temperature
Elimination of drafts, vibrations, etc.

Calibrate balances following established laboratory procedure  Level 2

Perform routine maintenance checks on all balances   Level 2

**Instrumentation: Centrifuges**

- Explain basic concepts of centrifugation Level 1
- Principles of centrifugal force
- Tachometer
- Relative centrifugal force

Identify basic components of a centrifuge  Level 1
- Head (rtor)
- Bowl and cover (chassis)
- Shields, cups
- Brushes
- Cushion

Describe operation of centrifuge  Level 1
- Function controls
- Balancing

Operate centrifuges   Level 2
- Load and balance
- Lock head
- Select appropriate speed (temperature, if applicable)
- Follow safety precautions

Perform routine maintenance checks on all centrifuges   Level 2

**Instrumentation: Heating Units**

Perform routine maintenance on heating units following established laboratory procedure  Level 1

Check/calibrate temperature setting of heating units Level 2
Correct malfunction according to manufacturer's manual  Level 2

**Instrumentation: Electrophoresis**

State basic concepts of electrophoresis  Level 1
- Principles of electrophoresis
- Voltage, current
- pH
- Ionic strength
- Buffers
- Temperature

Describe the basic components of electrophoresis  Level 1
- Support media: cellulose acetate/gel/agarose
- Chamber
- Buffer
- Electrodes
Power supply
Densitometer

Describe the operation of electrophoresis Level 1
Sample application
Time
Temperature
Voltage, current
Stains

Perform analyses according to laboratory procedure (if available) Level 2
Accept/reject results
Evaluate and record quality control data
Report results, if acceptable
Correlate results with disease/diagnosis Level 2

Instrumentation: Chromatography
State basic concepts of chromatography Level 1
Separation mechanisms (partition, absorption)
Define basic chromatography techniques Level 1
Column
Thin layer (TLC)
Liquid (HPLC)
Gas (GLC)

Describe the basic components of a chromatography system Level 1
Flow regulation
Mobile phase
Stationary phase
Column
Detectors

Instrumentation: Mass spectrophotometer
State basic concepts of mass spectrophotometry Level 1

Instrumentation: Automation
State basic concepts of automated analyzers Level 1
Discrete sample systems, self-contained and special purpose (POC)
Describe operations and principles of the automated systems Level 1
Describe the basic components of an automated system Level 1
Sample/reagent pick-up/dilution
Transfer module/mechanism
Spectrophotometer module
Control/calibration module
Readout/recorder
Operation/calibration
Maintenance/quality assurance
Troubleshooting
General Clinical Chemistry

Evaluate quality control data Level 3
Select control materials for use
Analyze data for acceptability
If data unacceptable, identify problems or causes
Follow corrective action to resolve problem and document

Verify or establish reference intervals ("Normal ranges") Level 3
List reference intervals for major analytes Level 1
Correlate all patient test data for acceptability Level 2
Review normal physiology and function (liver, cardiac, kidney, etc.)
Interpret patient test results using reference intervals and previous patient data
Recognize pathophysiology of "abnormal" results

Assess pre-analytic and analytic factors that can affect patient results Level 3
Sample integrity, draw time, preservation or storage
Age, gender, ethnicity
Diet, nutritional status, fasting, post prandial
Exercise, position or posture
Sample processing and identification
Method interfering substances/sources of error

Recording of results
Report results according to laboratory protocol Level 2
Routine
STAT
Action limits (critical values)

General Clinical Chemistry:
Carbohydrates

Define the following terms Level 1
Monosaccharide
Disaccharide
Polysaccharide
Glycosidic linkage
Aldose
Ketose
Hexose
Pentose
Isomer

State the components of the disaccharides Level 1
Lactose
Maltose
Sucrose

State the composition and function of each of the following polysaccharides Level 1
Starch
Glycogen

Discuss carbohydrate metabolism Level 1
State the purpose of digestion and absorption of dietary carbohydrates
State how glucose is transported in the blood
State the main physiologic functions of carbohydrates
State the purpose of the following glucose pathways
  - Glycolysis
  - Gluconeogenesis
  - Glycogenesis
  - Glycogenolysis
State whether the following hormones increase or decrease blood glucose levels Level 1
  - Insulin
  - Glucagon
  - Cortisol
  - Adrenocorticotrophic hormone (ACTH )
  - Epinephrine
  - Thyroxine
  - Growth hormone (GH)
  - Human placental lactogen (HPL)
Discuss the maintenance of blood glucose levels in the “fed state” (parenteral) and the “fasting state” Level 1
List disease states and disorders associated with carbohydrate metabolism Level 1
Explain etiology, symptoms, and effects of hyperglycemia Level 1
  - Type 1; Type 2 and gestational diabetes mellitus (GDM)
  - Cushing’s syndrome
  - Hyperthyroidism
  - Hyperpituitarism
  - Other diseases/conditions
Explain the diagnostic criteria for Type 1, 2 (impaired glucose tolerance and provisional diabetes mellitus), and GDM Level 1
Explain etiology, symptoms, and effects of hypoglycemia Level 1
  - Induced
  - Fasting
  - Reactive
State the general cause and resulting disorder(s) for inborn errors of metabolism Level 1
  - Galactosemia
  - Glycogen storage disorders
  - Lactose intolerance
Explain methodologies for carbohydrate determinations Level 1
  - State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness of each Level 1
  - Glucose oxidase
  - Hexokinase
  - Glycated hemoglobin (A1C)
Explain the usefulness of, patient preparation, and the procedure for a glucose tolerance
test; include normal and diagnostic levels Level 1
State the qualitative or quantitative method used for detection Level 1
Other reducing substances
Ketones
Urinary sugars
Cerebrospinal fluid (CSF) glucose
Explain the usefulness of Level 1
Insulin and C-peptide

Perform carbohydrate analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate all patient results and patient outcomes with disease state or disorder Level 2
State the usefulness of bedside or at-home glucose monitoring devices; compare results to non-POC analyzer results Level 1

General Chemistry:
Lipids

Define the lipid associated terminology Level 1
Lipid / Lipase
Simple / Complex lipid
Lipemia
Lecithin
Sphingomyelin
Glycolipid
Lipoprotein
Apolipoprotein
Esterification
Saturated/Unsaturated
State structural characteristics of lipids Level 1
Cholesterol
Fatty Acids
Triglycerides
Phospholipids
Compare the lipoproteins using the difference in lipid and protein composition Level 2
Chylomicron
Very low density lipoproteins (VLDL)
Low density lipoproteins (LDL)
High density lipoproteins (HDL)
Discuss lipid metabolism Level 1
State the main transport route of dietary lipids Level 1
State the main physiologic functions of lipids Level 1
State the origin, main function of each lipoprotein; include apoprotein(s) required for normal function: Level 1
Explain the lipid pathways; include exogenous, endogenous, reverse Level 1
For the following pre-analytical variations, identify, and explain the effects of each on serum
lipid levels Level 1
Intra-individual variation
Variation due to age, gender, and race
Lifestyle/behavior variations
Correlate disease states and disorders associated with hyperlipidemias Level 2
Hyperglycemia/ Hypoglycemia
List the lipid levels associated with hereditary disorders Level 1
abetalipoproteinemia
hypobetalipoproteinemia
Tangier disease
State the disorders/conditions associated with lipid imbalances Level 1
Atherosclerosis
Malabsorption states
Biliary obstruction
Pregnancy
Postmenopause
Ketosis
Fatty liver
Lipid storage diseases
Hyaline membrane disease/Respiratory Distress Syndrome
List methodologies for lipid determinations
State the principle of the chemical reaction, reference interval, most common
interfering substances/sources of error, and the usefulness Level 1
Cholesterol
Triglycerides
LDL
HDL
Explain the calculation for LDL
List the usefulness of apolipoprotein measurements
Explain recommended patient preparation protocol, specimen requirements, and abnormal
serum appearance when collecting or handling specimens for lipid analysis Level 1
Perform lipid analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2

General Chemistry:
Proteins

Define protein-associated terminology Level 1
Isoelectric point
Amino acid
Peptide bond
Complex or conjugated protein
State protein structures and classifications Level 1
Contrast protein structures Level 2
Primary
Secondary
Tertiary
Quaternary

State protein metabolism Level 1
State the main transport route of dietary amino acids Level 1

Discuss synthesis Level 1
- Non-essential amino acids
- Cellular proteins; include DNA and RNA

State the main physiologic functions of plasma proteins Level 1
State the main site of synthesis for plasma proteins Level 1

State the electrophoretic fraction in which each is located, the normal function, and disease states associated with abnormal levels Level 1
- Albumin
- Alpha-1-antitrypsin
- Fetal fibronectin
- Alpha-2-macroglobulin
- Haptoglobin
- Ceruloplasmin
- Transferrin
- Fibrinogen
- C-reactive protein
- Immunoglobulins

List the cause for elevated urine levels Level 1
- Albumin (microalbumin)
- Immunoglobulin
- Immunoglobulin light chains (Bence-Jones protein)
- Beta-2-microglobulin

Explain the role of fetal fibronectin in preterm delivery Level 1

State the reference range for serum total protein and albumin Level 1

Correlate disease states and disorders associated with total protein levels and other test results Level 2
- Dehydration
- Multiple myeloma
- Nephrotic syndrome
- Malabsorption
- Liver disease
- Hemolytic anemia
- Acute phase reaction
- Hypogammaglobulinemia
- Congestive heart failure (beta-natriuretic peptide)

Correlate the serum protein electrophoresis pattern with disorders Level 2
- Nephrotic syndrome
- Monoclonal gammopathy
- Hypogammaglobulinemia
Liver cirrhosis
Acute phase reaction
Polyclonal gammopathy/inflammation
Discuss methodologies for protein determinations Level 1
State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness Level 1
Biuret
Turbidimetry/nephelometry
Dye binding
Protein electrophoresis
State the property of proteins that allows separation or classification Level 1
Electrophoresis
Isoelectric focusing
Ion exchange chromatography
Ultracentrifugation
Immunochemical assay
Perform protein analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3

General Chemistry:
Enzymes
Define enzyme-associated terminology Level 1
Enzyme
Catalyst
Cofactor
Apoenzyme
Coenzyme
Prosthetic Group
Active Site
Substrate
Product
Inhibitor
Kinetic
International Unit
Isoenzyme
Vmax
Km
Activation Energy
Michaelis-Menten Constant
First Order Reaction
Zero Order Reaction
State enzyme classification, nomenclature, and structure Level 1
State the chemical composition of an enzyme Level 1
State the most common physiologic functions of enzymes Level 1
Explain theories of substrate binding by enzymes Level 1
Lock and key
Induced fit

List factors affecting enzyme reaction rates Level 1
- Temperature
- Substrate concentration
- pH
- Enzyme concentration
- Time
- Isoenzymes
- Substrate specificity

List types of activators Level 1
List types of inhibitors (reversible/irreversible) Level 1

List clinically significant enzymes Level 1
- Lactate dehydrogenase (LD)
- Creatine kinase (CK), CK-MB, CK isoforms
- Aspartate amino transferase (AST)
- Alanine amino transferase (ALT)
- Gamma glutamyl transferase (GGT)
- Alkaline phosphatase (ALP)
- Amylase (AMY)
- Lipase (LIP)
- Cholinesterase/pseudocholinesterase

Discuss the usefulness of measuring enzymes Level 1
State the primary tissue source(s) of clinically significant enzymes Level 1
Explain the significance of abnormal serum levels and correlate with specific disease states or disorders Level 2
- Myocardial infarction
- Liver disease
- Muscle disease
- Bone disease
- Malignancy
- Hematological disorders
- Pancreatitis

State the kinetic measurement (first order, zero order) that is preferred for use in an analytical method Level 1
Contrast endpoint and continuous monitoring kinetic methods Level 2
List examples of the use of enzymes as analytical reagents Level 1
State the chemical principle and reaction of the most commonly used methods for determining levels of the clinically significant enzymes Level 1
- Method of quantitation (kinetic, endpoint, immunoassay, etc.)
- Specimen required, special preservation, sample treatment
- Most common interfering substances/sources of error
- Reference interval and units

Perform enzyme analyses according to established laboratory protocol Level 2
- Determine acceptability of results Level 3
- Report results according to laboratory protocol Level 2
- Perform, document, and evaluate quality control Level 3
**Chemistry: Disease Markers**

State the origin and the usefulness in the detection of and risk assessment for an MI

<table>
<thead>
<tr>
<th>Level 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>CK/MB</td>
</tr>
<tr>
<td>Myoglobin</td>
</tr>
<tr>
<td>Troponin</td>
</tr>
<tr>
<td>hs-CRP</td>
</tr>
<tr>
<td>Lp(a)</td>
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<tr>
<td>Homocysteine</td>
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</tbody>
</table>

**Chemistry: Non-protein Nitrogen**

List disease states and disorders associated with urea measurement

<table>
<thead>
<tr>
<th>Level 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-re nal causes</td>
</tr>
<tr>
<td>Renal causes</td>
</tr>
<tr>
<td>Post-re nal causes</td>
</tr>
<tr>
<td>Decreased formation (liver disease)</td>
</tr>
<tr>
<td>Over-hydration; dilution</td>
</tr>
<tr>
<td>End stage renal disease</td>
</tr>
</tbody>
</table>

List methodologies for urea nitrogen

State the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error, and the usefulness

Perform urea nitrogen analyses according to established laboratory protocol

Determine acceptability of results

Report results according to laboratory protocol

Perform, document, and evaluate quality control

Correlate patient results with disease state or disorder

State the usefulness of creatinine measurement

Explain creatinine synthesis and mode of excretion

Discuss disease states and disorders associated with creatinine measurement

<table>
<thead>
<tr>
<th>Level 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal disease</td>
</tr>
<tr>
<td>Muscle wasting disease</td>
</tr>
</tbody>
</table>

List methodologies for creatinine

For the most common methods, state the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error

Perform creatinine analyses according to established laboratory protocol

Determine acceptability of results

Report results according to laboratory protocol

Perform, document, and evaluate quality control

Correlate patient results with disease state or disorder

Calculate creatinine clearance results using body surface area normalization

Differentiate eGFR and GFR

**Commented [MB3]:** Cross reference to Urinalysis
State the reference range and explain the usefulness of the BUN/creatinine ratio Level 1
State the usefulness of uric acid measurement Level 1
Explain uric acid synthesis and mode of excretion Level 1
List disease states and disorders associated with uric acid measurement Level 1
Renal disease
Gout
Increased cell turnover (Leukemia, Chemotherapy)
List methodologies for uric acid Level 1
Perform uric acid analyses according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2
List disease states and disorders associated with uric acid measurement Level 1
Renal disease
Liver disease
Inborn errors of metabolism

State the usefulness of ammonia measurement Level 1
Explain ammonia synthesis and mode of excretion Level 1
List methodologies for ammonia Level 1
For the most common methods, state the principle of the chemical reaction, sample types required, reference interval, most common interfering substances/sources of error Level 1
Perform ammonia analyses (if available) according to established laboratory protocol Level 2
Determine acceptability of results Level 3
Report results according to laboratory protocol Level 2
Perform, document, and evaluate quality control Level 3
Correlate patient results with disease state or disorder Level 2

General Chemistry: Electrolytes and Trace Elements
Define electrolyte-associated terminology Level 1
Electrolyte
Anion
Cation
Intracellular/extracellular
Anion Gap
Trace element
Discuss electrolyte metabolism Level 1
State the physiologic function and distribution of the following electrolytes Level 1
Sodium
Potassium
Chloride
Bicarbonate
Calcium
Magnesium
Phosphate

State the regulation of Sodium Level 1
Dietary intake
Aldosterone
Renin
Kidney function

State the regulation of Potassium Level 1
Dietary intake
Blood pH
Kidney function

State the regulation of Chloride Level 1
Follows sodium
Blood pH

State the regulation of Bicarbonate Level 1
Blood pH

State the regulation of Calcium Level 1
Parathyroid hormone (PTH)
Calcitonin
Protein affects total calcium
Blood pH
Vitamin D

State the regulation of Magnesium Level 1
Aldosterone
PTH

State the regulation of Phosphate Level 1
PTH
Calcitonin
Vitamin D

State the physiologic function and distribution Level 1
Iron
Copper

State the regulation of Iron Level 1
Iron
Intestinal absorption
Transferrin
Serum iron
Ferritin

State the regulation of Copper Level 1
Absorption
Ceruloplasmin

Explain water movement and metabolism Level 1
Intracellular
Extracellular
Osmosis
Maintenance of electrical equilibrium
Effect of macromolecules

Describe water regulation Level 1
- Anti-diuretic hormone (ADH) (vasopressin)
- Renin-angiotensin-aldosterone system
- Thirst center

State the basic concepts in the measurement of osmolality Level 1
- Definition
- Colligative properties of solutions

State the significance of results Level 1
- Reflection of electrolyte-fluid balance
- Assessment of renal concentrating ability

State the difference between a direct and indirect ISE Level 1

State electrolyte specimen requirements and most common sources of error

Perform electrolyte and trace elements analyses according to established laboratory protocol Level 2
- Determine acceptability of results Level 3
- Report results according to laboratory protocol Level 2
- Perform, document, and evaluate quality control Level 3
- Correlate patient results with disease state or disorder Level 2

Discuss disease states and disorders associated with electrolyte metabolism Level 3

State reference intervals and critical values Level 1
- Sodium
- Potassium
- Chloride
- Bicarbonate
- Calcium
- Magnesium
- Phosphate

Define by including the diagnostic level and list causes and symptoms Level 1
- Hyponatremia
- Hypernatremia
- Hypokalemia
- Hyperkalemia
- Hypochloremia
- Hyperchloremia
- Increased levels of bicarbonate
- Decreased levels of bicarbonate
- Hypocalcemia
- Hypercalcemia
- Hypomagnesemia
- Hypermagnesemia
- Hypophosphatemia
- Hyperphosphatemia
Define and explain the usefulness of the Anion Gap  Level 1
Given electrolyte data, calculate the Anion gap  Level 2
Correlate an increased or decreased Anion gap with specific disorders or conditions
Level 2
Utilize the Anion gap as a quality control measure when performing electrolyte
analyses  Level 2

General Chemistry: Acid-Base and Blood Gas Studies
Define blood gas analysis terminology Level 1
   Acid, acidosis, acidemia
Base, alkalosis, alkalemia, base excess
Buffer
pH
Partial pressure
Oxygen saturation, PSO, oxygen capacity
Hypoxia, hypoxemia
Henderson-Hasselbalch equation
Explain the application of the Henderson-Hasselbalch equation  Level 1
List blood buffer systems  Level 1
   Bicarbonate/carbonic acid
   Proteins
State the plasma buffering systems  Level 1
State the RBC/hemoglobin buffering mechanism  Level 1
State regulation of acid-base balance  Level 1
List the mechanisms of bicarbonate reabsorption by the renal tubules Level 1
   Sodium-hydrogen exchange/H+ secretion
   Sodium-potassium exchange/secretion of K+
   Secretion of ammonia
State the mechanisms of carbon dioxide excretion via the lungs  Level 1
   Mechanism for expiration of CO2
   Factors affecting pCO2 or H2CO3
Explain compensatory mechanisms  Level 1
   Pulmonary compensation with primary metabolic change (change in HCO3)
   Hypoventilation if bicarbonate increased (increased pCO2 if increased HCO3)
   Hyperventilation if bicarbonate decreased (decreased pCO2 if decreased HCO3)
   Renal compensation with primary respiratory change (change in CO2)
   Retention of bicarbonate, if CO2 is retained
   Excretion of bicarbonate, if CO2 is blown off
List causes for metabolic acidosis = bicarbonate deficit
List causes for metabolic alkalosis = bicarbonate excess
List causes for respiratory alkalosis = decreased carbonic acid
List causes for respiratory acidosis = increased carbonic acid
Evaluate blood gas results to determine defect  Level 3
Discuss oxygen metabolism Level 1

Define hemoglobin oxygen saturation

List factors that affect oxygen dissociation from hemoglobin 2,3-diphosphoglycerate (DPG) Level 1
- pH
- Temperature
- Carbon monoxide (CO)

State causes for a shift to the left Level 1
State causes for a shift to the right Level 1

Discuss blood gas analysis Level 1

State the components of cooximetry methodology Level 1 (refer to instrumentation)

Explain arterial blood gas specimen collection and handling requirements Level 1
Explain most common sources of error Level 1
If available, perform blood gas analyses according to established laboratory protocol Level 2
- Determine acceptability of results Level 3
- Report results according to laboratory protocol Level 2
- Perform, document, and evaluate quality control Level 3
- Correlate patient results with disease state or disorder Level 2

General Chemistry: Therapeutic Drug Monitoring (TDM) and Toxicology

Define the TDM-associated terminology Level 1
- Therapeutic drug monitoring
- Toxicology
- Steady State
- Half life (t1/2)
- Therapeutic range
- Peak and trough
- Drugs of abuse
- Emergency toxicology
- Chronic poisoning

List factors that influence toxicity Level 1

Explain and demonstrate proper specimen collection Level 2
- Time of blood draw relative to last dose
- Requirements for legal samples
- Requirements for forensic samples

Explain the usefulness of screening methods Level 1

Perform drug analyses (if available) according to established laboratory protocol Level 2
- Determine acceptability of results Level 3
- Report results according to laboratory protocol Level 2
- Perform, document, and evaluate quality control Level 3
**General Chemistry: Vitamins, Provitamins, Derivatives**

Correlate disease states with vitamin deficiencies  Level 2

**General Chemistry:**

**Hemoglobin**

State basic concepts relating to the significance of bilirubin  Level 1
- Heme catabolism
- Bilirubin conjugation

List diseases associated with bilirubin metabolism  Level 1
- Prehepatic jaundice (neonatal/hemolytic anemia)
- Dubin-Johnson syndrome
- Rotor’s
- Crigler-Najjar
- Hepatitis
- Cirrhosis
- Posthepatic jaundice

State methods of analysis for total/direct bilirubin  Level 1
Perform bilirubin analyses according to established laboratory protocol  Level 2
- Determine acceptability of results  Level 3
- Report results according to laboratory protocol  Level 2
- Perform, document, and evaluate quality control  Level 3
- Correlate patient results with disease state or disorder  Level 2

**Chemistry: Endocrinology**

Define endocrinology associated terminology — Level 1
- Hormone
- Endocrine
- Releasing factor/hormone
- Tropic hormone
- Effector hormone
- Glucocorticoid/Mineralcorticoid
- Diurnal variation

State the source and intended effect of protein hormones  Level 1
- Growth hormone
- Adrenocorticotrophic hormone (ACTH)
- Thyroid stimulating hormone (TSH)
- Follicle stimulating hormone (FSH)
- Luteinizing hormone (LH)
- Prolactin (PRL)
- Antidiuretic hormone (ADH)/vasopressin
- Calcitonin
- Parathyroid hormone (PTH)
- Insulin
- Glucagon
Human chorionic gonadotropin (HCG)

State the source and intended effect of steroid hormones Level 1
- Cortisol
- Aldosterone
- Androgens
- Testosterone
- Dehydroepiandrosterone (DHEA)
- Dehydroepiandrosterone-sulfate (DHEA-S)
- Progesterone
- Estrogens/estradiol/estriol

State the source and intended effect of amine hormones Level 1
- Catecholamines
- Thyroxine (T4)
- Triiodothyronine (T3)
- Serotonin/5-hydroxyindolacetic acid (5-HIAA)

List disease states and disorders associated with endocrine metabolism Level 1

State the difference between primary, secondary, and tertiary disorders Level 1

State the cause and symptoms associated with each disorder Level 1

State the most common screening and diagnostic testing for hypothyroid disorders Level 1
- Hashimoto's thyroiditis
- Myxedema
- Congenital

State the most common screening and diagnostic testing for hyperthyroid disorders Level 1
- Grave's disease

List factors that affect hormone levels other than endocrine diseases Level 1
- Emotional stress
- Time of day
- Menstrual cycle
- Menopause
- Food intake/diet
- Hormone therapy
- Drugs

List relevant hormone and/or metabolite determinations in Thyroid Testing Level 1
- TSH
- Free T4
- free T3
- reverse T3
- TBG
- Antithyroid antibodies

List relevant hormone and/or metabolite determinations in Adrenal Testing Level 1
- Cortisol
- Urinary/primary free cortisol
List relevant hormone and/or metabolite determinations in Metastatic carcinoid tumor analysis Level 1

List relevant hormone and/or metabolite determinations in Infertility Testing Level 1

Genetic Disorders

Define genetic disease Level 1
Categorize and list examples of genetic diseases Level 1
Chromosomal aberration
Inborn errors of metabolism
ELC – Chemistry MLT Deleted Items

**Math and Instrumentation:**
- Calculations: Logarithms, Hydrates, Specific gravity
- Non-metric units of measurement
- Instrumentation: Electronics
- Spectrophotometer calibration and maintenance
- AAS basic components
- Blood gas analyzer temperature maintenance and readout systems, electrode balance and slope adjustment with standard gases
- Balance maintenance
- RCF calculations
- Centrifuge maintenance
- Densitometer calibration
- ELP maintenance
- Establishment of lab procedures
- Chromatography calculations and maintenance
- Coulometric Amperometry

**Carbohydrates:**
- Fructosuria
- Hereditary fructose intolerance
- Glucose dehydrogenase
- Glycated serum protein/fructosamine
- Lactic acid methodology
- Insulin antibodies
- Lactose tolerance
- D xylose
- Discuss recent advances
**Lipids:**
- Steroids
- Terpenes
- Prostaglandins
- Carotenoids
- Fat-Soluble Vitamins
- Detailed Lipid Pathway information
- Urine fat methods (included in UA)
- Fecal Fat analysis patient prep and procedure
- Compare lipid results to non POC analyzer results
- Discuss recent advances

**Proteins:**
- Zwirterion
- Protein targeting
- Regulatory hormones
- Transamination, oxidative deamination, ketogenic and glycogenic amino acids
- AFP (in Immunology-tumor markers)
- Cause for elevated urine protein (in UA document)
- Recent advances

**Enzymes:**
- Metabolism
- Enzyme calculations
- Synthesis, catabolism and regulation
- Plasma vs. non-plasma specific enzymes
- Recent advances

**Disease Markers:**
- Methods: CK-MB, Myoglobin, Troponin, hs CRP
- Ischemia modified albumin (IMA)
**NPN:**
Creatinine chemical structure

**Electrolytes and Trace Elements:**
Zinc
Manganese
Chromium
Recent advances

**Acid-Base:**
Imidazole group of histidine
Disease states associated with ABG imbalance

**TDM and Toxicology:**
Pharmacokinetics
Metabolism, biotransformation, elimination
Toxicology terms
Mechanisms of toxicity
Toxicology analytic methods
Recent advances

**Vitamins:**
Deleted all EXCEPT correlation of disease states with vitamin deficiencies

**Hemoglobin:**
Heme synthesis (covered in Hematology)
Porphyrin disease states
Porphyrin analysis

**Body Fluids:**
Amniotic Fluid
Seminal Fluid (EXCEPT post-vasectomy)

**Endocrinology:**
Hormone structure and classification
Hormone synthesis, metabolism and mechanism of action
Non-thyroid illness causes of abnormal thyroid tests
Total T3, Total T4, T3 Uptake and FTE/FTI
Dexamethasone Supression Test
Metyrapone Test
ACTH Stimulation Test

**PENDING:**
SPELP patterns correlated with disease
Basic components of chromatography
IEM etiology and lab testing

**ELC – Chemistry MLT Added Items**

**Instrumentation:**
Turbidimetry and Nephelometry – basic concepts
AAS-basic concepts
Luminometer-basic concepts
Mass Spec-basic concepts

**Carbohydrates:**
Disaccharide components
Composition and function of starch and glycogen
Diagnostic criteria for Type 1, 2 (impaired glucose tolerance and provisional diabetes mellitus), and GDM

**Lipids:**
Lipemia
Saturated /Unsaturated fats
Atherosclerosis

**Proteins:**
Fetal fibronectin
Congestive heart failure (BNP)

**Disease Markers:**
Hs-CRP
Lp(a)
Homocysteine

**TDM & Toxicology:**
Drugs of abuse
Emergency toxicology
Chronic poisoning
Factors that influence toxicity

**Hemoglobin:**
Dubin-Johnson syndrome
Rotor’s
Crigler-Najjar
Education
MLT Entry Level Curriculum

Compare and contrast competency and proficiency Level 2

Describe the characteristics and qualities of an effective instructor Level 1

Define basic educational terms Level 1

Competence or competency

Objectives

Curriculum (as it applies to laboratory science programs)

Articulation (as it applies to laboratory science programs)

Continuing education unit (CEU)

Accreditation

Certification

Licensure

Evaluation

Reciprocity

Explain the purpose and use of the three domains of learning Level 1

Cognitive

Psychomotor

Affective

Explain the purpose and use of the three modified taxonomy levels for the cognitive domain Level 1

Level 1: Recall of information (knowledge)

Level 2: Understand information and applying it to other material or new situations (comprehension/application)

Level 3: Problem solving (analysis/synthesis/evaluation)

Explain the purposes and uses of objectives Level 1

1
DOCUMENT CHANGES
Registration removed as term to define and reciprocity was inserted

Addition:

Compare and contrast competency and proficiency

Given an example of an objective, identify the domain, and if in the cognitive domain, identify the correct taxonomic level

Given an example of an objective, identify the domain

Given an example of an objective, identify the domain, and if in the cognitive domain, identify the correct taxonomic level

Given an example of a learning activity, identify the domain

Editorial Comment:

Distance-based methods was replaced by a more granular level of differentiation (hybrid, online, simulation, etc).

Establish staff development programs, continuing education (formal and informal)

Discuss the importance of staff development programs and continuing education

Deletion with no replacement:

Establish in-service education programs.
General

MLT Entry Level Curriculum

Laboratory Safety

Identify the following safety equipment and explain their use Level 1

Fire extinguishers, blankets
Fume hood
Eye wash
Safety shower
Personal Protective Equipment
Splash guards
Vented storage cabinets
Acid storage cabinets
Flammable storage cabinets
Broken glass/sharps containers
Spill kits
Biological safety cabinet
Engineering controls

Inspect and maintain safety equipment Level 2

Follow procedures and techniques for maintenance, inspection and use of safety equipment
Determine location of safety of safety equipment
Monitor inspection, maintenance and documentation of safety equipment
Maintain safety data sheets (SDS)

Recognize and report hazardous situations Level 1

Identify potential sources of lab hazards

Fire
Electrical

Chemical

Biological/bioterrorism

Document laboratory accidents and unsafe procedures  Level 1

Utilize appropriate safety equipment and procedures according to established laboratory protocol  Level 1

Stock and maintain emergency medical supplies  Level 1

Follow laboratory protocol for disposal of contaminated materials  Level 2

Properly decontaminate work surfaces  Level 2

**General Laboratory Supplies and Equipment**

Identify attributes, advantages, advantages and disadvantages of specific type of glassware  Level 1

Select appropriate labware for specific procedures  Level 2

Nonvolumetric

- Beakers
- Flasks
- Cuvettes
- Pipettes

Volumetric

- Flasks
- Pipettes

Automated Pipets

Correctly use labware  Level 2

Correctly dispose of used labware  Level 2

Correctly clean Nondisposable labware  Level 2

Perform calibration of automatic pipets  Level 1
Select appropriate method of water purification Level 2
  Distilled
  Deionized
  Reverse Osmosis

Explain types of (CLSI) reagent grade water Level 1

**Chemicals**
Identify grades of purity Level 1
  Commercial or technical
  Commercially pure
  Reagent grade
  United States Pharmacopeia certified (USP)

Perform solution preparation Level 2
  Select correct chemical
  Perform necessary calculations
  Weigh/measure concentrates
  Label and store
  Observe safety requirements

**Standards/Controls**
Identify types of standards Level 1
  Primary
  Secondary

Identify types, uses and limitations of controls Level 1
  Assayed
  Unassayed

**Microscopes**
Prepare microscope for optimized viewing Level 2
Clean microscope components using appropriate care Level 2

Adjust light source for proper illumination level Level 3

Place filters (e.g., neutral density) in light path appropriately Level 2

Protect microscope from dust when not in use, i.e., dust cover Level 2

Select type of microscopy and adjust appropriately for optimum viewing (brightfield, phase contrast, polarizing, interference contrast, red compensating filters) Level 3

Optimize condenser position Level 3

- Height
- Centration

Adjust diaphragms appropriately for optimum viewing Level 3

- Field iris
- Condenser aperture

Check and perform phase ring alignment for phase microscopy Level 2

Place polarizing filters in light path correctly for polarizing microscopy Level 2

Operate microscope, i.e., place, focus, and scan mounted specimen Level 3

Secure microscope slide on mechanical stage Level 2

Check and perform interpupillary and diopter adjustments Level 3

Select and interchange objectives Level 3

Use coarse and fine adjustments Level 2

Use mechanical stage adjustment knobs to scan mounted specimen Level 2

**Information Technology**

Perform basic operation of computer systems Level 2

- Enter data
- Transmit
- Retrieve data
- Present data/information
Quality Assurance/quality control

Define quality control statistics Level 1

Mean
Mode
Median
Standard deviation
Coefficient of variation
Reference intervals
Variance
Linear regression
Correlation coefficient
Gaussian distribution
Scales, graphs, charts
Levey-Jennings charts
Westgard Multirule system

Define type of laboratory errors and biases Level 1

Preanalytical
Analytical
Random
Systematic
Postanalytical

Locate sources of lab error Level 1

Monitor and prevent laboratory errors Level 1

Perform maintenance, calibration and storage of laboratory supplies and equipment Level 1

Document quality assurance schedules Level 1

Maintain and troubleshoot quality control logs Level 2
Identify quality control programs       Level 1

Internal

External

Interpret statistical data       Level 2

Identify patterns       Level 2

Shifts

Trends

Perform all quality control procedures according to established protocol       Level 2

Collect data and perform statistical analyses

Monitor and interpret quality control data       Level 2

Recognize shifts, trends and other deviations

Identify sources of error

Verify laboratory proficiency

Implement corrective action

Point of Care Testing

Explain the value of point of care testing to patient care       Level 1

Discuss the advantages and disadvantages of point of care testing       Level 1

Identify healthcare professionals who may be responsible for point of care testing       Level 1

Use good educational principles to train non-laboratory healthcare professionals on appropriate use of point of care testing devices       Level 1
**DOCUMENT CHANGES**

Microcomputers section changed to Information Technology

Deleted section regarding basic elements of a computer

Deleted:

Identify types and uses of plasticware in the lab

Correctly dispose of used plasticware

Microscope section added
Normal Hematopoietic System
Define hematopoiesis Level 1
Theory of pluripotent stem cell development
Stem cell kinetics: Generative cell cycle
Regulatory growth factors and inhibitors

Identify phases and site of origin for cellular development of active hematopoietic tissue in
Embryo and fetus Level 1
Mesoblastic phase
Hepatic phase (extramedullary)
Medullary/myeloid phase

Identify phases and site of origin for cellular development of active hematopoietic tissue in
Infant and young child Level 1
All red marrow spaces (all cell lines)
Thymus fully developed (T lymphs)
Secondary lymphoid tissue (T and B lymphs)

Identify phases and site of origin for cellular development of active hematopoietic tissue in
Adults Level 1
Red marrow (axial skeleton and proximal ends of long bones)
Primary and secondary lymphoid tissue (T and B lymphs)

Explain the role of other organ systems in hematopoiesis Level 1
Mononuclear phagocyte system
Spleen (structure, blood flow, function)
Liver (structure, blood flow, function)
Lymph nodes (structure, blood flow, function)
Thymus (structure, blood flow, function)

State the physical findings commonly present in hematologic disease Level 1
Splenomegaly
Hypersplenism
Hepatosplenomegaly
Lymphadenopathy

Bone marrow tissue
Describe bone marrow collection techniques Level 1
Aspiration
Core biopsy

Describe the preparation of bone marrow smears and stains used Level 1
Romanowsky polychrome stain
Prussian Blue (iron) Stain

Describe key terms used to assess bone marrow structure and function Level 1
Myeloid to erythroid ratio (M:E)/erythroid to granulocyte ratio (E:G)
Erythropoiesis
Granulopoiesis
Megakaryopoiesis
Non-hematopoietic cells
Cellularity: fat (yellow marrow) to cell (red marrow) ratio
Aplastic marrow
Hypo/Hyperplastic marrow
Peripheral Blood Examination

Perform differential cell count on normal specimens  Level 2
Distinguish between normal and abnormal hematopoietic elements found within the peripheral blood  Level 2
Correlate complete blood count findings with peripheral blood smear evaluation  Level 2
Prepare peripheral blood for routine hematologic procedure and smear analysis
  Determine specimen acceptability  Level 2
  List appropriate anticoagulants  Level 1
  Identify acceptable ratio of anticoagulant to blood for specimens obtained from venipuncture and skin puncture  Level 1
  List reasons for rejecting specimens  Level 1
Stain smears using Romanowsky dyes and techniques according to established procedures  Level 2
  Manual
  Automated
List and define components of commonly used stains  Level 1
Judge the acceptability of blood smears through microscopic evaluation and established criteria  Level 3
  Random distribution of cells
  Acceptable stain quality
  Absence of artifact
Troubleshoot staining problems  Level 3

Erythropoiesis

Describe the distinctive features used to characterize developing cells  Level 1
  Overall cell size
  Cell Nucleus
  Shape
  Relative size
  Staining reaction
  Chromatin pattern
  Presence or absence of nucleoli
  Staining reaction and size of cytoplasm
List the maturation sequence of developing erythrocytes  Level 1
Distinguish nucleated erythrocyte precursors from other hematopoietic elements  Level 2
Categorize red cells
  Shape
  Color
  Inclusions
  Distribution patterns
List nutritional and regulatory factors with associated with erythropoiesis  Level 2
  Erythropoietin (EPO)
  Iron
  Vitamins (B12/ folate)
  Intrinsic factor
Discuss components of the mature red cell that are essential for survival and function

- Membrane composition and function
- Lipids/Proteins
- Maintain RBC shape, deformability, and permeability
- Support system for surface antigens
- Transport and exchange of gases and ions (cationic pumps)

Describe the purpose of the metabolic pathways used by erythrocytes

- Embden-Meyerhof
- Hexose monophosphate shunt
- Methemoglobin reductase
- Luebering-Rapoport

**Erythrocytic Hemoglobin**

Summarize the mechanisms by which normal hemoglobin is structured and synthesized in the developing red cell

- Iron transport, uptake, and supply
- Protoporphyrin IX (heme) formation
- Globin synthesis and genetic control
- Chromosome 11 and 16
- Embryonic hemoglobins (Gower 1, 11, Portland)
- Adult hemoglobins (Hb A, Hb A2, Hb F)

Describe normal hemoglobin-oxygen function using the oxygen dissociation curve (ODC)

Identify the effect various conditions can have on an oxygen disassociation curve

- pH (Bohr effect)
- Temperature
- CO2
- 2,3-DPG
- Hb F and other variants

Interpret the effect of various factors on the concentration of hemoglobin

- Age and gender
- Altitude
- Smoking
- Associated disease
- Altered hemoglobin derivatives (carboxyhemoglobin /sulfhemoglobin/ methemoglobin)

**Erythrocytic Catabolism**

Explain the mechanism by which red cells are catabolized

Identify phased (extra/intravascular)

Trace the basic steps associated with each phase

Define terms associated with red cell destruction

- Biliverdin
- Bilirubin (conjugated/ unconjugated)
- Urobinogen
- Urobilin
- Hemoglobin dimers
- Haptoglobin
Hemopexin
Hemoglobinemia
Hemoglobinuria
Hemosiderinuria
Methemalbumin

**Erythrocyte Evaluation**

Describe procedures to evaluate erythrocytes using patient blood and quality control samples  
Level 1

Perform procedures to evaluate erythrocytes using patient blood and quality control samples  
Level 2

State the clinical utility of histogram review in erythrocyte evaluation  
Level 1
Determine if results are in accordance with prescribed criteria for accuracy and precision  
Level 2

Discuss the automated hemogram parameters used for erythrocyte evaluation  
Level 1
- Hemoglobin
- Hematocrit
- Mean cell volume (MCV)
- Mean cell hemoglobin (MCH)
- Mean cell hemoglobin concentration (MCHC)
- Red cell distribution width (RDW)

Calculate red blood cell indices when provided appropriate data  
Level 2

Perform erythrocyte sedimentation rates  
Level 2
- Wintrobe
- Westergren and its modifications
- Automated

Perform standard reticulocyte assays  
Level 2
- Supravital smear method with Miller disc
- Supravital smear method without Miller disc
- Automated flow cytometry methods

Perform calculations associated with reticulocyte assays  
Level 1
- Corrected
- Absolute
- Production index (RPI)

Determine the appropriate area of a peripheral blood smear to evaluate red blood cell morphology  
Level 2

Distinguish between normal and abnormal red blood cell morphology  
Level 1

List red blood cell count and indices reference values that account for variations in gender and age  
Level 1

Correlate automated hemogram parameters with each other and with peripheral smear exam results  
Level 3

Calibrate and perform preventive maintenance on instruments used to evaluate erythrocytes and their physical properties  
Level 1
Take corrective action to resolve unexpected results and/or events on instruments used to evaluate erythrocytes Level 1

**Leukopoiesis**
State reference values that reflect variations in gender and age for the leukocyte counts in peripheral blood Level 1
- Total leukocyte count
- Absolute lymphocyte count
- Absolute neutrophil count

List common factors that alter leukocyte values Level 1
- Physiologic variation
- Cellular abnormalities

Enumerate and/or calculate absolute and relative leukocyte counts Level 2
- Relative values
- Absolute values

List morphologic features used to differentiate developing leukocytes Level 1
- Overall cell size
- Nucleus
- Shape
- Nuclear to cytoplasmic ratio (N:C)
- Staining reaction
- Chromatin pattern
- Presence or absence of nucleoli
- Relative amount of cytoplasm
- Cytoplasmic staining reaction
- Presence or absence of granules and staining reaction in cytoplasm

**Leukopoiesis: Granulocytes**
List the maturation sequence of neutrophils, eosinophils, and basophils Level 1
Differentiate band neutrophils, segmented neutrophils, eosinophils, and basophils Level 2
Determine if a granulocyte is mature or immature Level 1
Explain mechanisms that regulate and modulate granulopoiesis Level 1
- Regulatory growth factors and inhibitors
- Kinetics
- Life span
- Circulation
- Granule content and surface membrane receptors

Explain the functions associated with granulocytes Level 1
- Phagocytosis and killing
- Allergic response (eosinophils and basophils)
- Host defense against parasites (eosinophils)
- Hypersensitivity mediator (basophils and mast cells)

Discuss the clinical utility of the absolute neutrophil count Level 1

**Leukopoiesis: Lymphocytes and Monocytes**
Summarize structural and functional features that characterize monocytes and macrophages Level 2
Summarize structural and functional features that characterize lymphocytes  
List the maturation sequence of monocytes and macrophages  
List the maturation sequence of lymphocytic cells  
Describe the use of monoclonal antibodies to differentiate lymphocytes by CD antigens  
B lymphs and subsets  
T lymphs and subsets  
Plasma cell (immunoglobulin antibody production)  
List the sites of formation and production of lymphocytes  
Bone marrow  
Thymus  
Lymph nodes and secondary lymphoid tissue  
Kinetics: Life span/ Migration  
Describe monocyte and macrophage function  
Describe lymphocyte function  
Humoral immunity (B lymphs and subsets)  
Cell mediated immunity (T lymphs and subsets)  
Natural killing and antibody dependent cellular cytoxicity

**Leukocyte Evaluation**

Perform routine methods to assess leukocytes (e.g. manual and automated white blood cell counts and differentials)  
State the principles and clinical utility of histogram/scatterplot review  
Determine absolute and relative white cell counts on patient and control specimens using manual or automated methods in accord with prescribed criteria for accuracy and precision  
Calibrate and perform preventive maintenance on instruments used to evaluate white cells  
Examine white cell histograms and scatterplots for diagnostic and quality control purposes  
Identify and classify normal white blood cells on a properly stained Romanowsky blood smear  
Verify automated cell counts and differentials using established criteria  
Estimate the total white blood count from a smear  
Correct leukocyte counts for the presence of nucleated red cells

**Nonmalignant Leukocyte Disorders**

Explain the classification of nonmalignant leukocytic disorders  
Quantitative changes  
Qualitative changes  
Compare and contrast the utility of absolute values with relative values  
State common causes of alterations in absolute and relative cell counts for the mature myeloid cells  
Neutrophilia
Neutropenia
Eosinophilia
Eosinopenia
Basophilia

Associate quantitative and qualitative leukocyte disorders with expected results Level 1
Bone marrow production and release
Rate of entry into peripheral circulating pools
Shifts between circulating and marginating pools
Rate of exit into tissues

Identify morphologic changes in neutrophils that may accompany nonmalignant neutrophilic disorders Level 1
Shift to the left
Toxic granulation
Dohle bodies
Vacuolization
Hypossegmentation
Hypersegmentation

State characteristic abnormalities and clinical features for the qualitative/functional disorders of neutrophils Level 1
Pelger-Huet anomaly
Alder-Reilly anomaly
Chediak-Higashi anomaly
May-Hegglin anomaly
Chronic granulomatous disease (CGD)
Myeloperoxidase deficiency

Describe qualitative and quantitative alterations of monocytes Level 1
Define monocytosis Level 1
State absolute monocyte reference values and relative reference values Level 1
State causes of monocytosis Level 1
Identify abnormal lipid accumulations within monocytes and macrophages Level 1
List causes of non-neoplastic disorders of lymphocytes and plasma cells Level 1
Define lymphopenia/lymphocytosis Level 1
State lymphocyte absolute reference values with relative reference values Level 2
Compare and contrast morphologic features of reactive lymphocytes and normal lymphocytes Level 2
Size
Nucleus
Cytoplasm
Heterogeneity

Differentiate between reactive and resting lymphocytes on Romanowsky stained smears Level 2
List the causes of reactive lymphocytosis Level 1

Red Blood Cell Disorders: Anemia
Define anemia Level 1
State the clinical signs and symptoms of anemia Level 1
Hemoglobin
Hematocrit
RBC indices
Peripheral smear
Reticulocyte count
Bone marrow evaluation
Red blood cell distribution Width

List the categories used in a morphological classification of the anemias

Describe the expected laboratory results seen in the various pathophysiologic classifications of anemia

Decreased red cell production
Increased red cell destruction: Ineffective erythropoiesis/ Hemolytic processes
Loss of red cells

Explain sources of error of the red blood cell indices

Discuss the clinical utility of the RBC indices

Use the RBC indices as a quality control mechanism for assessing the validity of the erythrocyte count, hemoglobin, and hematocrit values

Define common words used to describe red cell morphology

Anisocytosis
Poikilocytosis
Polychromatic
Rouleaux
Agglutination
Acanthocyte/Spur Cell
Codocyte/Target Cell/Leptocyte
Dacryocyte/Tear Drop Cell
Drepanocyte/Sickle Cell
Echinocye/Burr Cell
Elliptocyte
Keratocyte
Schistocyte
Spherocyte
Stomatocyte
Basophilic stippling
Cabot rings
Heinz bodies
Howell-Jolly bodies
Malarial parasites
Pappenheimer bodies/siderotic granules
Hemoglobin crystals
Hemoglobin H

Differentiate between normal and abnormal RBC morphology

Associate a given red blood cell morphology with routinely encountered conditions

Iron deficiency/alterations in iron metabolism
Vitamin B12/Folate deficiency
Thalassemia
Sickle Cell Disease/Trait/otherhemoglobinopathies
Malaria
Hereditary membrane abnormalities (spherocytosis, elliptocytosis, ovalocytosis, etc)
RBC Enzyme abnormalities (G6PD and PK deficiencies)
Extracorpuscular (immune and non-immune) mediated RBC defects
Describe methods used to identify and/or confirm the composition of various red blood cell inclusions Level 1

**Red Cell Disorders: Erythrocytosis (Polycythemia)**
Define polycythemia Level 1
Differentiate between absolute polycythemia and relative polycythemia Level 2
Compare and contrast polycythemia rubra vera, secondary polycythemia, and relative erythrocytosis Level 2
- Etiology
- Clinical features
- Laboratory findings
Describe changes in the bone marrow and peripheral blood with polycythemia Level 2

**Red Cell Disorders: Hypochromic anemias**
Define hypochromic anemia Level 1
List the causes of hypochromic anemias Level 1
Compare and contrast laboratory findings in hypochromic anemias Level 2
- Serum ferritin
- Serum iron
- Transferrin/ Total Iron Binding Capacity (TIBC)
- Percent transferrin saturation

**Red Cell Disorders: Megaloblastic anemias**
Discuss the absorption and metabolism of vitamin B12 and folate Level 1
Describe clinical features of megaloblastic anemia Level 1
State the hematologic abnormalities present in megaloblastic anemia Level 1
- Peripheral blood changes
- Bone marrow morphology
Compare and contrast causes and laboratory features of the megaloblastic anemias Level 2
Discuss tests methods commonly used to assess megaloblastic anemia Level 1
- Mean cell volume (MCV)
- Blood and bone marrow smear evaluation
- Serum B12
- Serum folate
- Red cell folate
- Anti-intrinsic factor antibodies
- Anti-parietal cell antibodies
Differentiate nonmegaloblastic macrocytosis from megaloblastic anemia Level 2
- Peripheral blood and bone marrow characteristics
- Serum vitamin B12 level
- Serum folate level
- Red cell folate level
Red Cell Disorders: Hypoproliferative anemias: Congenital and Acquired

Define aplastic anemia
Describe the clinical features of hypoproliferative anemias
Describe the laboratory findings of hypoproliferative anemias
  Peripheral blood changes
  Bone Marrow Changes
Define pure red cell aplasia
  Describe the clinical features
  Describe the laboratory findings

Red Cell Disorders: Hemolytic anemias
Describe the clinical features and laboratory findings of red cell membrane defects
  Hereditary spherocytosis
  Hereditary elliptocytosis
  Paroxysmal nocturnal hemoglobinuria (PNH)
  Hereditary pyropoikilocytosis
Discuss the principle of the Osmotic fragility test
  Perform /observe the procedure
  Apply appropriate quality control procedures
  Correlate results
Describe the utility of flow cytometry in assessing red cell membrane defects
Describe the laboratory features of red cell enzyme abnormalities
  Glucose-6-phosphate dehydrogenase (G6PD) deficiency
  Pyruvate kinase (PK) deficiency
Discuss the principles of G6PD assay, pyruvate kinase assay and staining for Heinz Bodies
  Perform /observe the procedure
  Apply appropriate quality control procedures
  Correlate results
Describe the hematologic findings associated with nonimmune hemolytic anemias
  Malaria
  Babesiosis
  Thermal injury
  Disseminated intravascular coagulation
Identify mechanisms of immune-mediated hemolytic anemias
Describe the clinical features and laboratory findings of Alloimmune hemolytic anemias
  Acute hemolytic transfusion reaction
  Delayed hemolytic transfusion reaction
  Hemolytic disease of the newborn (HDN)
Describe the clinical features and laboratory findings of autoimmune hemolytic anemias
  Warm autoimmune hemolytic anemia (WAIHA)
  Cold autoimmune hemolytic anemia idiopathic/secondary
  Paroxysmal cold hemoglobinuria
Discuss mechanisms of drug-induced immune hemolytic anemia
Hemoglobinopathies
  Define hemoglobinopathy Level 1
  Distinguish between qualitative and quantitative hemoglobin defects Level 2
  Describe the clinical and laboratory findings of hemoglobinopathies Level 1
    Hb SS
    Hb AS
    Hb CC
    Hb SC
  State the amino acid substitutions associated with sickle cell anemia and hemoglobin C disease Level 1
  Describe the hemoglobin defect in thalassemia Level 1
  List the characteristic clinical and laboratory findings associated with thalassemia Level 1
  Describe the peripheral blood morphology associated with hetero and homozygous beta thalassemia Level 1
  Describe the terminology associated with thalassemias Level 1
    Hb H
    Bart’s hemoglobin
    Hereditary persistence of fetal hemoglobin
  Discuss the principle of the solubility test for sickling hemoglobin Level 1
    Perform /observe the procedure Level 1
    Apply appropriate quality control procedures Level 1
    Correlate results Level 2
  Discuss the principles of hemoglobin electrophoresis (cellulose acetate, alkaline pH vs. citrate agar, acid pH) Level 1
    Perform /observe the procedure Level 1
    Apply appropriate quality control procedures Level 1
    Correlate results Level 2
  Discuss the principles of hemoglobin quantification (HbA, HbA2, HbF) Level 1
    Perform /observe the procedure Level 1
    Apply appropriate quality control procedures Level 1
    Correlate results Level 2
  Identify the electrophoretic patterns when provide appropriate data Level 2
    Hb F
    Hb A
    Hb S
    Hb C
    Hb A2

Acute Blood Loss
  Describe the etiology of anemia of acute blood loss Level 1
  List the clinical symptoms of acute blood loss Level 1
  List the laboratory findings of acute blood loss Level 1

Anemias associated with systemic disorders
  Describe the laboratory findings associated with nonhematologic disorders Level 1
    Chronic disorders and inflammation
    Malignant diseases
    Renal disease
Liver disease
Alcoholism

**Neoplastic Disorders**

Define and list categories associated with Neoplastic Disorders of Leukocytes Level 1
Leukemias
Myelodysplastic syndromes
Myeloproliferative disorders
Lymphoproliferative disorders

List major systems used to classify neoplastic disorders of leukocytes Level 1
French, American-British (FAB) Cooperative Group
World Health Organization (WHO)

Observe and/or perform procedures, apply appropriate quality control procedures, and interpret laboratory findings for laboratory procedures used in the identification, classification and differentiation of neoplastic disorders Level 1
Complete blood count
Hemograms
Scatterplots and histograms

Compare and contrast the principles of various cytochemical stains and the cell lineages they react with Level 2
Myeloperoxidase
Tartrate resistant acid phosphatase (TRAP)
Iron staining

Describe the use of various diagnostic techniques used to assess neoplastic disorders of blood and bone marrow cells Level 1
Cytochemical Stains
Immunophenotyping
Cytogenetics
Molecular genetics

**Acute Leukemias**

Describe general criteria to classify leukemias Level 1
Cell maturity (Acute/Chronic)
Cell lineage (Myeloid /nonlymphoid)
Lymphoid

List the clinical findings and laboratory results for acute leukemia Level 1
Contrast the FAB with the WHO acute myeloid leukemia subgroups Level 2
FAB classification
M0--acute myeloid leukemia with minimal differentiation
M1--acute myeloid leukemia without maturation
M2--acute myeloid leukemia with maturation
M3--acute promyelocytic leukemia
M4--acute myelomonocytic leukemia
M5--acute monoblastic leukemia
M6--acute erythroleukemia
M7--acute megakaryoblastic leukemia

WHO classification
AML with recurrent genetic abnormalities
AML with myelodysplasia-related changes
Therapy-related myeloid neoplasms
AML, not otherwise specified

Correlate diagnostic blood and bone marrow findings to various sub-types of acute myeloid leukemia

List the WHO acute lymphocytic leukemia subgroups

WHO classification:
  B lymphoblastic leukemia/lymphoma, not otherwise specified
  T lymphoblastic leukemia/lymphoma

**Myelodysplastic Syndromes (MDS)**

Define and describe cellular features that characterize the MDS
- Dyserythropoiesis
- Dysgranulopoiesis
- Dysmegakaryocytopenia

List subgroups recognized by the World Health Organization (WHO) Cooperative Groups for the MDS classification

**Chronic Myeloproliferative Neoplasms**

List the Chronic Myeloproliferative Neoplasms by cell type
- Granulocytes--Chronic myelogenous/granulocytic leukemia (CML/CGL)
- Erythrocytes--polycythemia vera (PV)
- Megakaryocytes--essential thrombocytopenia (ET)

Discuss and compare features commonly shared by Chronic Myeloproliferative Neoplasms
- Clinical manifestations
- Pathophysiologic mechanisms
- Blood and bone marrow findings
- Transitional forms between stages
- Disease evolution with potential for blastic transformation

List the clinical and laboratory findings commonly found in MPD

CML/CGL
- Leukocytosis with absolute neutrophilia and left shift maturation
- Absolute basophilia and eosinophilia
- Thrombocytosis
- Bone marrow hypercellularity with granulocytic proliferation
- Leukocyte alkaline phosphatase (LAP) activity
- Philadelphia chromosome
- Cytogenetic (karyotype)
- Molecular (DNA) techniques
- PV
- Increased red blood cell (RBC) mass
- Leukocytosis with mild left shift maturation and basophilia
- Thrombocytosis
- Bone marrow hypercellularity with all cell lines increased
- LAP activity
- Red cell morphology (initial phase/ “spent” phase)
- ET
Marked thrombocytosis with platelet aggregates and abnormal forms
Megakaryocytic hyperplasia of bone marrow
LAP activity
AMM
Leukoerythroblastosis with teardrop-shaped red cells
Leukocytosis with left shift maturation to occasional immature myeloid cell
Bone marrow fibrosis and relationship to megakaryocytic hyperplasia
LAP activity

**Chronic Lymphoproliferative Disorders**

Classify the chronic lymphoid leukemias by T and B cell lineage

- Chronic lymphocytic leukemia (CLL)
- Prolymphocytic leukemia (PLL)
- Hairy cell leukemia (HCL)

List diagnostic features CLL

- Median age of onset
- Symptoms and clinical findings
- Blood and bone marrow findings of CLL
- Peripheral blood absolute lymphocytosis
- Leukemic cell line of mature, small lymphocytes with monotonous Morphology and smudge/basket cells
- Bone marrow lymphocytosis

List diagnostic features of PLL

- Median age of onset and gender
- Clinical finding of severe splenomegaly
- Blood and bone marrow findings of PLL
- markedly elevated white count with absolute lymphocytosis
- white cell differential predominantly of prolymphocytes
- immunophenotypic profile
- Survival rates

List diagnostic features of HCL

- Median age of onset and gender
- Clinical finding of severe splenomegaly
- Review blood and bone marrow findings of HCL
- Pancytopenia
- Leukemic cell line of “hairy” cells
- Tartrate resistant acid phosphatase (TRAP) stain reaction
- “Dry”tap; marrow fibrosis and infiltrates

List diagnostic features of Adult T-cell leukemia

- Human T-cell lymphotropic virus-1 (HTLV-1)
- Endemic areas
- blood and bone marrow findings of Adult T-cell leukemia
- Lymphoid cell line of small to large cells with cloverleaf/knotty nucleus

**Lymphoma**

Define lymphoma and generally classify using key terminology

- Hodgkin
- Reed-Sternberg cells
Outline the laboratory tests used to diagnose and stage Hodgkin’s lymphoma
- Complete blood count (CBC)
- Liver function tests
- Renal function tests

Review blood and bone marrow findings of Hodgkin’s lymphoma
- Radiologic studies
- Physical examination
- Lymph node biopsy

Recognize lymphoma cells

Plasma Cell Disorders
Name disorders based on proliferation of plasma cells and abnormal production of immunoglobulins

Discuss classification based on proliferation of plasma cells and abnormal production of immunoglobulins
- Multiple myeloma
- Waldenstrom’s macroglobulinemia
- Plasma cell leukemia (PCL)
- Heavy-chain disease
- Monoclonal gammopathy of undetermined significance (MGUS)

Compare the clinical findings and laboratory features of various plasma cell disorders
Identify key morphologic features for plasma cell

Thrombopoiesis/megakaryopoiesis
List the maturation sequence of platelets
State reference values for absolute platelet counts in the peripheral blood
Associate quantitative variations with clinical manifestations
- Thrombocytopenia
- Thrombocytosis

Associate functional or qualitative variations with clinical manifestations
Perform absolute platelet counts on patient and control specimens using manual and automated methods in accord with prescribed criteria for accuracy and precision
State the principles of method analysis and histogram review
Compare absolute count with those estimated from smear exam
Identify and recognize factors that may alter platelet values
- Platelet satellitism
- Platelet aggregates
- Giant platelets
- Cell fragments
- Extreme microcytosis

Hemostasis/Coagulation
Define hemostasis
Explain the general interaction of systems involved in maintaining hemostasis
Describe how changes in one homeostatic system affect the other systems
- Vasculature
Platelets
Plasma coagulation factors
Fibrinolysis
Differentiate between primary and secondary hemostasis Level 1

Vascular
Explain the functions of the vascular system in maintaining hemostasis Level 1
Describe metabolic functions of the endothelium and substances contributing to the thromboresistance properties of endothelium Level 1
Heparan sulfate
Thrombomodulin
Tissue plasminogen activator
Prostacyclin (PGI2)
Tissue factor pathway inhibitor

Platelets
Discuss the production of platelets Level 1
State the average time in circulation, normal peripheral count, and total body distribution of platelets Level 1
Describe the ultrastructural components of a platelet Level 1
Alpha granules
Dense bodies
Lysomes
Microtubules
Open canalicular system
Platelet membrane
Glycocalyx
Discuss the physiological role of platelets in hemostasis Level 1
Platelet plug formation
Maintaining normal vascular integrity
Describe the series of morphologic changes that occur in platelets following physiologic stimulation Level 1
Adhesion
Aggregation
Activation
Discuss the effect of aspirin on platelet function Level 1
Biochemical mechanism
Duration of the effect
Compare and contrast test methodologies for the bleeding time test Level 1
Describe the principle of the platelet function assay Level 1
Review results of a bleeding time and/or platelet function assay test Level 2
Significance in terms of platelet function
Associated abnormal conditions
Sources of error
Discuss the principle and clinical significance of platelet aggregation Level 1
Perform the procedure Level 1
Describe the procedure Level 1
Describe appropriate quality control procedures and sources of error Level 1
Interpret results

**Plasma coagulation factors**

Define the coagulation factors
- Roman numerals
- Common names
- Synonyms

Discuss the physiological role of the coagulation phase within the hemostatic process

Discuss characteristics of the coagulation factors
- Contact group
- Prothrombin group
- Fibrinogen group

List the vitamin K-dependent factors

Diagram the pathways of coagulation
- Intrinsic
- Extrinsic
- Common

Identify substances that are contact activators

Explain the interaction of the coagulation system with the vascular and platelet systems to form a hemostatic plug

Describe the physiologic controls of hemostasis
- Blood flow
- Feedback inhibition
- Liver clearance

Identify the inhibitors of hemostasis
- Antithrombin
- Tissue factor pathway inhibitor (TFPI)
- Protein C
- Protein S

Discuss the special precautions that must be taken in the collection and subsequent handling of specimens for coagulation testing
- Anticoagulant
- Ratio of blood to anticoagulant
- Patient hematocrit values
- Centrifugation
- Storage

Identify and describe tests that are used to monitor the coagulation phase of hemostasis

Discuss the principle and clinical significance of the Prothrombin time test
- Perform the procedure
- Describe the procedure
- Describe appropriate quality control procedures and sources of error
- Interpret results

Discuss the principle and clinical significance of the Activated partial thromboplastin time

Discuss the principle and clinical significance of the

**Calculate an INR given the international sensitivity index of the thromboplastin**

**Level 1**
Perform the procedure Level 2
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Discuss the principle and clinical significance of the Activated clotting time Level 1
Perform the procedure Level 2
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Discuss the principle and clinical significance of the Thrombin clotting time Level 1
Perform the procedure Level 2
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Discuss the principle and clinical significance of the Fibrinogen assay Level 1
Perform the procedure Level 1
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Discuss the principle and clinical significance of Factor assays Level 1
Perform the procedure Level 1
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Identify technical conditions that cause false coagulation testing results Level 1

Fibrinolytic system
Define fibrinolysis Level 1
Discuss the physiological role of the fibrinolytic system Level 1
Identify the major components of the fibrinolytic system Level 1
Discuss the mechanisms of the activation of plasminogen Level 1
Intrinsic activators
Extrinsic activators
Exogenous activators
List the major fragments of fibrinogen degradation Level 1
Explain the role and clinical significance of physiologic controls Level 1
Alpha-2-antiplasmin
Alpha-2-macroglobulin
Plasminogen activator inhibitors (PAI)
Identify and describe laboratory procedures that are used to evaluate the fibrinolytic system Level 1
Discuss the principle and clinical significance of the FDP assay Level 1
Perform the procedure Level 1
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 3
Discuss the principle and clinical significance of the D-Dimer Assay Level 1
Perform the procedure Level 1
Describe the procedure Level 2
Describe appropriate quality control procedures and sources of error Level 1
Interpret results Level 1
Identify technical conditions that cause false coagulation testing results with or without established protocol Level 1

**Disorders of primary hemostasis**

Define the following terms associated with hemostasis disorders Level 1
- Thrombocytopenia
- Thrombocytosis
- Thrombocythemia

Describe the clinical features, and laboratory findings of quantitative defects of platelets Level 1
- Idiopathic thrombocytopenic purpura
- Thrombotic thrombocytopenic purpura
- Disseminated intravascular coagulation
- Hemolytic uremic syndrome

Describe the clinical features and laboratory findings of qualitative defects of platelets Level 1
- von Willebrand’s disease
- Bernard-Soulier syndrome
- Glanzmann’s thrombasthenia

**Disorders of secondary hemostasis**

Describe the clinical features and laboratory findings of hemophilia and other congenital disorders of secondary hemostasis Level 1
- Factor I deficiency
- Factor II deficiency
- Factor V deficiency
- Factor V Leiden
- Factor VII deficiency
- Factor VIII deficiency (Hemophilia A)
- Factor IX deficiency (Hemophilia B)
- Factor X deficiency
- Factor XI deficiency
- Factor XII deficiency
- Factor XIII deficiency
- von Willebrand’s disease
- Antithrombin deficiency
- Protein C deficiency
- Protein S deficiency
- Plasminogen deficiency
- Homocystinemia/homocystinuria

Describe clinical features and laboratory findings of acquired coagulation disorders Level 1
- Vitamin K deficiency
- Liver disease
- Renal disease
Describe the significance and clinical implications of the development of circulating anticoagulants

Specific factor inhibitors
Non-specific factor inhibitors

Identify and describe laboratory procedures that are used to evaluate circulating anticoagulants or inhibitors

Discuss the principle and clinical significance of Correction study using normal plasma
Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

Discuss the principle and clinical significance of the Dilute Russell viper venom time (DRVVT)
Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

Disorders of fibrinolysis

Differentiate between primary and secondary fibrinolysis
Define disseminated intravascular coagulation (DIC)
Identify mechanisms by which clotting is initiated during DIC
Describe the effect of DIC on laboratory procedures
Prothrombin time
Activated partial thromboplastin time
Thrombin clotting time
Platelet count
Fibrinogen
Fibrin/fibrinogen degradation products (FDP)
D-dimer
Blood smear

Describe conditions that are predisposing to recurrent thrombosis
Antithrombin III deficiency
Heparin cofactor II deficiency
Primary antiphospholipid antibody syndrome
Protein C deficiency
Protein S deficiency
Activated Protein C resistance

Describe laboratory tests for antithrombin III, protein C, and protein S comparing activity vs. antigen techniques
Perform the procedure
Describe the procedure
Describe appropriate quality control procedures and sources of error
Interpret results

**Anticoagulant therapy**
- Explain the action of anticoagulant therapy
- Vitamin K Reductase inhibitors
- Direct acting oral anticoagulants
- Heparin high/low molecular weight
- Antiplatelet agents
- Identify laboratory tests used to monitor anticoagulant therapy
  - Oral anticoagulant therapy (warfarin)
  - Heparin high/low molecular weight

**Instrumentation**
- Identify basic concepts of electrical impedance, optical detection, radio frequency, and of light scatter plus cytochemical stain systems
- Discuss the principle
- List components
- Describe operation
- Perform Analysis
- Describe maintenance and troubleshooting
- Perform maintenance/corrective action
- Identify basic concepts of quality assurance for automated hematology cell counting systems
- Describe acceptable practices
- Perform basic quality assurance
- Assess data to ensure quality.
- Monitor quality assurance program
- Describe the limitations and list interfering substances
- Identify and describe hemogram parameters
- Evaluate patient data
- Describe the flagging system
- Correlate scatter plots, histograms and data plots with the peripheral smear
- Describe the mathematical calculations used to monitor instruments
- Recognize unexpected results
- Troubleshoot and corrective action
- Discuss the principle of Automated reticulocyte counting
- Describe acceptable practices
- Perform basic quality assurance
- Assess data to ensure quality.
- Monitor quality assurance program
- Describe the limitations and list interfering substances
- Identify basic concepts of electromechanical and photo-optical systems
- Describe acceptable practices
- Perform basic quality assurance
- Assess data to ensure quality.
- Monitor quality assurance program
- Describe the limitations and list interfering substances
- Identify basic concepts of quality assurance for automated coagulation systems
Describe acceptable practices                      Level 1
Perform basic quality assurance                   Level 2
Assess data to ensure quality.                   Level 3
Monitor quality assurance program                 Level 3
Describe the limitations and list interfering substances Level 1

Identify basic concepts of spectrophotometric, chromogenic substrate assays Level 1
Describe acceptable practices                     Level 1
Perform basic quality assurance                   Level 2
Assess data to ensure quality.                   Level 3
Monitor quality assurance program                 Level 3
Describe the limitations and list interfering substances Level 1

Identify basic concepts of overall laboratory quality assurance Level 1
Describe acceptable practices                     Level 1
Perform basic quality assurance                   Level 2
Assess data to ensure quality.                   Level 3
Monitor quality assurance program                 Level 3


**DOCUMENT CHANGES**

Associate physical findings with the presence of hematologic disease

State the physical findings commonly present in hematologic disease

**Prepare and stain bone marrow smears**

Describe the preparation of bone marrow smears and stains used

**Deletion w/ no replacement:**

Cytochemical stains deleted from bone marrow stains

**Describe terms and apply concepts to assess bone marrow**

Describe terms used to assess bone marrow structure and function

**Describe key terms and apply concepts to assess iron stores in bone marrow**

Describe concepts related to the assessment of iron stores in bone marrow

**Perform differential counts**

Perform differential counts on normal specimens

**Addition:**

Distinguish between normal and abnormal hematopoietic elements found within the peripheral blood

**Correlate bone marrow findings with peripheral blood evaluation**

Correlate complete blood count findings with peripheral blood smear evaluation

**Addition:**
List and define components of commonly used stains

**Good-stain Quality**

Acceptable stain quality

**Deletions with no replacements**

Research new concepts and emerging technologies

Describe therapeutic use of growth factors and stem cells to stimulate hematopoietic recovery

Discuss bone marrow/stem cell transplant to treat hematologic disease

Discuss molecular biologic techniques in hematology analysis

Identify distinctive features used to characterize developing cells

Describe the distinctive features used to characterize developing cells

List and identify stages of the maturation sequence of erythrocytes

List the maturation sequence of developing erythrocytes

**Addition:**

Distinguish nucleated erythrocyte precursors from other hematopoietic elements

Associate nutritional and regulatory factors with erythropoiesis

List nutritional and regulatory factors with associated with erythropoiesis

**Deleted with no replacement:**

List hormones associated with erythropoiesis
The hormones were merged with another objective

**Describe metabolic pathways used for red cell ATP**

Describe the purpose of the metabolic pathways used by erythrocytes

**Graph and interpret shifts to the oxygen disassociation curve when altered**

Identify the effect various conditions can have on an oxygen disassociation curve

**Grammatical change:**

Removed ‘Standard operational’ from procedures

**Discuss automated hemogram parameters**

Discuss the automated hemogram parameters used for erythrocyte evaluation

**Calculate MCV, MCH, and MCHC**

Calculate red blood cell indices when provided appropriate data

**Perform standard procedures to evaluate reticulocytes**

Perform standard reticulocyte assays

**Perform standard operational procedures in peripheral smear examination for red cell morphology**

Determine the appropriate area of a peripheral blood smear to evaluate red blood cell morphology

**Addition:**

Distinguish between normal and abnormal red blood cell morphology
List the maturation sequence and identify distinguishing morphology for stages of developing blood granulocytes using Romanowsky-stained smears, photographs, electronic images, or kodachrome slides.

**Editorial change:**
Deletion of all kodachrome slide references.

**Additions:**
- Differentiate band neutrophils, segmented neutrophils, eosinophils, and basophils
- Determine if a granulocyte is mature or immature
- Discuss the clinical utility of the absolute neutrophil count

**Editorial Change:**
- Agranulocytes changed to lymphocytes and monocytes

**Addition:**
- List the maturation sequence of monocytes and macrophages
- List the maturation sequence of lymphocytic cells
- Describe monocyte and macrophage function

**Deletion with no replacement:**
- Determine differential cell counting using automated methods
Identify and classify white cells on a properly Romanowsky stained blood smear.

Identify and classify normal white blood cells on a properly stained Romanowsky blood smear.

Deleted with no replacement:

Characterize granulopoietic alterations.

Discuss pathophysiology, causes and conditions quantitative and qualitative leukocyte disorders with expected results.

Associate quantitative and qualitative leukocyte disorders with expected results.

Identify on Romanowsky stained smears, photographs, electronic images or kodachrome slides morphologic changes in neutrophils that may accompany nonmalignant neutrophilic disorders.

Identify morphologic changes in neutrophils that may accompany nonmalignant neutrophilic disorders.

Review and compare characteristic abnormalities and clinical features for the qualitative/functional disorders of neutrophils.

State characteristic abnormalities and clinical features for the qualitative/functional disorders of neutrophils.

Deleted with no Replacement:

List the defect, substance accumulated, and clinical features for the major disorders characterized by an accumulation of lipids in monocytes and macrophages—

_____________Gaucher’s disease_______

_____________Neimann-Pick disease_____

_____________Tay-Sachs disease_______

_____________Mucopolysaccharidoses.
Sea-blue histiocytosis

Identify from Romanowsky-stained smears, photographs, electronic images, or kodachrome slides of the bone marrow.

Gaucher’s cells

Neimann-Pick cells

Sea-blue histiocytes

Addition:

Identify abnormal lipid accumulations within monocytes and macrophages

*Be it noted that this objective succinctly achieves what the above deletions aimed to accomplish.

Appraise non-neoplastic disorders of lymphocytes and plasma cells

Identify causes of non-neoplastic disorders of lymphocytes and plasma cells.

Identify reactive/variant lymphocytes on Romanowsky-stained smears, photographs, electronic images, or kodachrome slides of peripheral blood

Differentiate between reactive and resting lymphocytes on Romanowsky stained smears

Evaluate among benign causes of lymphocytosis

Identify the causes of reactive lymphocytosis

Deletion with no replacement:

Perform infectious mononucleosis evaluation

Presence of reactive/variant lymphocytes

Positive serologic tests

Cytomegalovirus (CMV)
Toxoplasmosis
Pertussis (whooping cough)
Infectious lymphocytosis
Viral hepatitis

List the major immune deficiencies in relation to T and B cell development

Recognize hematologic alterations in acquired immune deficiency syndrome (AIDS)

Lymphocytopenia (T cell CD4 and CD 8 ratio)
Leukopenia
Anemia
Thrombocytopenia

Identify the clinical signs, symptoms of hematologic findings of anemia

State the clinical signs and symptoms of anemia

Describe the categories used in a morphological classification of the anemias

List the categories used in a morphological classification of the anemias

Describe the pathophysiologic classification of the anemias

Describe the expected laboratory results seen in the various pathophysiologic classifications of anemia

Define and calculate RBC indices; explain sources of errors

Explain sources of error of the red blood cell indices

Deletion with no replacement:

Interpret results and relate results to physiologic conditions
State the criteria that define

Define common words used to describe red cell morphology

Additions:

Differentiate between normal and abnormal RBC morphology

Associate a given red blood cell morphology with routinely encountered conditions

Iron deficiency/alterations in iron metabolism
Vitamin B12/Folate deficiency
Thalassemia
Sickle Cell Disease/Trait/other hemoglobinopathies
Malaria
Hereditary membrane abnormalities (spherocytosis, elliptocytosis, ovalocytosis, etc)
RBC Enzyme abnormalities (G6PD and PK deficiencies)
Extracorpuscular (immune and non-immune) mediated RBC defects

Deletions with no replacements:

Recognize and quantitatively/qualitatively evaluate red cells

____________ Normal size erythrocytes
____________ Microcytes
____________ Macrocytes

State the criteria that define variations in color

____________ Normal
____________ Hypochromic
____________ Polychromatic
State the criteria that define poikilocytosis.

- Microscopically, identify alterations in red cell distribution.
  - Rouleaux
  - Agglutination

Describe the composition and morphology, methods to identify, and list the possible pathologic inclusions.

Correlate clinical conditions associated with the abnormal changes in size, shape, color, distribution, and inclusions.

Identify and describe changes in the bone marrow and peripheral blood with polycythemia.

Discuss the etiology and pathophysiology.

- Iron deficiency anemia
- Sideroblastic anemia
- Anemia of chronic disease
- Hemochromatosis/ Hemosiderosis
- Porphyrias
- Thalassemia

List the causes of hypochromic anemias.

Deletions with no replacement:

Outline a laboratory approach to the evaluation of a patient’s iron status.

Discuss megaloblastic transformation.
Outline a sequential approach to the differential diagnosis of megaloblastic anemia using the following laboratory procedures—

Discuss tests methods commonly used to assess megaloblastic anemia

Deletions with no replacement:

Identify common factors associated with the development

Describe the possible pathophysiology

Define Congenital dyserythropoietic anemias (Types I, II, and III)

Describe the clinical features

Describe the laboratory findings

Describe the etiology, pathophysiology, clinical features, and laboratory findings of red cell membrane defects

Describe the clinical features and laboratory findings of red cell membrane defects

Deletions with no replacement:

Identify and correlate data from laboratory tests that are used to detect increased RBC destruction and production

Discuss the principle of the Sugar water (sucrose hemolysis) test

Describe the clinical features

Describe the laboratory findings

Perform /observe the procedure

Apply appropriate quality control procedures

Evaluate results
Discuss the principle of the acidified serum (Ham’s) test

Describe the clinical features

Describe the laboratory findings

Perform /observe the procedure

Apply appropriate quality control procedures

Evaluate results

Addition:
Describe the utility of flow cytometry in assessing red cell membrane defects

Describe the etiology, pathophysiology, and clinical features of red cell enzyme abnormalities

Describe the clinical and laboratory features of red cell enzyme abnormalities

Editorial Change
Non-immune and immune mediated hemolytic anemias were merged into one category for all hemolytic anemias.

Describe the physiologic abnormalities and clinical findings

Describe the clinical and laboratory findings of hemoglobinopathies

Deletions with no replacement:

Describe the physiologic abnormality

Hemoglobin variants with altered oxygen affinity

Unstable hemoglobins

Methemoglobinemia

Describe the clinical features associated with different gene combinations in alpha and beta thalassemia
Describe the pathophysiology of alpha and beta thalassemia

Correlate screening test for sickling hemoglobin with peripheral blood morphology and electrophoretic patterns of hemoglobin

Additions:

Describe the etiology of anemia of acute blood loss

List the clinical symptoms of acute blood loss

Identify the laboratory findings of acute blood loss

Describe the etiology and pathophysiology and identify laboratory findings associated with nonhematologic disorders

Describe the clinical features and laboratory findings associated with nonhematologic disorders

Additions:

Identify major systems used to classify neoplastic disorders of leukocytes

Editorial Comment:

Hematology educators were unsure of need for LAP and TRAP stains

Deletion with no replacement:

Read case studies of neoplastic disorders and apply knowledge and skills in interpreting laboratory results

Editorial Comments:

Incorporation of WHO system into Acute Leukemia objectives and removal of FAB system from myelodysplastics

Removal of pathophysiology, etiology, and treatment objectives from Acute leukemia objectives
No expectation that MLT students would perform acute leukemia differentials at the entry level

Deletions with no replacements:

Identify key morphologic features on permanently stained blood and bone marrow smears, photographs, kodachromes, or electronic images

Correlate the diagnostic blood and bone marrow findings to the differential identification

Refractory anemia (RA)
Refractory anemia with ringed sideroblast (RARS)
Refractory anemia with excess blast (RAEB)
Chronic myelomonocytic leukemia (CMML)
Refractory anemia with excess blasts in transition (RAEB-t)

Describe characteristics of MDS

Epidemiology
Chromosomal association with pathogenesis
Clinical course with associated hematologic changes
Treatment options

Identify key morphologic features on permanently stained blood and bone marrow smears, photographs, kodachromes, or electronic images

Correlate diagnostic criteria to these findings for the differential identification

Describe the clinical and laboratory findings commonly found in MPD

Deletion with no replacement:

Identify treatment options and recognize effects on peripheral blood white cells, red cell parameters, and platelets

Chemotherapy
Splenic irradiation/splenectomy
Phlebotomy

Bone marrow transplant

Apply diagnostic criteria to blood and bone marrow findings for the differential identification of chronic lymphoid leukemias.

Identify key morphologic features on permanently stained blood and bone marrow smears, photographs, kodachromes, or electronic images.

Recognize and describe features associated with aggressive forms of the disease.

Autoimmune hemolytic anemia (AIHA)

Chromosome abnormality–trisomy 12

Richter’s syndrome

Name and compare systems used to stage disease severity and progress.

Modified Rai

Binet

Editorial comment:

The hematology educators felt that knowing immunophenotypic profiles of chronic lymphocytic neoplasms was not appropriate at the MLT level.

Deletion with no replacement:

Describe the presence of lymphoma cells on permanently stained blood and body fluid smears, photographs, kodachromes, or electronic images.

Addition

Describe the principle of the platelet function assay.

Deletion with no replacement:

Perform a bleeding time test.
Differentiate between disorders of the vasculature

- Acquired purpura
- Henoch-Schölein purpura
- Hereditary hemorrhagic telangiectasia
- Hlers-Danlos syndrome
- Pseudoxanthoma elasticum
A. Basic principles
1. Differentiate among microorganisms Level 2
   a. Bacteria
   b. Yeasts, molds
   c. Viruses
   d. Parasites
   e. Prions
2. Describe the classification of bacteria Level 1
   a. Taxonomy
   b. Nomenclature
   c. Identification
3. Describe the phenotypic characterization of bacteria Level 1
   a. Cell growth and reproduction
   b. Metabolism and nutrition
4. Describe the staining characteristics of bacteria Level 1
   a. Gram-positive, Gram-negative and Gram-variable
   b. Acid-fastness
5. Differentiate microscopic morphologies of bacteria Level 2
   a. Cocci in chains, clusters, tetrads, pairs
   b. Diplococci and coccobacilli
   c. Bacilli/Rods
   d. Lancet
   e. Fusiform
   f. Pleomorphic
   g. Branching
   h. Palisading
   i. Endospores
   j. Capsules
   k. Flagella
   l. Spirochetes
   m. Intra- and extra-cellular
6. Define terms used in bio- and molecular technology Level 1
   a. Deoxyribonucleic acid (DNA) relatedness
   b. Nucleic acid probes/hybridization
   c. Amplification procedures including but not limited to polymerase chain reaction
7. Demonstrate the proper use of the microscope (also found in General Practice) Level 2
   a. Use
   b. Maintenance
   c. Troubleshooting
B. **Role of the Clinical Microbiology Laboratory**

1. **Pre-analytical Phase**
   a. Communicate with health professionals to insure quality specimens for submission  **Level 1**
   b. Recognize **(Level 2)** potential errors and resolve **(Level 1)** according to predetermined criteria

2. **Analytical Phase**
   a. Accurately perform appropriate and timely testing in a cost effective manner  **Level 1**

3. **Post-analytical Phase**
   a. Provide accurate and timely results  **Level 2**

C. **Laboratory examination of specimens for bacterial culture**

1. **Properly identify specimen type**  **Level 2**
   a. CSF
   b. Blood and bone marrow
   c. Pleural
   d. Synovial
   e. Peritoneal
   f. Pericardial
   g. Amniotic
   h. Gastric
   i. Genital
   j. Eye/ear/throat
   k. Nasopharynx/sinuses
   l. Sputum/Bronchial
   m. Tissue, skin, and bone
   n. Catheter tips
   o. Urine
      i. Catheterized
      ii. Clean voided midstream
      iii. Suprapubic
   p. Wound
      i. Abscess aspiration/purulent material
      ii. Surgical
      iii. Soft tissue
   q. Gastrointestinal
   r. Autopsy

2. **Provide proper accession of specimens**  **Level 1**
   a. Log in
   b. Request form information/Laboratory information system orders
   c. Labeling
3. Evaluate acceptability of the specimen  
   a. Collection method/site preparation/asceptic technique  
   b. Collection time  
   c. Container/sampling device  
   d. Transport system (temperature, atmosphere, media)  
   e. Time in transit  
   f. Patient therapy  
   g. Number  
   h. Quality/Rejection criteria  
   i. Quantity  
   j. Contamination/spillage  

4. Select appropriate storage temperature/environment if delay in processing  

B. Growth and Media  

1. Choose appropriate growth media and tests  
   a. Select proper routine primary isolation media  
      i. Enriched  
      ii. Selective (differential/enrichment)  
      iii. Nutrient/general purpose  
   b. Describe the purpose of each media  
      i. Nutrients/constituents/supplements  
      ii. Antibiotics  
      iii. pH  
      iv. Antibiotic removal  
      v. Environment  
   c. Select special isolation media  
   d. Select special stains/direct tests  

2. Prepare specimen for inoculation  
   a. Centrifugation  
   b. Homogenization  

3. Perform proper inoculation of media  
   a. Order of media for inoculation  
   b. Quantitative  
   c. Semi-quantitative  
   d. Standard inoculation and streaking techniques  
   e. Swab  
   f. Loop sterilization  
      i. Reusable metal  
      ii. Plastic  
      iii. Calibrated  
   g. Streaking for isolation  
   h. Stab
i. Pipette  

j. Automated plater

4. Determine appropriate conditions
   a. Choose appropriate atmosphere
      i. Aerobic-ambient
      ii. Capneic (3-5%, 5-10%, microaerophilic)
      iii. Anaerobic
   b. Choose appropriate temperature
      i. 4°C
      ii. 25°C
      iii. 30°C
      iv. 35°C
      v. 42°C
   c. Humidity
   d. Determine appropriate length of incubation

5. Prepare direct microscopic smears of specimen
   a. Prepare smear (one cell thick, dry, fixed)
   b. Stain smear appropriately
      i. Wet mounts
         1) Saline
         2) Iodine
         3) KOH
         4) Methylene Blue
      ii. Gram
      iii. Spore
      iv. Acid-fast
         1) Ziehl-Neelsen
         2) Kinyon
         3) Modified Kinyons
      v. Fluorescent
         1) Acridine orange
         2) Auramine-rhodamine
         3) Calcofluor white
         4) Fluorescein conjugated (FITC)

6. Interpret direct microscopic smears of specimen
   a. Wet mounts and Vaginal wet preps
      i. Saline
      ii. Iodine
      iii. KOH
   b. Gram
7. Evaluate and quantitate microscopically
   a. Bacteria
      i. Structures
      ii. Capsule
      iii. Spores
   b. Yeasts and hyphal elements
   c. White and red cells
   d. Epithelial cells - columnar and squamous, i.e. Clue cells
   e. Artifacts and background material
8. Quantitate organisms and cells
9. Evaluate quality of a specimen
10. Differentiate normal flora from potentially pathogenic organisms based on body site and specimen type

D. Bacterial Culture Examination
1. Distinguish colony morphologies
   a. Staphylococci
   b. Streptococci and Enterococci
   c. Gram-negative cocci
   d. Enterobacteriaceae
   e. Pseudomonads
   f. Other non-fermentative Gram-negative rods
   g. Fastidious and other miscellaneous Gram-negative rods
   h. Non spore-forming Gram-positive rods
   i. Spore-forming Gram-positive rods
   j. Branching and filamentous Gram-positive rods
2. Differentiate common growth characteristics
   a. Blood Agar media
      i. Hemolysis (alpha/beta/gamma)
         1) Double beta
         2) Subtle or narrow zone
   b. Selective Gram Negative media (i.e. MacConkey)
      i. Fermenter vs. non-fermenter
      ii. Detection of H2S
      iii. Lysine decarboxylation
   c. Chocolate media
      i. Modified Thayer Martin (MTM)
   d. Campy-blood agar (BA)
      i. Cefoperazone
      ii. Vancomycin
      iii. Amphotericin B (CVA)
e. Colistin-nalidixic acid (CNA) blood agar
   i. Phenylethyl alcohol (PEA)
   ii. Mannitol salt agar (MSA)
f. Anaerobic media
   i. Anaerobic blood agar
   ii. Kanamycin-vancomycin laked (KVL)
g. Other media
   i. Group B selective broths
   ii. Routine enrichment broths
   iii. Mueller-hinton
   iv. Chromogenic agar

3. Select for significant uncommon organisms using selective media
   a. Enrichment media
   b. Buffered charcoal yeast extract (BCYE)
   c. Stool selective media
   d. Corynebacterium selective media

4. Evaluate growth on primary isolation media
   a. Correlation of direct gram stain results and culture results
   b. Correlation of clinical diagnosis and specimen source
   c. Variations in colony morphology
      i. Colony characteristics
         1) Size
         2) Shape
            a) Elevation
            b) Form
            c) Margin
               i) Umbilicated
               ii) Swarming, etc.
            d) Surface appearance
               i) Mucoid
               ii) Transparent
               iii) Opaque, etc.
            e) Pigmentation
            f) Changes in media
               i) Hemolysis
               ii) Pitting
               iii) Fermentation, etc.
         3) Correlation of growth on different media
         4) Normal flora vs. potential pathogens
         5) Characteristic odors of selected organisms
         6) Growth quantitation

E. Organism identification
1. Apply principles of identification
   a. Limitations and sources of errors
   b. Troubleshooting according to set guidelines
   c. Sensitivity and specificity
   d. Environmental requirements atmosphere, growth temperature, etc.

2. Perform confirmatory identification tests (including rapid tests)
   a. Catalase
   b. Oxidase/DMSO modified
   c. Coagulase
   d. TSI and KIA slants
   e. Methyl Red
   f. Phenylalanine deaminase (PAD)
   g. Amino acid (ornithine and lysine) decarboxylase, i.e., lysine iron agar (LIA)
   h. Acid production from carbohydrates
      i. Fermentation/oxidation
      i. Indole
      ii. Tube
      ii. Spot
   r. Porphyrine (Delta aminolevulinic acid) (ALA)
   s. Pyrrolidonyl arylamidase (PYR)
   t. Salt tolerance
   u. Esculin hydrolysis
      i. Rapid
      ii. Bile esculin slant
   v. Hippurate hydrolysis
   w. H2S production
   x. Nitrate reduction
   y. Citrate utilization
   z. Urease
   aa. Butyrate esterase
   bb. Voges-Proskauer
   cc. Bile solubility
   dd. Growth factors (X, V, and XV)

3. Perform Disk identification tests
   a. Novobiocin
   b. Optochin (ethylhydrocupreine hydrochloride)
   c. Special potency disks
   d. Bacitracin
   e. Beta lactamase
   f. Colistin, Kanamycin, Vancomycin

4. Choose other testing
a. Satellitism, i.e., *Staphylococcus aureus* streak  
b. Motility  
c. Aerotolerance  
d. Colony fluorescence  

5. Explain basic principles and concepts of commercial identification systems  

a. Non-automated  
   i. Miniaturized  
   ii. Rapid  
      3) Substrate based  
      4) Spot tests  

b. Automated  
   i. Nucleic acid detection  
      1) Nonamplified  
         a) Hybridization probes  
      2) Amplified, including but not limited to real time polymerase chain reaction (PCR)  
      3) Maldi-TOF  
      4) Microarray  

6. Discuss basic concepts of serological identification  

a. Coagglutination  
b. latex agglutination  
c. urine antigen detection  
d. Toxin detection  
e. Immunofluorescent assays (Direct-DFA/Indirect-IFA)  
f. Enzyme linked immunoabsorbant assay (ELISA)  
g. Serotype  

7. Use established algorithms and databases to establish identification  

F. Clinically Significant Organisms  

6. Isolate organisms  

7. Isolate organisms at the identification levels  
   
     Heard of it  
     Can identify it  
     Can assess significance of culture findings based on identification and specimen site  

a. Staphylococci  
   i. *Staphylococcus aureus* (Level 3)  
   ii. Methicillin-resistant *Staphylococcus aureus* (MRSA) (Level 3)  
   iii. Vancomycin-intermediate *S. aureus* (VISA) (Level 3)  
   iv. Vancomycin-resistant *S. aureus* (VRSA) (Level 3)  
   v. *Staphylococcus epidermidis* (Level 1)  
   vi. *Staphylococcus saprophyticus* (Level 2)  
   vii. *Staphylococcus lugdunensis* (Level 1)  
   viii. Other coagulase-negative Staphylococci (Level 2)  

b. Micrococcus spp. (Level 2)
c. Streptococci
   i. *Streptococcus pyogenes* (Group A) *(Level 3)*
   ii. *Streptococcus agalactiae* (Group B) *(Level 3)*
   iii. Other beta-hemolytic Streptococci *(Level 3)*
   iv. *Streptococcus pneumoniae* *(Level 3)*
   v. Viridans group *(Level 3)*
   vi. Alpha and non-hemolytic Streptococci *(Level 2)*

d. Enterococci, VRE,
   i. *Enterococcus faecalis* *(Level 3)*
   ii. *Enterococcus faecium* *(Level 3)*

e. Group D Streptococcus ie *S. galolyticus* (previously *S. bovis*) *(Level 3)*

f. Aerobic Gram-negative cocci
   i. *Neisseria gonorrhoeae* *(Level 3)*
   ii. *Neisseria meningitidis* *(Level 3)*
   iii. *Moraxella catarrhalis* *(Level 3)*

g. Enterobacteriaceae
   i. *Escherichia coli* *(Level 3)*
      1) Enterohemorrhagic *E. coli* due to Shiga toxin
      2) Other diarrheagenic *E. coli*
   ii. *Shigella sp.* *(Level 3)*
   iii. *Klebsiella sp.* *(Level 3)*
      1) *K. pneumoniae*
      2) *K. oxytoca*
   iv. *Enterobacter sp.* *(Level 3)*
      1) *E. aerogenes*
      2) *E. cloacae*
   v. *Serratia sp.* *(Level 3)*
   vi. *Citrobacter sp.* *(Level 3)*
   vii. *Salmonella spp.*, i.e., *Salmonella enterica biovar typhi* *(Level 3)*
   viii. *Proteus sp.* *(Level 3)*
      1) *P. mirabilis*
      2) *P. vulgaris*
   ix. *Providencia sp.* *(Level 1)*
   x. *Morganella morganii* *(Level 1)*
   xi. *Yersinia enterocolitica* *(Level 3)*

h. Other facultative Gram negative rods
   i. *Vibrio cholera* *(Level 3)*
   ii. *Aeromonas sp.* *(Level 3)*
   iii. *Campylobacter jejuni* *(Level 3)*
   iv. *Helicobacter sp.* *(Level 1)*
   i. Glucose non-fermenting Gram-negative rods
i. *Pseudomonas aeruginosa* (Level 3)
ii. *Stenotrophomonas maltophilia* (Level 2)
iii. *Moraxella sp.* (Level 2)
j. HACEK and other fastidious Gram negative rods
   i. *Aggregatibacter aphrophilus* (previously known as *Haemophilus aphrophilus/H. paraphrophilus*) (Level 1)
   ii. *Aggregatibacter actinomycetemcomitans* (previously known as *Actinobacillus actinomycetemcomitans*) (Level 1)
   iii. *Cardiobacterium hominis* (Level 1)
   iv. *Eikinella corrodens* (Level 1)
v. *Kingella sp.* (Level 1)
k. Other delicate/fastidious Gram-negative coccobacilli
   i. *Bordetella sp.* (Level 1)
   ii. *Brucella sp.* (Level 1)
   iii. *Francisella tularensis* (Level 1)
   iv. *Haemophilus influenzae* (Level 3)
      1) Serotypes b and non-b
      2) Biovar aegyptius
   v. Other *Haemophilus sp.* (Level 2)
   vi. *Legionella pneumophila* (Level 1)
   vii. *Pasteurella multocida* (Level 2)
l. Aerobic Gram-positive rods
   i. *Gardnerella vaginalis* (Level 1)
   ii. *Corynebacterium diphtheriae* (Level 1)
   iii. Other *Corynebacterium species* (Level 2)
   iv. *Listeria monocytogenes* (Level 1)
   v. *Bacillus anthracis* (Level 1)
   vi. *Bacillus cereus* (Level 2)
   vii. other *Bacillus sp.* (Level 2)
m. Anaerobic Gram-positive rods
   i. *Clostridium perfringens* (Level 1)
   ii. *Clostridium difficile* (Level 1)
   i. *Propionibacterium acnes* (Level 1)
n. Anaerobic Gram-positive cocci
   i. *Peptostreptococcus sp.* (Level 1)
o. Anaerobic Gram-negative rods and cocci
   i. *Bacteroides fragilis* group (Level 1)
   ii. *Bacteroides sp.* (Level 1)
   iii. *Fusobacterium sp.* (Level 1)
   iv. *Prevotella sp.* (Level 1)
   v. *Veillonella sp.* (Level 1)
10. Use public health and reference laboratories for special tests
   a. Reference laboratory resource information
   b. Specimen handling
      i. Packaging and shipping regulations
      ii. Safety precautions
      iii. Transport conditions
   c. Requisition information
   d. Records/documentation/protocols
   e. Cost

F. Antimicrobials

1. Apply standard performance principles and quality control to antimicrobial susceptibility tests
   a. Principles
   b. Limitations and sources of errors
   c. Troubleshooting according to set guidelines
   d. Sensitivity and specificity
   e. Quality control

2. Perform disk diffusion (Kirby Bauer) and antimicrobial gradient method (E-test)
   a. Media
      i. Depth
      ii. Supplements
      iii. Storage
   b. Inoculum
      i. Organism
      ii. Standardized suspension
      iii. Time limit for inoculation
      iv. Pattern of inoculation
      v. Time limit for application of disks
      vi. Disk placement
   c. Incubation
      i. Time
      ii. Temperature
      iii. Atmosphere
   d. Disk potency and storage
   e. Reading
   f. Interpretation
      i. Qualitative
      ii. Quantitative
   g. Reporting
   h. Special techniques
      i. Error detection and resolution according to predetermined criteria
3. Discuss the importance and principles of Beta-lactamase detection  
   Level 1
4. Identify organisms using Minimum inhibitory concentration (MIC) – micro-broth and automated systems  
   Level 2
   a. Inoculum
   b. Selection of appropriate organism for method
   c. Incubation
   d. Reading
   e. Interpretation
   f. Reporting
   g. Supplements and special techniques
   h. Error detection and resolution according to predetermined criteria
5. Discuss Clinical and Laboratory Standards Institute (CLSI) guidelines  
   Level 1
6. Perform susceptibility testing and special resistance detection methods on appropriate organisms  
   Level 2
   a. Oxacillin resistance for Staphylococcus spp.
   b. Inducible clindamycin resistance for Staphylococcus, beta-hemolytic Streptococcus spp. and Streptococcus pneumoniae
   c. Vancomycin resistance for Staphylococcus and Enterococcus spp.
   d. High level aminoglycoside resistance for Enterococcus spp.
   e. Penicillin resistance for Streptococcus pneumoniae
   f. Extended spectrum beta-lactamases (ESBL) for Enterobacteriaceae
   g. ampC enzymes for Gram-negative rods
   h. Carbapenemase resistant Enterobacteriaceae (CRE)
8. Interpret results according to set guidelines  
   Level 3
   a. Qualitative
   b. Quantitative
9. Recognize unusual antimicrobial profiles according to set guidelines  
   Level 1
10. Recognize “predictor” antimicrobial agents used to detect specific resistance mechanisms  
   Level 1
11. Recognize multidrug-resistant organisms (MDRO)  
   Level 1
12. Report data according to set guidelines and utilizing cascade and selective reporting  
   Level 1
13. Relate antimicrobial agents to mode of action and spectrum of activity  
   Level 1
14. Explain the common mechanisms of bacterial resistance  
   Level 1

F. Results
1. Prioritize reporting of direct smears  
   Level 1
2. Prepare (Level 2) culture reports and assure (Level 2) quality of results based on predetermined criteria
   a. Culture correlation with
      i. Direct Gram stain
      ii. Body site/specimen type
      iii. Patient history/population
      iv. Identification testing results
      v. Susceptibility testing results
vi. Clinical significance of organisms
vii. Other significant information

b. Selective reporting of antimicrobials

3. Report normal flora appropriately

4. Designate preliminary or finalized status

5. Recognize (Level 2) and resolve (Level 1) issues according to predetermined criteria

6. Report cultures concisely, clearly and in a timely fashion

7. Document work performed
Mycology – MLT Entry Level Curriculum

A. Basic principles of Mycology
   1. Describe characteristics of fungi Level 1
      a. Classification, Taxonomy
      b. Eukaryotic cells
      c. Reproduction
      d. Growth requirements
      e. Morphologic structures

B. Laboratory examination of fungal specimens
   1. Describe proper collection methods Level 1
   2. Discuss appropriate transportation and storage of specimen Level 1
   3. Determine acceptability of specimen Level 2
   4. Select appropriate media for culture of fungal specimens Level 1
      a. Primary isolation media
      b. Without antibacterial or antifungal agents
      c. With antibacterial agents (chloramphenicol, ciprofloxacin, gentamicin, penicillin or streptomycin)
      d. With antibacterial agents and antifungal agents (cyclohexamide)
      e. Dermatophyte test medium (DTM)
      f. Mycosel or mycobiotic agar
      g. Selective and differential for yeast, eg CHROMagar Candida
   5. Discuss the purpose of each media preparation Level 1
      a. pH
      b. Antibacterial agents
      c. Antifungal agents
   6. Inoculate media using Level 2
      a. Aspirates, tissue, bone
      b. Blood and bone marrow
      c. CSF and other body fluids
      d. Upper and lower respiratory specimens
      e. Urine
      f. Hair, skin, nails
   7. Discuss the influence on incubation Level 1
      a. Temperature
      b. Length of incubation and examination schedule
   8. Perform (Level 2) and interpret (Level 2) direct microscopic smears of fungal specimen according to set guidelines
      a. KOH
      b. India ink
c. Gram stain

9. Differentiate common yeasts and molds from bacteria on routine mycology media  
   Level 2

10. Describe procedures for microscopic observation of fungi  
    Level 1
    a. Germ tube
    b. Cornmeal/rice (chlamydospore agars)
    c. Scotch tape preparation with LPCB
    d. Slide cultures

11. Relate patient history and clinical symptoms with growth on media, colonial morphology and microscopic structures to assist in identification of fungi and assessment of clinical significance  
    Level 1
    a. Yeasts
       i. Candida
          1) C. abicans
          2) C. glabrata
          3) C. tropicalis
          4) Other Candida sp.
       ii. Cryptococcus
          1) C. neoformans
          2) Other Cryptococcus sp.
       iii. Trichosporon sp.
       iv. Geotrichum sp.
       v. Malassezia spp., ie M. furfur
    b. Dimorphic moulds
       i. Blastomyces dermatitidis
       ii. Coccidioides spp., ie C. immitis
       iii. Histoplasma capsulatum
       iv. Sporothrix schenckii
       v. Paracoccidioides brasiliensis
    c. Brightly colored/hyaline molds
       i. Aspergillus spp.
          1) A. fumigatus
          2) A. flavis
          3) A. niger
          4) Other A. sp.
       ii. Penicillium sp.
       iii. Fusarium sp.
    d. Dermatophytes
       i. Microsporum spp.
       ii. Trichophyton spp.
       iii. Epidermophyton floccosum
    e. Zygomyces
i. *Rhizopus spp.*
ii. *Mucor spp.*
iii. *Absidia spp.*

f. other fungi
   i. *Pneumocystis jiroveci*

12. Describe test methodologies for fungi identification  
   Level 1
   a. Principles
   b. Limitation and sources of errors
   c. Troubleshooting according to set guidelines
   d. Sensitivity and specificity
   e. Rapid and traditional testing methods
      i. Assimilation/fermentation
      ii. Temperature tolerance
      iii. Mould/yeast conversion
      iv. Wood’s lamp fluorescence
      v. In-vitro hair perforation
      vi. Antigen detection methods
         1) Cryptococcal antigen
      vii. Commercial methods
      viii. Molecular methods

13. Use databases and reference materials in identification of fungi  
   Level 1
A. Taxonomy and terminology for categories of parasites
   1. Describe the distinguishing characteristics of categories of parasites Level 1
      a. Nematodes (roundworms)
         i. Tissues
         ii. Intestinal
      b. Cestodes (tapeworms)
      c. Trematodes (flukes)
      d. Protozoan
      e. Amebae
      f. Flagellates
      g. Sporozoa
         i. Plasmodium spp.
         ii. Coccidia
      h. Ciliates
   2. Recognize characteristic structures of adults, larvae, ova, cysts, trophozoites, etc. Level 1

B. Specimen Collection and handling
   1. Determine specimen acceptability in parasitic identification Level 2
      a. Collection method
      b. Collection time/receipt time
      c. Specimen storage
      d. Number of specimens
      e. Presence of interfering or contaminating substances
      f. Preservatives for parasitic specimen
         i. Polyvinyl alcohol (PVA)
         ii. 10% Formalin
         iii. Schaudinn solution (mercury free)
         iv. Sodium acetate-acetic acid-formalin (SAF)
         v. Less toxic single tube systems
      g. Rejection criteria

C. Examination of specimens
   1. Examine the specimen macroscopically Level 2
      a. Color
      b. Presence of blood or mucous
      c. Consistency (watery/Loose,semisolid,formed)
      d. Worm components (proglottids, adult, scolex, etc)
   2. Describe the process of direct microscopic examination of specimen Level 1
      a. Proper use of the microscope, objectives, and light source
b. Use of ocular micrometer for measurement of size  
   i. Calibration

c. Use of direct wet mounts with saline and iodine preparations

d. Systematic examination of prepared slide

e. Detection of parasites

3. Select and perform appropriate concentration methods and stains  
   Level 1  
   a. Principles
   b. Limitations and sources of errors
   c. Trouble-shooting according to set guidelines
   d. Sensitivity and specificity
   e. Quality control
   f. Concentration methods
      i. formalin-ethyl acetate
      ii. alternate solvents sedimentation
   g. Permanent stained smears
      i. trichrome/modified trichrome
      ii. iron-hematoxylin
      iii. modified Kinyons (acid-fast)
      iv. Calcofluor white
      v. Auromine O
   h. Preparations of reagents and stains
      i. Preparation of malarial smears
         i. Thick smears
         ii. Thin smears

4. Explain the detection and differentiation of specific parasites  
   Level 1  
   a. Immunoassays
   b. Nucleic acid assays

5. Detect and identify parasites
   Heard of it  
   Can identify it  
   Level 2  
   a. Nematodes
      i. Intestinal
         1) *Ascaris lumbricoides* (Level 2)
         2) *Strongyloides stercoralis* (Level 1)
         3) Hookworm (Level 2)
            a) *Necator spp.*
            b) *Ancylostoma spp.*
         4) *Trichuris trichiura* (Level 2)
         5) *Enterobius vermicularis* (Level 2)
      ii. Blood and tissue
         1) *Trichinella spiralis* (Level 1)
2) *Wuchereria bancrofti* (Level 1)
3) *Brugia malayi* (Level 1)
4) *Loa loa* (Level 1)
5) Mansonella (Level 1)
6) *Onchocerca volvulus* (Level 1)
7) *Dracunculus medinensis* (Level 1)

b. Cestodes
   i. *Taenia solium* (Level 2)
   ii. *Taenia saginata* (Level 2)
   iii. *Echinococcus granulosus* (Level 1)
   iv. *Diphyllobothrium latum* (Level 2)
   v. *Hymenolopis nana* (Level 2)
   vi. *Hymenolopis diminuta* (Level 1)

c. Trematodes
   i. *Paragonimus westermani* (Level 2)
   ii. *Fasciolopsis buski* (Level 2)
   iii. *Fasciola hepatica* (Level 2)
   iv. *Clonorchis sinensis* (Level 2)
   v. *Schistosoma mansoni* (Level 2)
   vi. *Schistosoma haematobium* (Level 2)
   vii. *Schistosoma japonicum* (Level 2)

d. Protozoa
   i. Amoeba
      1) *Entamoeba hystolytica* (Level 2)
      2) *Entamoeba dispar* (Level 2)
      3) *Entamoeba coli* (Level 2)
      4) Other *Entamoeba* sp. (Level 2)
      5) *Iodamoeba bütschlii* (Level 2)
      6) *Endolimax nana* (Level 2)
      7) *Acanthamoeba sp.* (Level 1)
      8) *Naegleria fowleri* (Level 1)
      9) *Blastocystis hominis* (Level 2)
   ii. flagellates
      1) *Giardia lamblia/intestinalis* (Level 2)
      2) *Trichomonas vaginalis* (Level 2)
      3) *Dientamoeba fragilis* (Level 2)
   iii. *Trypanosoma spp.* (Level 1)
   iv. *Leishmania spp.* (Level 1)
   v. Sporozoa (Level 2)
      1) *Plasmodium spp.*
      2) *Babesia spp.*
3) *Cryptosporidium parvum*

e. Ciliates
   i. *Balantidium coli* (Level 2)

6 Use pertinent clinical information in order to identify parasites
   i. Diagnostic stage, i.e., characteristic structure(s) present
   ii. Knowledge of life cycle
   iii. Specimen of choice for detection
   iv. Detection methods available

7 Differentiate artifacts from parasites (Level 2)
   i. White and red blood cells
   ii. Epithelial cells
   iii. Pollen granules
   iv. Vegetable fibers and cells
   v. Yeast cells
   vi. Charcot-Leyden crystals
   vii. Fungal spores (morels)
   viii. Diatoms
   ix. Hair

8 Examine specimens other than stool (Level 1)
   i. Cellophane tape/vaspar paddle preparation for *Enterobius vermicularis*
   ii. Wet mount/culture for *Trichomonas species*
   iii. Duodenal capsule or string technique (Entero-Test)
   iv. Thick and thin blood films
   v. Bone marrow and body fluids
   vi. Urine
   vii. Lower respiratory
   viii. Biopsy
Mycobacteriology – MLT Entry Level Curriculum

A. General Characteristics
   1. Describe the general characteristics of mycobacteria Level 1
      a. Acid-fastness
      b. Growth requirements
      c. Rate of growth
      d. Atmosphere requirements
      e. Temperature

B. Specimen management
   1. State the safety requirements for working with mycobacteria Level 1
      a. Biological safety cabinet (BSC/Biosafety level (BSL)
      b. Personal protective equipment
         i. Respirator
         ii. Gloves
         iii. Liquid impervious gowns
         iv. Centrifuges with safety carriers
         v. Germicides
      c. Equipment
      d. Negative pressure facility
      e. Annual tuberculin skin test
         i. Chest x-ray if skin test is positive
         ii. Effects of BCG vaccine
   2. Discuss specimen collection and transportation procedures Level 1
      a. Pulmonary sites
         i. Sputum, expectorated and induced
         ii. Bronchial alveolar lavage (BAL), bronchoscopy, etc.
      b. Extrapulmonary sites
         i. Non-contaminated
            1) Blood and bone marrow
            2) Body fluids
            3) Tissue
         ii. Contaminated
            1) Urine
            2) Skin lesions, wound, abscesses
            3) Gastric lavage or aspirate
            4) Stool for Mycobacterium avium complex
         iii. Blood for interferon gamma release assay (QuantiFERON – TB test)
      c. Collection method/site preparation
         i. Container
ii. Collection time
iii. Number of specimens
iv. Quality
v. Optimum volume
vi. Rejection criteria

3. Describe (Level 1) specimen processing procedures
   i. Contaminated specimens
      1) Digestion and decontamination
         a) Liquefication
         b) Decontamination
         c) Centrifugation
            i) Speed
            ii) Time
            iii) Equipment required
         d) Limitations and potential sources of errors
         e) Quality assurance, e.g., maintenance of a contamination rate of 3-5%
   ii. Non-contaminated specimens
      1) Centrifugation
      2) Direct inoculation

C. Smears and Stains
   1. Discuss the preparation, staining and screening of smears
      a. Specimen selection
         1. Smear preparation, standardization, fixation
            1) Direct
            2) Concentrated
            3) Cytocentrifugation with bleach
      b. Stains
         i. Reagent preparation
         ii. Acid-fast stain procedures
            1) Principle
            2) Acid-fast: fuchsin
               a) Ziehl-Neelsen
               b) Kinyoun
            3) Acid-fast: fluorochrome
               a) Auramine O
               b) Auramine-rhodamine
      iii. Quality control
      iv. Limitations and potential sources of errors
      v. Troubleshooting and according to set guidelines
      vi. Sensitivity and specificity
c. Microscopic evaluation
   i. Magnification
   ii. Scanning pattern
   iii. Organism morphology, e.g., serpentine cording
   iv. Specificity
   v. Sensitivity

2. Describe the interpretation and reporting of smear
   a. Sources of false positives
      i. Nocardia
      ii. Rhodococcus
      iii. Cryptosporidium, Cystoisospora and Cyclospora oocysts
      iv. *M. gordonae* from a tap water source
      v. Other
   b. Appearance of artifacts, debris, background
   c. Reporting scheme
   d. Internal review process for quality assurance

D. Culture medium

1. Describe the culture media most appropriate for primary cultures by specimen type
   a. Egg-based
      i. Lowenstein-Jensen
   b. Agar-based
      i. Middlebrook 7H10 and 7H11
   c. Liquid based
      i. Middlebrook 7H9, 7H12 and 7H13
   d. Commercial systems
   e. Other

2. Discuss the incubation of the primary media
   a. optimal temperature to isolate mycobacteria
      i. 35°C vs. 37°C
      ii. 25-33°C
   b. optimal atmospheres of incubation
   c. optimal length of incubation
   d. Reading schedule for inoculated media

E. Identification

1. Describe the identification of isolates using established algorithms and databases
   a. Acid-fastness of the organism
   b. Preferred temperature of growth
   c. Rate of growth
      i. Rapid grower (< 7 days)
ii. Slow grower (> 7 days)

2. Discuss variations in colony morphology
   i. Pigment

F. Testing

1. Discuss Biochemical testing of mycobacteria
2. Describe other methods for organism identification
   a. Molecular diagnostics
   b. Amplification methods for direct detection of *Mycobacterium tuberculosis*
3. Describe mycobacteria based on key criteria
   a. *Mycobacterium tuberculosis* complex
   b. *M. tuberculosis*
   c. *Mycobacterium avium-intracellulare* complex (MAC or MAI)
4. Correlate the presence of organisms with the most common types of clinical infections and clinical significance according to set guidelines
   a. Routes of transmission
   b. Signs and symptoms

G. Reporting

1. Describe the turnaround time and reporting of direct smear, culture, and susceptibility results
Virology – MLT Entry Level Curriculum

A. Characteristics of viruses
1. Describe the basic structure/components of viral agents Level 1
   a. Virion
      i. Type of nucleic acid present (RNA or DNA)
      ii. Capsid
      iii. Envelope
      iv. Glycoprotein spikes
2. Differentiate viruses from bacteria Level 2
   a. Requirement for living cells
   b. Size
   c. Structure
   d. Replication
   e. Therapy

B. Classification of viruses
1. Outline the criteria for classifying or grouping viruses Level 1
   a. Nucleic acid type (RNA or DNA)
   b. Host
2. Associate agents of infections infection with disease or pathologic manifestations and route of transmission Level 2
   a. Hepatitis viruses
   b. Simplex virus, Herpesvirus 1 and 2
   c. Cytomegalovirus (CMV)
   d. Varicella-Zoster (VZV)
   e. Influenza virus A
      i. H1N1
      ii. H5N1
   f. Influenza virus B
   g. Respiratory syncytial virus (RSV)

C. Specimen collection and processing
1. Discuss important information for specimen collection and processing of specimens Level 1
   a. Selection of body site/Specimen type
   b. Collection methods, devices and containers
   c. Safety precautions
   d. Transport media
   e. Temperature
   f. Time
2. Utilize proper specimen storage upon receipt in laboratory  
3. Utilize proper specimen shipment methods are used 
4. Utilize specimen processing algorithms based on most likely virus present  
   a. Rejection criteria 
   b. Specimen type/body site 
   c. Specimen preparation 
   d. Age of patient 
   e. Time of year/virus seasonality 
   f. Virus suspected 
   g. Immune status 

D. Laboratory procedures 
1. Describe laboratory procedures for detection of viral agents and particles 
   a. Principles 
   b. Limitations and sources of errors 
   c. Troubleshooting according to set guidelines 
   d. Sensitivity and specificity 
   e. Quality control 
   f. Direct detection methods 
      i. Immunodiagnostic 
         1) Direct and indirect immunofluorescent 
         2) Antibody methods 
         3) Enzyme immunoassay methods (EIA)(ELISA) 
      ii. Molecular methods 
      iii. Cell culture systems 
      iv. Serology
Infection Prevention and Control – MLT Entry Level Curriculum

A. Disease transmission
   1. Define terms associated with disease transmission Level 1
      a. Epidemiology
      b. Community acquired infections
      c. Nosocomial infections
      d. Epidemic
      e. Endemic
      f. Outbreak
      g. Cluster
      h. Surveillance
      i. Morbidity
      j. Mortality
   2. Describe the origin and mode of spread Level 1
      a. Droplet
      b. Airborne
      c. Fomite
      d. Vector
      e. Reservoir
      f. Endogenous
      g. Exogenous
   3. Compare and contrast Level 2
      a. Colonization
      b. Infection
      c. Carrier state

B. Infection prevention methods
   1. Relate underlying patient condition/factors to acquisition of infection Level 1
      a. Medical devices (Catheters, respirator)
      b. Immunocompromised
      c. Immunosuppressive therapy
      d. Antimicrobial therapy
      e. Malignancy
      f. Age
      g. Occupation
      h. Surgery
      i. Prosthetic devices (pacemaker, artificial heart valve, shunt, joint)
   2. Apply concepts of disease transmission to disease prevention Level 2
a. Education
   i. Health care professionals
   ii. Patients
   iii. Environmental services (housekeeping)
b. Precautions
   i. Standard Precautions
   ii. Transmission-based
      1) Direct and indirect contact
      2) Droplet
      3) Airborne
   iii. Immunizations
   iv. Treatment
      1) Antibiotics
      2) Antiviral
      3) Antifungal
      4) antiparasitic

C. Role of clinical microbiology laboratory
   1. Culture microbial pathogens
      a. Common bacteria
      b. Multiple drug resistant organism (MDRO)
      c. Mycobacteria
      d. Fungi
      e. Unusual organisms
      f. Viruses
      g. Parasites
   2. Identify common bacteria through culture, microscopic, or rapid testing
   3. Detect microbial organisms through microscopic or rapid testing
      a. Mycobacteria
      b. Fungi
      c. Unusual organisms
      d. Viruses
      e. Parasites
   4. Report relevant cultures/organisms to infection control personnel
   5. Assist medical laboratory scientists with surveillance of infectious diseases
      a. Environmental samples
      b. Personnel specimens
      c. Patient specimens
      d. Rapid diagnostic testing
e. Organism identification
f. Antimicrobial susceptibility testing
g. Epidemiologic analysis of microorganisms
   i. Phenotypic techniques
   ii. Genotypic techniques
6. Report communicable diseases/organisms to the appropriate public health agencies  Level 1
7. Monitor for bioterrorism agents and emerging infections  Level 1
   a. Centers for Disease Control (CDC) categories of organisms
   b. CDC laboratory response network
   c. Specimen packing and shipping
   d. Biosafety
   e. Protocols to rule in/rule out critical agents
8. Handle and dispose of biohazard materials  Level 2
   a. QC of autoclaves
   b. Identification of biological, pathological, and surgical infectious materials
   c. Cleaning, sterilization, disinfection
   d. Laboratory safety procedures manual
   e. Aseptic technique
Laboratory Practice – MLT Entry Level Curriculum

A. Quality management
   1. Follow policies and procedures Level 2
   2. Perform (Level 2) procedures and review (Level 2) results of standard quality control
      a. Media
      b. Stains
      c. Reagents/kits
      d. Equipment
      e. Physiological tests
      f. Antimicrobial testing
      g. Serological tests
      h. Stock organisms
      i. Inventory
      j. Automated systems
      k. Immunological test
      l. Microscope calibration
   3. Recognize errors according to set guidelines Level 2
   4. Participate in data collection for a quality management plan Level 2
   5. Assist in the education and training of others Level 2
      a. Laboratory science students
      b. Healthcare personnel
      c. Co-workers
   6. Maintain knowledge and skills through continuing education Level 2

B. Laboratory Safety
   1. Describe (Level 1) and use (Level 2) accepted safety precautions to prevent laboratory acquired infections
      a. Standard Precautions
         i. Handwashing
         ii. Protective clothing/devices
      b. Engineering controls
         i. HEPA filtration
         ii. Ultraviolet germicidal irradiation
         iii. Negative pressure room
      c. Emergency action protocol
      d. Training
      e. Health care facilities
         i) Emergency care
ii) Respirator fit testing

iii) Treatment

f. Aseptic techniques
g. Handling and disposal of sharps
h. Use of biological safety cabinets
i. Center for Disease Control and Prevention (CDC)/biological safety level (BSL) classification
   i. Classifications of BSL requirements
   ii. Correlation of specific organisms and required BSL
j. Bio-hazardous materials discard
k. Decontamination, disinfection, sterilization
l. Emergency first aid, eye wash, showers
m. Immunizations
n. Employee health services

2. Take immediate and appropriate action when an incident occurs Level 3

3. Describe the procedures for prevention of aerosolization of microbial agents (mycobacteria and other bacteria, fungi, and viruses) Level 1
   a. Aseptic techniques
   b. Containment procedures
   c. Decontamination, disinfection, sterilization
d. Centrifuge use
e. Bio-hazardous materials discard

4. Describe the collection and discard of infectious waste materials Level 1
   a. Environmental Protection Agency (EPA)/state regulations
   b. Definition of infectious waste

5. Discuss hazards of chemicals in the workplace Level 2
   a. Safety data sheets (SDS)
b. Storage, labeling and use
   i. Physical hazards
      1) Flammable
      2) Oxidizer
      3) Corrosive
   ii. Health hazards
      1) Toxicity
      2) Carcinogenicity
   iii. Environmental hazards

6. Outline fire safety guidelines Level 1
   a. Fire protocol (RACE - rescue, alarm, contain, extinguish)
b. Classes of fire extinguishers
c. Fire evacuation plan
d. Fire extinguisher protocol (PASS - pull pin, aim, squeeze, sweep base of fire)
C. **Laboratory Information System (LIS)**

1. Describe data entry
   a. Automated/Manual

2. Describe the reporting of data

3. Discuss data retrieval to provide relevant information for microbiology
   a. Analysis
   b. Integration
   c. Antibiogram

4. Describe the retrieval of information by clinics/providers
   a. Results
   b. Services provided
   c. Specimen handling
   d. Education

D. **Administrative tasks**

1. Explain the responsibilities of laboratory management
   a. Personnel
      i. Safety
      ii. Training
      iii. Proficiency
      iv. Competency
   b. Physical facilities
   c. Communication
      i. Public health authorities
      ii. Infection prevention/epidemiology
      iii. Service providers/clinicians
      iv. Administration
      v. Education
      vi. HIPAA
      vii. Finance, i.e., cost containment
DELETIONS & ADDITIONS

DELETIONS

- Bacteriology
  - TM, NYC, Jembec, and ML agar, leaving only MTM agar for choc media types
  - CCFA agar
  - CAMP
  - India Ink
  - Some of the more unusual tests
  - Nutritionally variant Strep.
  - Unusual organisms
  - Mechanism of action for antibiotics
  - E-test
  - Minimum bactericidal concentration (MBC)
  - Standard performance principles to bioassays of body fluids

- Mycology
  - Structural characteristics of mycology
  - Generalized media into groupings – removed specific types (changed to Level 1)
  - Interpretation of fungal smears
  - Periodic acid Schiff, Gomori methenamine silver, hematoxylin and Eosin stains
  - Scotch tape prep and tease prep
  - Correlation of clinical symptoms with fungal identification
  - Some fungal pathogens

- Parasitology
  - Structural terms
  - Malaria consolidated into species instead of specific organisms.

- Mycobacteriology
  - Taxonomic differentiation of Nocardia, Rhodococcus, Streptomyces, and Mycobacterium
  - Phenotypic characterization
  - Microscopic morphology (coccoid, filamentous, beading, cording, ghosts)
  - Colony morphology and identification

- Virology
  - Helical/icosahedral/complex
  - EBV

- Administration
  - Issues of staff performance
  - Budget
  - Implement safety precautions
ADDITIONS

- Catheter tips
- Group B selective broths (dropped specific types and added a general category)
- Routine enrichment broth category (consolidated enrichment broths instead of specific types)
- Stool selective media (consolidated TCBS, Yersinia, and CIN media)
- Corynebacterium selective media (Consolidated Bordet Gengou/Reagan Lowe, Loeffler’s and Tinsdale media)
- Added back anaerobic identification disks
- Maldi-TOF and Microarray
- *Aeromonas sp.*
Molecular Diagnostics – MLT Entry Level Curriculum

1. Basic Foundation Concepts
   a. Describe a brief history of the development of molecular diagnostics
   b. Discuss the impact molecular diagnostic will have on:
      i. Laboratory medicine
      ii. Diagnosis and management of diseases
      iii. Ethical implications
   c. Discuss the basic functions of DNA

2. Nucleic Acid Biochemistry
   a. Explain semi-conservative DNA replication
   b. Describe DNA
      i. Central dogma
      ii. Transcription
      iii. Translation (codons/anticodons, ribosomes, genetic code/degensation)
      iv. Extrachromosomal (plasmid, mitochondrial transmission)

3. Genetics
   a. Describe chromosome morphology
   b. Discuss Mendelian and non-Mendelian genetics
   c. Define mutations and polymorphisms

4. Molecular methodologies
   a. Describe nucleic acid extraction/isolation/quantitation/purification techniques
      i. purpose of technique
      ii. reagents and purpose
      iii. acceptable sample types
   b. Discuss nucleic acid modifying enzymes
      i. storage criteria
      ii. enzyme inactivation
      iii. basic function of the following enzymes
         1. Endonucleases
         2. Exonucleases
         3. Ligases
         4. Polymerases
         5. Reverse transcriptases
         6. Phosphatases
         7. kinases
   c. Discuss Nucleic acid electrophoresis
      i. role of size, charge, and shape or conformation in migration/movement
   d. Compare and contrast blotting techniques
1. Western, northern, and southern blotting
2. Nucleic substance tested (DNA, RNA, protein)
3. Consider the following variables when performing various blotting techniques
   a. Restriction fragment length polymorphism (RFLP)
   b. Stringency
   c. Hybridization
4. Pros and cons of each method

   e. Discuss Amplification assays
      i. polymerase chain reaction (PCR)
         1. Amplification reaction
         2. Cycle (denature, anneal, extend)
         3. Stringency
         4. Components/concentration
            a. Primers and primer design
            b. DNA template, bases, and polymerase
            c. Buffer
5. Probe assays
6. Master mix

   ii. List types of amplification assays
      1. Target amplifications
         a. Polymerase Chain Reaction (PCR)
         b. Differentiate PCR modification techniques (end-point versus real-time)
            i. Real time PCR
            ii. Nested PCR
            iii. Multiplex PCR
            iv. Reverse transcription-polymerase chain reaction (RT-PCR)
      2. Probe amplification
      3. Signal amplification

      iii. Explain florescence in situ hybridization (FISH)

5. Laboratory Operations, Quality Control and Quality Assurance in the molecular laboratory
   a. State variables of concern for pre-analytical testing
      i. Test request
      ii. Specimen collection/handling
   b. State variables for the analytical phase
      i. specimen extraction and storage
      ii. Lab design
      iii. Contamination monitoring
      iv. Contamination prevention
      v. QC/preventive maintenance
   c. State concerns for the post-analytical phase
i. Reporting of results
ii. Follow-up recommendations
iii. Confidentiality

d. Describe controls used in molecular testing  \textbf{Level 1}

e. Compare and Contrast test system categories  \textbf{Level 2}
   i. analyte specific reagent (ASR)
   ii. research use only (RUO)
   iii. \textit{in vitro} diagnostics (IVD)
   iv. lab developed test (LDT)

f. Discuss regulations and standards (CLIA; CAP; CLSI)  \textbf{Level 1}

\textbf{6. Impact of molecular testing on the following}

a. Discuss the role of molecular testing in evidence based medicine  \textbf{Level 1}

b. List ethical issues associated with molecular testing  \textbf{Level 1}
   i. Discrimination
   ii. Confidentiality
   iii. Informed consent
The Health Care System and Services

- List components of the health care delivery system and the services each provides- Level 1
  - Inpatient facilities:
    - Hospitals
    - Long term care facilities
    - Birthing Centers
  - Outpatient facilities:
    - Managed Care Systems including Health Maintenance Organizations (HMO)
    - Solo practices--Physicians' Offices
    - Prenatal care facilities
    - Respite care facilities
    - Hospice
    - Home health care
    - Chronic care facilities
    - Blood donor collection facilities

- Name and describe various departments and services within the health care setting in which interactions with patients, departments, and services occur because of duties related to phlebotomy- Level 1
  - Emergency facilities—emergency room (ER) or emergency department (ED) and trauma center
    - Cardiac care units
    - Electrocardiography
    - Encephalography
    - Geriatrics
    - Intensive care units
    - Nuclear medicine
    - Nursery
    - Occupational Therapy
    - Pediatrics
    - Pharmacy
    - Physical Therapy
    - Psychiatric units
    - Radiation Therapy
    - Radiology and diagnostic imaging services
    - Respiratory therapy
    - Surgical Units
    - Outpatient laboratory
    - General Medicine units

- List each laboratory specialty area, including the reference laboratory and list tests most frequently performed in each area- Level 1
  - Clinical Chemistry
- Name medical specialty areas within the health care delivery system such as obstetrics, gynecology, oncology, etc.- Level 1
- List and generalize the roles and qualifications of the health care professionals most often encountered in phlebotomy- Level 2
  - Medical laboratory scientists
  - Medical laboratory technicians
  - Cytotechnologists
  - Electrocardiogram (EKG) technicians
  - Histologists
  - Histotechnicians
  - Patient care technicians
  - Phlebotomists
  - Nurses
  - Nurse practitioners
  - Occupational therapists
  - Physical therapists
  - Pathologist
  - Physicians
  - Physicians assistants
  - Radiologists
  - Respiratory therapists
  - Others as applicable
- Demonstrate a knowledge and proficiency in the use of computers as related to job duties and responsibilities- Level 2
- Define and utilize medical terminology pertinent to phlebotomy, and laboratory testing, and patient care-Level 2

Patient and Laboratory Safety
- List and discuss precautions, practices and procedures to assure patient safety- Level 1
  - Correct identification of patients
  - Communication and its applications to patient safety
Use of proper equipment and procedures for specimen/sample collection
Identification and avoidance of safety risks including but not limited to nerve damage
Preventing errors in specimen/sample collection
Preventing errors in point-of-care testing
Relevance of specimen/sample collection to preventing errors in testing procedures
Identification of improper specimens/samples and the impact on testing, e.g., hemolysis, insufficient blood collected in tubes with anti-coagulant, improper draws, etc.

- Demonstrate an understanding of safety hazards and precautions and identify symbols - Level 2
  - Biological hazard
  - Electrical safety
  - Chemical safety
  - Radiation safety
  - Fire safety
  - Mechanical safety

- Discuss and apply OSHA standards and compliance within phlebotomy and clinical laboratory practice - Level 2

- Discuss institutional safety procedures and practices - Level 1
  - Handling biological specimens routinely
  - Biological and physical safety of oneself and others in the workplace
  - Proper labeling of biohazardous specimens/samples routinely
  - Handling biological substances in cases of bioterrorism and emergency response situations relevant to the scope of practice
  - Hazardous materials
  - Natural disasters including weather emergencies
  - Fire and electrical safety
  - Cleaning protocols including cleaning phlebotomy trays and equipment, cleaning up of specimen/sample spills, and other biohazard spills
  - Waste disposal

- Comply with federal and state mandates and regulations and organizational requirements regarding safety policies - Level 2
- Develop and evaluate safety protocols for phlebotomy - Level 3
- Select and evaluate safety equipment for use in phlebotomy - Level 3

Infection Prevention

- List the principles of infection prevention - Level 1
  - Source of infection
  - Modes of transmission
  - Hosts
  - Susceptibility to infection
• List the elements of the chain of infection and mechanisms to break the chain- Level 1
• Discuss and demonstrate sterile technique related to the scope of practice- Level 2
• Discuss and apply the OSHA bloodborne pathogen standards and compliance with these standards- Level 2
• Discuss and apply standard precautions, workplace practices and engineering controls as related to phlebotomy and related services- Level 2
  o Use of solution procedures
  o Masking
  o Use of gloves
  o Gowning
  o Face shields
  o Hand washing and hand antisepsis
  o Sterile technique
  o Needle and other sharps disposal
  o Environmental controls- use of approved surface disinfectants
  o Other
• Discuss and apply the isolation procedures and personal protective equipment requirements in accordance the standard precautions and identify an example of when each would be used- Level 2
  o Airborne/droplet precautions
  o Contact precautions
  o Protective precautions
  o Body substance isolation
• Relate the types of isolation associated with specific inpatient or clinical treatment units- Level 2
  o Burn unit
  o Dialysis
  o Intensive care units
  o Nursery
• Discuss and evaluate protocols for exposure to blood and other body fluids, including accidental sticks with contaminated needles- Level 3
• Discuss and demonstrate proper handwashing procedure and hand asepsis- Level 2

**Human Anatomy and Physiology**

• Describe terminology related to direction, anatomic positions, body planes and body cavities- Level 1
• Describe body systems by discussing- Level 1
  o Major organs
  o Components and structures
  o Primary functions
  o Common disorders and clinical laboratory tests/results
• State specimen/sample requirements and laboratory tests commonly performed for evaluation of each body system- Level 1

• List components of and describe the circulatory system- Level 1
  o Characteristics of blood and its components
  o Blood vessels for arterial, capillary and venipuncture

• Discuss the proximity of nerves to arteries and veins and the impact on phlebotomy- Level 1

• Discuss the vascular system in the skin and how it applies to phlebotomy and phlebotomy practices- Level 1
  o Sites for skin puncture for capillary blood collection
  o Limitations and precautions related to capillary blood collection

Specimens/Samples

• Define specimen/sample- Level 1

• List types of specimens tested in the clinical laboratory- Level 1

• Discuss requirements for assuring integrity of each type of specimen- Level 1

• Discuss specimen/specimen collection including order of draw, preservation processing, and analysis integrity of each specimen/sample type- Level 1

• Name the components of blood- Level 1

• List and discuss factors that affect basal state of specimens/samples- Level 1
  o Age
  o Dehydration
  o IV therapy
  o Diet
  o Exercise
  o Stress
  o Posture
  o Diurnal variation
  o Tourniquet application
  o Altitude
  o Smoking
  o Lipidemia
  o Obesity
  o Use of improper collection devices

• Describe the procedures and discuss the rationale for handling urine specimens- Level 1
  o Collection
  o Preservation
  o Transporting
  o Handling
  o Processing

• State factors that compromise the integrity of specimens/samples as related to the accuracy of clinical laboratory testing- Level 1
- Timing of collection, transport and testing
- Order of draw during specimen/sample collection
- Light
- Temperature
- Medications/drugs
- Evaluate specimens/samples and determine the integrity and appropriateness for specific tests requested- Level 3
- Name the types of additives used for blood collection- Level 1
  - EDTA (citrate, potassium and disodium forms)
  - Heparin
  - Sodium fluoride
  - Oxalate
  - Antiglycolytic agents
  - Clot activators
  - Thixotropic gel, polymer gel
  - Preservatives
- Discuss the modes of action and appropriate use of each additive used for blood collection- Level 1
- Match the blood collection tube colors with the correct additive- Level 1
- Name, select, and evaluate appropriate equipment and supplies to be used for skin puncture and venipuncture for a variety of patient type- Level 3
- List specimens/samples used for commonly ordered clinical tests- Level 1
- Match the laboratory section in which commonly ordered tests are performed- Level 1

**Equipment and Supplies**

- Name, select and evaluate equipment and supplies used for phlebotomy and discuss proper use of each- Level 3
  - Evacuated tube system
  - Syringes
  - Winged and non-winged infusion sets
  - Micro collection containers
  - Skin puncture devices
  - Arterial blood collection equipment
  - Blood culture collection equipment
  - Micro pipette dilution systems
  - Tourniquets
  - Antiseptics
  - Disinfectants
  - Puncture resistant containers
  - Phlebotomy trays and carts
  - General supplies (gauze, bandages, etc)
  - Newborn screening testing kits
• Name, select and evaluate appropriate protective wear to be used during blood collection, transport, and handling- Level 3
• Use equipment and supplies appropriately such that specimens/samples of quality and high integrity are obtained and efficient service of high quality are realized- Level 2
• Appropriately store equipment and supplies- Level 2
• Appropriately dispose of used or contaminated equipment and supplies- Level 2

Specimen/sample collection

• Instruct the patient on specimen/sample collection- Level 2
• Discuss patient readiness for quality specimen/sample collection including adherence to diet, medication, and determination of patient readiness through interviews/communication- Level 1
• Prepare and organize equipment and supplies prior to performing phlebotomy and related services- Level 3
• Name and select the appropriate collection site for arterial puncture, skin puncture, and venipuncture after considering factors that affect site selection- Level 2
  o Intravenous fluid lines
  o Transfusion
  o Presence of burns
  o Broken skin
  o Scars
  o Mastectomy
  o Other
• Collect blood via appropriate collection site and standard venipuncture techniques - Level 2
  o Syringe system
  o Winged and non-winged infusion set system
  o Evacuated tube system using correct order of draw
• Collect blood via appropriate collection site using standard skin puncture techniques on various patient types- Level 2
  o Adults
  o Infants
  o Children
• Evaluate specimen/sample integrity by proper patient preparation for tests ordered- Level 3
  o Accurate patient identification
  o Use of proper collection site and supplies, devices and procedures including order of draw
  o Accurate labeling, transport and handling of specimens/samples collected
• Discuss and appropriately use special precautions when collecting blood specimens/samples- Level 2
  o Decontaminating the skin for routine collection
  o Aseptic technique for blood cultures
• Warming devices
• Collecting appropriate Sample size
• Suitability of site for collection
• Implementing, monitoring, and evaluating quality assurance methods relevant to the scope of practice
• Discuss the purpose of performing arterial punctures- Level 1
• Discuss the modified Allen test- Level 1
• Discuss the factors in donor blood collection- Level 1
  o Donor screening
  o Procedures and precautions
  o Blood products
• Discuss technical complication associated with blood collection and methods of correction- Level 1
  o Needle insertion
  o Loss of vacuum
• Discuss patient factors or physiological conditions that affect phlebotomy specimen/sample collection- Level 1
  o Vein damage
  o Collapsed veins
  o Scar tissue
  o Infections
  o Difficult veins
  o Pain
  o Petechiae
  o Excessive bleeding
  o Syncope
  o Seizures
  o Nausea
  o Vomiting
  o Insulin shock
  o Tatoos
• Discuss methods to prevent or address technical and physiological complications in phlebotomy- Level 1
• Define and discuss the prevention of phlebotomy complications- Level 1
  o Hematoma
  o Hemoconcentration
  o Hemolysis
• Prepare peripheral blood smears that are appropriate for testing using standard procedure- Level 2
  o Technical error associated with peripheral blood preparation and precautions to alleviate complications
• Label specimens/sample with appropriate information- Level 2
• Name and label biohazard specimens/samples- Level 2
• Prepare specimens/samples for transport or mailing to reference laboratories or other off site laboratory using appropriate standard protocol (triple packing system)- Level 2
• Describe and demonstrate proper disposal of contaminated equipment, supplies and discard specimens/samples- Level 2

**Point of Care Testing (POCT)**

• List tests commonly performed at the patients’ bed side or chair side- Level 1
• Name practitioners who are qualified to perform point of care tests- Level 1
• Discuss qualifications of practitioners who may perform point of care tests- Level 1
• Name and select equipment and supplies used for point of care tests, and newborn screens such as phenylketonuria- Level 2
• Perform point of care procedures as established using standard protocol and predetermined criteria for testing and quality assurance- Level 2
• Demonstrate knowledge and proficiency in operating equipment and use of supplies in POC testing procedures performed- Level 2
• Demonstrate accurate measurement and proper use of measuring systems in calculating results- Level 2
• Discuss the purpose of each POCT test- Level 1
  o Sample/specimen requirements
  o Precautions
  o Limitations
  o Sources of error
  o Reference values
  o Quality assurance
• Record and report POCT tests appropriately and accurately- Level 2
• List critical values and follow established criteria for reporting such values- Level 2

**Quality Assurance**

• Define and distinguish among the terms quality control, quality assurance and quality improvement- Level 3
• Discuss quality assurance in phlebotomy and related services- Level 1
  o Requisitioning
  o Patient preparation
  o Phlebotomy procedures
  o Aspects of post phlebotomy care
  o Specimen labeling, transport, handling and procurement
  o Point of Care testing
• Discuss methods of improving phlebotomy services and related patient outcomes- Level 1
• Discuss and demonstrate proper documentation of procedure and quality assurance using established standards- Level 2
  o Specimen logs
  o Tracking specimens manually and with the computer system
• Evaluate specimens/samples for acceptability for tests requested- Level 3
  o Labeling discrepancies or absence of labels
  o Hemolysis
  o Specimen collection using the Wrong additive
  o Use of outdated supplies
  o Improper storage or transport
• Discuss the volume of blood that can be taken from a patient with regard to age and standard practice- Level 1
• Discuss standard practices related to the number of time a patient can be punctured by the same phlebotomist- Level 1

Human communication theory and application to practice
• Discuss effective human communication in phlebotomy and related services- Level 1
  o Definitions
  o Theories
  o Key components
• Discuss and demonstrate the application of communication theories in practice as a means of assuming the role of listener, speaker, and ultimately, effective communicator as a phlebotomist and patient care provider- Level 2
• Demonstrate effective communication in providing patients with instructions for preparing for phlebotomy procedures- Level 2
  o Fasting specimens/samples
  o Glucose tolerance tests
  o Urine collection
  o Occult blood test
• Demonstrate proper communication skills in interviewing a patient/client as related to phlebotomy and phlebotomy services- Level 2
• Demonstrate proper greeting of patients/clients, visitors, peers, and other health care professionals- Level 2
• Discuss and demonstrate effective communications with diverse clients encountered including pediatric and geriatric patients- Level 2
• Describe factors that influence effective communications between patient/client and phlebotomists, medical laboratory technician (MLT) or medical laboratory scientist (MLS), the health care professional and their colleagues/other health care professionals, the health care professional, and patients’ families and guests- Level 2
  o Cultural sensitivity
  o Language barriers
  o Technical jargon
  o Disabilities
  o Age
  o Stress
  o Medication
Professionalism, legal and ethical aspects

- Discuss professionalism and behaviors associated with professionals practicing phlebotomy- Level 1
- Demonstrate professional appearance by proper grooming and wearing professional attire- Level 2
- Discuss basic theories of ethics and application to persons practicing phlebotomy- Level 1
- Discuss the Patients’ Bill of Rights and its application to phlebotomy and related services- Level 1
- Discuss the importance of patient confidentiality and demonstrate maintenance of patient confidentiality and how it related to HIPPA- Level 1
- Discuss the legal and ethical implications associated with breach of patient confidentiality- Level 1
- Discuss and apply laws that impact upon phlebotomy and related services- Level 2
  - Clinical Laboratory Improvement Amendments of 1988
  - Occupational Safety and Health Administration regulations
  - Health Insurance Portability & Accountability Act (HIPPA)
  - Patient Self-Determination Act of 1990
  - Affordable Care Act (2010)
  - Other
- Discuss and apply the ethical and legal responsibilities of the Patient’s Bill of Rights especially as they relate to phlebotomy and phlebotomy service- Level 2
  - HIPPA
  - The Patient Self-Determination Act of 1990
  - Confidentiality
  - Right to refuse treatment
  - Informed consent
  - Privacy
  - Other
- Discuss the United States legal system as it relates to Phlebotomists, MLTs, MLSs participating in duties related to phlebotomy- Level 1
- Discuss the importance of standard of care and legal implications associated with standards of care- Level 1
- Discuss the importance of labeling specimens/samples and the legal ramifications associated with improper specimen labeling- Level 1
- Discuss the legal ramifications of testing specimens/samples that lack integrity- Level 1
- Discuss the interrelationship of ethics, morals, professional and personal values, and legal aspects of care in performing phlebotomy- Level 1
- Discuss stress and the effects of stress on professionals performing phlebotomy and related services- Level 1
- State methods of handling stress or eliminating stress in the work place- Level 1
- Discuss measures that can be taken to avoid or reduce risks and liability in performing phlebotomy and related duties- Level 1
Phlebotomy MLT ELC Deletions

The Health Care System and Services
  Deleted outdated names

Samples/Specimens
  Bleeding time

Specimen/Sample Collection
  Modified Allen test: demonstrate was taken out discuss was left in
  Donor Blood: expiration and storage (Blood bank specific)

Human communication theory and application to practice
  Bleeding time

Removed categories stress and legal combined with professionalism

Phlebotomy MLT ELC Additions

The Health Care System and Services
  various inpatient and outpatient facilities
  various departments in the hospital setting
  various laboratory professionals and other healthcare professionals
  computer use

Infection Control changed to infection prevention

Human Anatomy and Physiology
  Vascular system and capillary draws

Samples/Specimens
  Identify, select, and evaluate appropriate equipment and supplies to be used for skin puncture and venipuncture for a variety of patient type

Equipment and supplies
  Updated test supplies and equipment
  Equipment use for quality specimen
  Storage and disposal
Specimen/Sample Collection

Various sites
Quality assurance
Biohazard

Point of Care Testing

Equipment for newborn screening

Quality Assurance

Improvements in phlebotomy

Human communication theory and application to practice

Cultural sensitivity

Professionalism

Standard of care
Labeling
Specimens lacking integrity
interrelationship of ethics, morals, professional and personal values, and legal aspects of care
HIPPA
Patient Self-Determination Act of 1990
Affordable Care Act (2010)
Renal Anatomy and the Urinary System

Describe the anatomy of the kidney  Level 1

Shape
Size
Placement in the abdominal cavity

Describe the main role of each structure  Level 1
Cortex
Medulla

Pyramids
Papilla
Calyces
Pelvis

Diagram each portion of the nephron  Level 1
Bowman's capsule
Proximal convoluted tubule
Ascending and descending limbs of Loop of Henle
Distal convoluted tubule (macula densa)
Collecting duct

Describe the function of each portion of the nephron  Level 1

State the function of each component of the glomerulus  Level 1
Capillary endothelium
Basement membrane
Podocytes (epithelium)

Describe the renal blood circulation  Level 1
Afferent and efferent arterioles
Glomerulus
Peritubular capillaries
Vasa recta

Describe renal system structure anatomy and function Level 1
Ureters
Bladder
Urethra

**Renal Physiology**

Describe the process of glomerular filtration Level 1
Define hydrostatic and oncotic forces
Define glomerular filtration barrier (GFB)
Define glomerular filtration rate

Describe the process of urine formation Level 1
Tubular reabsorption and secretion

Define active and passive transport
List the solutes that are actively reabsorbed by the nephron Level 1
List the solutes that are passively reabsorbed by the nephron Level 1
List the solutes that are secreted by the nephron Level 1
State the nephron location of secretion for each solute Level 1

Explain changes in solute composition as ultrafiltrate passes through the nephron Level 1
Define tubular transport capacity in relation to renal threshold level Level 1
Summarize secretory mechanisms that regulate acid-base balance Level 1
   Hydrogen ion secretion to recover bicarbonate
   Hydrogen ion secretion to form acids
   Hydrogen ion secretion to form ammonium ions

Discuss mechanisms that maintain osmotic gradient of renal medulla Level 1
   Countercurrent exchange mechanism
   Role in urine formation and concentration
Discuss changes in urine volume and solute composition Level 1
Volume and composition of normal urine
Role of ADH/vasopressin in water reabsorption

Define the renin-angiotensin-aldosterone system Level 1
Define urine volume terminology Level 1

Anuria
Oliguria
Polyuria

**Renal Disease**

Describe Glomerular disease Level 1

Clinical features
Nephrotic syndrome

Correlate typical urinalysis findings in glomerular diseases Level 2

Acute glomerulonephritis
Chronic glomerulonephritis
Nephrotic syndrome

List tubular dysfunction diseases and discuss typical urinalysis findings Level 1

Acute tubular necrosis (ATN)
Cystinosis and cystinuria
Renal glycosuria
Renal tubular acidosis (RTA)
Fanconi Syndrome Level 1

Correlate clinical features and typical urinalysis findings in tubulointerstitial disease and urinary tract infections Level 2

Acute pyelonephritis
Acute interstitial nephritis (AIN)
Lower urinary tract infections (e.g. cystitis)

Explain the presence of non-bacterial organisms found in urine Level 1
Describe the etiology of renal vascular disease Level 1
Discuss effect of renal vascular disease on renal function Level 1
Describe formation of renal calculi Level 1
List factors that influence calculi formation Level 1

Extrarenal Diseases
List amino acid disorders and describe typical urinalysis findings Level 1
  Cystinuria and cystinosis
  Alkaptonuria
  Maple Syrup Urine Disease
  Phenylketonuria
  Tyrosinuria and melanuria
List carbohydrate disorders and describe typical urinalysis findings Level 1
  Glycosuria
  Diabetes Mellitus
  Galactosuria
List metabolic disorders and describe typical urinalysis findings Level 1
  Diabetes Insipidus
  Porphyrin disorders

Urinalysis
Instruct others in proper collection of urine specimens Level 2
Describe urine specimen collection techniques/procedures Level 1
  Random void
  Midstream clean void
  Catheterization
  Suprapubic aspiration
  Pediatric collection bags
  Timed collection
Describe characteristics of urine specimen types Level 1
  Random void
  First morning void
  Timed
Evaluate acceptability of urine specimens  Level 3

Labeling and patient information

Sufficient volume

Time elapsed since specimen collection

Timed test intervals

Storage (light, temperature, preservatives)

Visual evidence of contamination

Collection technique and specimen container is appropriate

Storage parameters for testing

   Temperature

   Light protection

   Preservative requirements

Communicate to health care provider’s criteria for specimen rejection  Level 2

Document unacceptable specimens and action taken  Level 2

Determine and record temperatures in work area  Level 2

   Room

   Refrigerator

   Freezer

Examine reagents for correct storage conditions  Level 2

   Tightly sealed in properly labeled container

   Temperature

   Protected from light if necessary

   Expiration date not exceeded

Prepare calibration and quality control materials  Level 2

   Reagent strip controls

   Refractometer calibrators and controls (if applicable)

   Microscopic controls

   Other chemical test controls
Perform and record calibration checks, quality control checks and equipment maintenance
Level 2
   Refractometer  (if applicable)
   Centrifuge
   Microscope
   Osmometer
   Automated instrument

Recognize and follow established protocol when calibration or quality control check fails or equipment malfunctions  Level 2

Evaluate quality control values to determine analytical errors and implement corrective action  Level 3

Perform and record basic troubleshooting on equipment  Level 2

Prepare specimens for analysis  Level 2
   Mix specimen
   Aliquot for macroscopic and microscopic
   Prepare dilutions as necessary
   Centrifuge and remove supernatant
   Re-suspend sediment and stain if necessary
   Transfer sediment to standardized commercial slide

Ensure appropriate conditions for macroscopic evaluation  Level 2
   Adequate room illumination
   Homogenous specimen
   Temperature

Interpret and record specimen color using established terminology  Level 2
   Correlate color with specimen concentration  Level 2
   Correlate color with patient medication  Level 2

Correlate color and substances that produce them with clinical significance  Level 2

Interpret and record specimen clarity using established terminology  Level 2
   Correlate clarity with microscopic examination  Level 2

State substances that affect urine clarity and their clinical significance  Level 1
Perform specific gravity measurements Level 2
- Refractometer (if applicable)
- Reagent strip
- Automated technology (if available)

Perform osmolality measurements Level 2

Identify principles employed in each method of concentration measurement Level 1
- Osmolality
- Refractometry
- Reagent strip specific gravity

Correlate urine concentration with clinical significance Level 2

Correlate abnormal urine odor and clinical significance Level 2

Perform (manually or using instrument) and record reagent strip chemical tests Level 2
- Dip and remove strips in urine appropriately and correctly, time and read, and interpret reactions Level 2
- State limitations of various chemical techniques Level 1

Apply criteria for results that require confirmatory testing, alternate chemical testing, and/or dilutions Level 2

Describe principles and limitations of various chemical tests on urine Level 1
- pH
- Blood and myoglobin
- Leukocyte esterase
- Nitrite
- Protein
- Carbohydrates
- Ketones
- Bilirubin
- Urobilinogen
- Ascorbic acid by reagent strip
- Albuminuria (Microalbumin) by reagent strip
Creatinine by reagent strip

Use established terminology to report chemical examination results Level 2

Correlate chemical examination results for acceptability and clinical significance Level 2

Detect errors, discrepant and/or contradictory results and action to be taken before reporting results Level 2

Preanalytical errors
  improper timing
  improper preservative
  exposure to light
  mislabeled specimens

Analytical errors
  interfering substances present in urine
  deteriorating reagents
  instrument malfunction

Postanalytical errors

Correlate results of macroscopic examination with microscopic examination Level 2

Apply protocol for initiation of microscopic examination based on macroscopic examination Level 2

Prepare microscope for optimal viewing (See microscope section in MLT General) Level 2

Clean ocular and objective lenses

Adjust light source for proper illumination

Place filters in light path

Protect microscope from dust

Select type of microscopy and adjust for optimum viewing Level 2

Optimize condenser position

Adjust field iris and condenser aperture diaphragms

Describe and utilize various microscopic techniques Level 2

Brightfield
Phase contrast
Polarizing (if available)

Check and perform phase ring alignment for phase microscopy Level 2
Place polarizing filters in light path for polarizing microscopy Level 2

Place, focus and scan mounted specimen on microscope
Secure microscope slide on mechanical stage
Check and perform interpupillary and diopter adjustments
Use course and fine adjustments
Use mechanical stage adjustments to scan specimen

Distinguish and quantitate cellular elements Level 2

Red blood cells (typical, ghost and crenated forms) using high power magnification (400x)

White blood cells using high power magnification (400x)

Typical white blood cells
Atypical white blood cells (degenerative forms)

Oval Fat Bodies

Epithelial cells (squamous @100x, transitional, renal tubular @400x)

Abnormal and/or atypical cells

Distinguish, quantitate, and determine the type of casts, using 100x to locate and 400x to identify Level 2

Hyaline
Waxy

Cellular inclusions (RBC, WBC, renal epithelial, mixed)

Inclusions (finely and coarsely granular, fatty, crystals, hemosiderin)
Pigmented (hemoglobin, bilirubin)

Distinguish acidic, neutral, and alkaline crystals Level 2

Associate with pathology

 Derived iatrogenically

Distinguish miscellaneous formed elements Level 2
Bacteria
Fat globules
Hemosiderin
Mucus
Parasites
Spermatozoa
Yeast

Contaminants (starch, fibers, fecal material, clue cells, etc)

Record microscopic examination results using established protocol and terminology
Level 2

Correlate microscopic with macroscopic and chemical examination Level 2

Correlate microscopic results with clinical significance Level 2

Use protocol to identify specimens that require confirmatory testing before reporting results
Level 2

Check for preanalytical and post analytical errors

Perform additional testing to resolve conflicting results

Interpret and report results Level 2

Evaluate quality control data and take necessary corrective action

Evaluate patient results for completeness

Intercept questionable and/or contradictory results and verify appropriate action is taken and documented

Utilize reference intervals to determine clinical significance Level 2

Correlate results with clinical significance Level 2

Correlate results with other tests results on same patient Level 2

Compare current results with previous results on same patient Level 2

Utilize protocol for identifying and reporting "critical values" Level 2

Utilize protocol to communicate results via computer, verbal or written Level 2

Respond to inquiries from health care personnel concerning test results, reference intervals, specimens Level 2
Renal Function Tests

Describe renal function tests Level 1

Creatinine Clearance

Estimated Glomerular Filtration

Cystatin C

Beta₂Microglobulin

Differentiate the advantage and disadvantages of substances for determination of renal clearance Level 2

Creatinine

Inulin

Cystatin

List factors that can influence creatinine clearance results (timing, complete collection, body size) Level 1

Use protocol for performing creatinine clearance tests Level 2

Calculate creatinine clearance results using body surface area normalization Level 2

Differentiate eGFR and GFR Level 2

Identify factors that can influence eGFR results (age, muscle mass, pregnancy, ethnicity, race) Level 2

Interpret and report results Level 2

Evaluate quality control data and take necessary corrective action

Evaluate patient results for completeness

Intercept questionable and/or contradictory results and verify appropriate action is taken and documented

Ensure results are recorded in established format and terminology Level 2

Utilize reference intervals to determine clinical significance Level 2

Correlate results with clinical significance Level 2

Correlate results with other tests results on same patient Level 2

Compare current results with previous results on same patient Level 2

Utilize protocol to communicate results via computer, verbal or written Level 2
Renal Calculi
List factors that can influence calculi formation (increase in chemical salts, change in pH, urinary stasis, foreign body seed) Level 1

Describe the chemical composition of most renal calculi Level 1

Body Fluids
Explain basic concepts relating to the clinical significance of body fluids Level 1
Describe types of body fluids (production, source, function) used in analysis Level 1

- Cerebral spinal fluid (CSF)
- Pleural
- Peritoneal
- Pericardial
- Synovial
- Amniotic
- Seminal
- Sweat

Define body fluid analysis associated terminology Level 1
- Paracentesis
- Thoracentesis
- Arthrocentesis
- Ascites
- Effusion (transudate/exudate)
- Xanthochromia
- Chylous
- Pseudochylous
- Traumatic tap

Perform processing of specimens according to established laboratory protocol Level 2
- Storage conditions
- Specimen transport

Perform body fluid analysis according to laboratory protocol for CSF, Serous, Synovial Level 2

- Physical exam
- Chemical exam (glucose, total protein, other)
- Hematologic exam (cell count/differential)
- Microbiologic exam (gram stain, other)
- Crystal analysis (synovial)

Perform body fluid analysis according to laboratory protocol for seminal fluid Level 2
- Post-vasectomy

Perform fecal analysis Level 2

Evaluate acceptability of results Level 3
- Report results according to laboratory protocol Level 2
- Perform, document, and evaluate quality control Level 2
- Correlate patient results with disease state or disorder Level 2
**MLT- Urinalysis and Body Fluids**

**Deleted Items**
Diagram glomerulus
Diagram renal blood circulation
Role of renal blood circulation related to renal function
Define capillary endothelium, basement membrane, podocyte filtration diaphragms
Explain the changes in osmolality as the ultrafiltrate passes through the nephron
Countercurrent multiplier mechanism
Urea cycle
Physiologic factors involved in determining the volume of urine excreted
Pathogenesis of glomerular damage
Compare and contrast acute and chronic renal failure
Verify acceptability of work area, equipment and supplies
Assemble worksheets and other documenting materials
Evaluate and select methodology
Dispense standardized volume of sediment to glass microscope slide and apply appropriate coverslip
Sulfosalicylic acid for protein
Watson-Schwartz for urobilinogen/porphobilinogen
Qualitative metabolic screening tests & substances detected to correlate with metabolic disease
Explain purpose of macroscopic tests to health care personnel
Interference contrast microscopy
Advantages/Disadvantages of microscopy types
Special stains (eosinophils, lymphocytes, etc.)
Record maintenance for accreditation
 Continuing education participation
Renal calculi chemical composition testing
Quality Management in the Urinalysis Laboratory

**Body Fluids:**
Amniotic Fluid
Seminal Fluid (EXCEPT post-vasectomy)

**Additions**

Specimen Collection technique - Timed collection

Specimen preparation - mix specimen

Reagent Strip Chemical Testing - Dip and remove strips in urine appropriately and correctly, time and read, and interpret reactions

Ascorbic acid by reagent strip

Microalbumin by reagent strip

Creatinine by reagent strip

Renal Function Tests - Creatinine Clearance, Estimated Glomerular Filtration, Cystatin C, Beta2Microglobulin

Differentiate eGFR and GFR

Describe the chemical composition of most renal calculi

**Body Fluids:**

Sweat

Traumatic Tap

Post-Vasectomy semen analysis

Fecal Analysis